Proposal for Canadian Neurocognitive Rights and Advanced Neurotechnology Act

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JUSTIFICATION FOR THE CANADIAN NEUROCOGNITIVE RIGHTS AND ADVANCED NEUROTECHNOLOGY ACT

NECESSITY AND URGENCY

Canada stands at a critical technological inflection point that demands immediate legislative action. The Canadian Neurocognitive Rights and Advanced Neurotechnology Act represents an essential and timely legislative framework to address unprecedented advances in neurotechnology that can access, monitor, and potentially manipulate the human brain—the most intimate domain of human existence and the foundation of personal autonomy and dignity.

Recent developments in computational neuroscience, neural signal processing, and brain modulation technologies have progressed at an exponential rate, far outpacing our legal frameworks. Canadian research institutions, including the Montreal Neurological Institute, the University of Toronto's Centre for Neural Engineering, and MILA (Quebec Artificial Intelligence Institute), are at the forefront of developing neurotechnologies that operate at specific electromagnetic frequencies and leverage artificial intelligence to interact with neural systems in ways that conventional technologies cannot.

Canada already faces concrete challenges requiring urgent regulatory response:

1. Canadian neurotechnology companies, including InteraXon (makers of Muse), NeuroQore, and Functional Neuromodulation, have developed sophisticated brain-computer interfaces for clinical and commercial applications, with minimal oversight regarding privacy and security protocols for neural data.

2. The Canadian Armed Forces and Defence Research and Development Canada have invested in neurotechnology research for training, cognitive enhancement, and mental health applications, creating potential for dual-use technologies that could be repurposed for unauthorized applications.

3. Health Canada has approved several invasive and non-invasive neurotechnology devices without comprehensive frameworks to evaluate long-term impacts on cognitive autonomy and mental privacy.

4. Canadian venture capital firms have significantly increased investment in neurotechnology startups, with over $500 million invested in the past five years, creating a rapidly expanding market operating in a regulatory vacuum.

5. Early clinical trials of cognitive enhancement technologies at Canadian research hospitals raise profound questions about equitable access and potential creation of cognitive disparities across socioeconomic lines, threatening Canada's commitment to healthcare equality.

6. International competitors are rapidly developing their own neurotechnology capabilities and regulatory frameworks, creating geopolitical imperatives for establishing Canadian leadership in ethical standards and governance.

7. Canada's unique demographic landscape, including its significant Indigenous population with distinct rights and perspectives on cognitive sovereignty, requires

tailored approaches to neurotechnology governance that reflect Canada's multicultural values.

CONSTITUTIONAL AND LEGAL FOUNDATION

The Canadian Neurocognitive Rights and Advanced Neurotechnology Act builds upon Canada's strong constitutional tradition of protecting individual rights and freedoms while adapting these protections to emerging technological realities. The rights protected in this Act can be understood as extensions and specifications of rights already enshrined in the Canadian Charter of Rights and Freedoms:

- Section 2(b): Freedom of thought, belief, opinion, and expression
- Section 7: Right to life, liberty, and security of the person
- Section 8: Right to be secure against unreasonable search or seizure
- Section 15: Equality rights and protection against discrimination

Distinguished Canadian legal scholars including Professor Jennifer Chandler of the University of Ottawa, Professor Stefanie Blain-Moraes of McGill University, and Professor Peter Reiner of the University of British Columbia's National Core for Neuroethics have articulated the need for specific neurorights protections in Canadian jurisprudence. Their work demonstrates that traditional privacy and autonomy doctrines are insufficient to address technologies that can potentially access thoughts, memories, and cognitive processes.

The Supreme Court of Canada has recognized in cases like R v. Spencer (2014) and R v. Fearon (2014) that new technologies require evolutionary interpretations of constitutional protections. The Court's reasoning in these cases can be extended to neurotechnology, which represents perhaps the most significant frontier for extending these principles, as it concerns not merely data about a person but access to the very processes that constitute personhood itself.

Furthermore, Canada's Privacy Act and Personal Information Protection and Electronic Documents Act (PIPEDA) were not designed to address the unique challenges posed by neural data, which is arguably the most intimate form of personal information. This legislation addresses this gap while harmonizing with existing privacy frameworks.

NATIONAL SECURITY AND COMPETITIVE IMPERATIVES

Establishing a comprehensive legal framework for neurotechnology is not merely a matter of individual rights but a national security imperative. Canada must develop its own standards and regulatory frameworks for neurotechnology to ensure these technologies advance Canadian values of liberty, dignity, and self-determination, while addressing specific security concerns in the Canadian context.

Defence Research and Development Canada has invested in neurotechnology research through various programs, including their Human Systems Integration group and Human

Performance Enhancement initiatives. These investments demonstrate the strategic importance of neurotechnology for national defence and security.

Without a comprehensive regulatory framework, Canada risks:

1. Becoming dependent on foreign neurotechnology developed according to values and standards that may not align with Canadian interests and principles
2. Creating vulnerabilities in neural security that could be exploited by malicious actors
3. Enabling the proliferation of unregulated neurotechnology with potential for misuse
4. Undermining public trust in legitimate and beneficial applications of neurotechnology
5. Failing to protect sensitive neural data that could be exploited for economic, political, or military advantage

Canada's position as a middle power with significant influence in international standard-setting makes it particularly well-positioned to lead in developing balanced approaches to neurotechnology governance that can serve as models for other nations.

ECONOMIC AND INNOVATION BENEFITS

The neurotechnology sector represents a significant growth opportunity for the Canadian economy. According to market analyses, the global neurotechnology market is projected to reach $34 billion by 2027, with Canada positioned to capture a substantial portion of this growth due to its strong neuroscience research base, world-class artificial intelligence capabilities, and robust biomedical sector.

Canada's existing strengths in this domain include:

1. World-renowned neuroscience research institutions, including the Montreal Neurological Institute's open science platform
2. Leadership in artificial intelligence research through organizations like MILA, Vector Institute, and CIFAR
3. Strong medical device manufacturing capacity and experience with regulatory pathways
4. Established expertise in brain-computer interface development through companies like InteraXon
5. Public healthcare system that provides a structured pathway for adoption of therapeutic neurotechnologies

Far from impeding innovation, this legislation will create the regulatory certainty needed for responsible investment and development. By establishing clear guidelines, certification processes, and specialized judicial oversight, the Act will:

1. Provide regulatory clarity that encourages long-term investment in Canadian neurotechnology

2. Create standards that facilitate interoperability and sector growth
3. Build public trust necessary for widespread adoption of beneficial neurotechnologies
4. Establish Canada as a global leader in ethical neurotechnology development
5. Create a competitive advantage for Canadian companies through "ethics by design" approaches
6. Facilitate access to international markets through harmonized standards

Companies developing neurotechnology applications for healthcare, education, entertainment, and productivity will benefit from clear rules of engagement, reducing legal uncertainty and liability exposure. The specialized tribunals established by this legislation will develop expertise necessary to adjudicate complex technical disputes efficiently, reducing costly litigation uncertainties.

SPECIALIZED NEUROCOGNITIVE RIGHTS TRIBUNALS: A NECESSARY INNOVATION

The establishment of Neurocognitive Rights Tribunals responds to the unprecedented challenges posed by neurotechnology cases. These specialized tribunals build upon successful Canadian precedents in specialized adjudication:

- The Competition Tribunal for complex competition matters
- The Canadian Human Rights Tribunal for discrimination cases
- The Patent Appeal Board for patent disputes
- The Canadian International Trade Tribunal for trade matters

Specialized tribunals with technical expertise have proven effective in these domains, and neurotechnology presents even greater technical complexities that require specialized adjudicative knowledge. Conventional courts lacking neuroscientific and technical expertise risk inconsistent rulings that could either stifle innovation through overly restrictive interpretations or fail to adequately protect fundamental rights through insufficient scrutiny.

As noted by Canadian legal scholars, the judiciary faces unprecedented challenges in evaluating evidence related to emerging technologies that can potentially interfere with mental autonomy and cognitive privacy. The creation of specialized neurocognitive tribunals would establish Canada as a global pioneer in neurocognitive justice—an area that will inevitably become central in coming decades.

The proposed tribunals would operate within Canada's existing framework of administrative law, with appropriate provisions for appeals to the Federal Court, ensuring both specialized expertise and integration with the broader judicial system. This approach respects Canada's legal traditions while providing the innovation needed to address novel challenges.

ALIGNMENT WITH CANADIAN VALUES AND INTERNATIONAL COMMITMENTS

The Canadian Neurocognitive Rights and Advanced Neurotechnology Act aligns with core Canadian values and international commitments:

1. **Respect for human dignity**: This foundational Canadian value is directly threatened by unregulated neurotechnology that could compromise cognitive autonomy and identity.
2. **Multiculturalism and diversity**: The Act includes provisions to ensure neurotechnology respects diverse cultural perspectives, including Indigenous worldviews on cognition and consciousness.
3. **Social justice and equality**: By establishing provisions for equitable access to beneficial neurotechnology and prohibiting discrimination based on neural data, the Act upholds Canada's commitment to equality.
4. **Peace, order, and good government**: By providing a comprehensive framework for neurotechnology governance, the Act fulfills the federal government's responsibility to address emerging issues that affect the peace, order, and good government of Canada.
5. **International human rights commitments**: The Act helps fulfill Canada's obligations under various international human rights instruments that protect privacy, autonomy, and dignity.

The Act also positions Canada to influence emerging international standards for neurotechnology governance, consistent with Canada's tradition of constructive international engagement and middle-power diplomacy. By developing a balanced approach that protects rights while enabling innovation, Canada can model responsible neurotechnology governance for other nations.

INDIGENOUS PERSPECTIVES AND RECONCILIATION

The Canadian Neurocognitive Rights and Advanced Neurotechnology Act includes specific provisions addressing Indigenous perspectives on neurotechnology and neural data, recognizing that:

1. Many Indigenous communities have distinct cultural understandings of mind, cognition, and consciousness that must be respected in neurotechnology governance
2. The principle of Indigenous data sovereignty extends to neural data collected from Indigenous individuals and communities
3. Historical contexts of colonization and medical experimentation necessitate particular attention to prevent neurotechnology from becoming a new frontier for exploitation
4. Indigenous governance and legal traditions must be respected in the regulation of neurotechnology used in or developed from research involving Indigenous peoples

By explicitly addressing these considerations, the Act contributes to Canada's ongoing commitment to reconciliation with Indigenous peoples and the implementation of the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). This approach recognizes that neurocognitive rights must be understood in culturally appropriate contexts, not merely as universal abstractions.

FEDERALISM CONSIDERATIONS

The Canadian Neurocognitive Rights and Advanced Neurotechnology Act has been carefully crafted to respect the division of powers in Canada's federal system while providing a cohesive national approach to neurotechnology governance.

The Act's approach to federal-provincial-territorial cooperation recognizes that:

1. Aspects of neurotechnology governance touch on both federal jurisdiction (e.g., criminal law, interprovincial trade, peace, order and good government) and provincial jurisdiction (e.g., healthcare delivery, professional regulation, property and civil rights)
2. A harmonized national approach is necessary to prevent a patchwork of inconsistent provincial regulations that would create barriers to innovation and uneven protection of rights
3. Cooperative federalism principles can allow for national standards while respecting provincial implementation authority in areas of provincial jurisdiction
4. Provincial and territorial input is essential for effective implementation, particularly in healthcare contexts

The Act establishes mechanisms for federal-provincial-territorial coordination, including the option for provincial neurocognitive rights tribunals that can apply both federal and provincial law, similar to successful models in environmental protection and human rights enforcement.

CROSS-PARTY APPEAL

The Canadian Neurocognitive Rights and Advanced Neurotechnology Act transcends traditional political divides, offering compelling justifications for support across the political spectrum:

For **Conservatives**, the Act protects the ultimate domain of individual liberty—the freedom of thought and cognitive autonomy—from potential governmental or corporate intrusion, while creating a balanced regulatory environment that provides certainty for business investment.

For **Liberals**, the Act establishes a rights-based framework that protects human dignity and autonomy in the digital age, while promoting Canada's innovation economy through responsible development.

For the **New Democratic Party**, the Act establishes equity guarantees ensuring that neurotechnology benefits are widely accessible while preventing the creation of new forms of discrimination based on cognitive capacities or neural data.

For the **Bloc Québécois**, the Act respects Quebec's jurisdiction while allowing for provincial implementation that can reflect Quebec's distinct approach to technology regulation and healthcare.

For the **Green Party**, the Act promotes responsible innovation and precautionary approaches to powerful new technologies with potential environmental and social implications.

INTERNATIONAL LEADERSHIP

Several nations are moving forward with neurorights protections:

- Chile amended its constitution to explicitly protect neural rights
- Spain has developed legislative frameworks for neurotechnology regulation
- The European Union is developing comprehensive regulations for neurotechnology as evidenced by their recent legislative proposal
- The United Kingdom will introduce the Neurocognitive Rights and Advanced Neurotechnology Act
- The United States is considering the Neurocognitive Rights and Technologies Act

By enacting comprehensive legislation now, Canada can establish itself as a leader in this emerging field, developing an approach that balances rights protection with innovation in a distinctly Canadian way. Canada's international reputation for balanced, pragmatic, and human rights-oriented policy positions it ideally to influence global standards in this domain.

Canada has historically played important roles in developing international norms and standards in areas ranging from peacekeeping to human rights to environmental protection. Neurotechnology governance represents a new frontier where Canadian leadership can make a significant global contribution.

Failure to act would cede leadership to other nations whose frameworks may not reflect Canadian values and interests to the same degree, potentially leading to the adoption of international standards that are either overly restrictive (hampering innovation) or insufficiently protective (compromising rights).

CONCLUSION

The Canadian Neurocognitive Rights and Advanced Neurotechnology Act represents essential legislation for the emerging era of advanced neurotechnology. By establishing fundamental neurocognitive rights, creating appropriate regulatory frameworks, ensuring proper data protections, and establishing specialized judicial expertise, this legislation will protect the most intimate domain of human autonomy while enabling responsible innovation.

The window for establishing these protections is narrowing as neurotechnology advances at an accelerating pace. By acting decisively now, Parliament has the opportunity to establish landmarks in the protection of human dignity for the digital age that reflect distinctly Canadian values and approaches.

This legislation will position Canada as a global leader in ethical neurotechnology development and neurocognitive rights protection—upholding Canada's commitment to individual liberty, human dignity, and responsible innovation in the face of unprecedented technological capabilities to access and influence the human mind.

The time for action is now, before potentially invasive technologies become widespread and before international standards are set by nations that may not share Canada's balanced approach to rights protection and technological development. We urge Parliament to prioritize passage of this vital legislation to secure cognitive liberty for current and future generations of Canadians.

BILL C-XX

An Act respecting neurocognitive rights and the regulation of advanced neurotechnologies

First Session, Forty-Fifth Parliament, 74 Elizabeth II, 2025

THE HOUSE OF COMMONS OF CANADA

BILL C-XX

AN ACT RESPECTING NEUROCOGNITIVE RIGHTS AND THE REGULATION OF ADVANCED NEUROTECHNOLOGIES

First reading, Date, 2025

SUMMARY

This enactment establishes a comprehensive legal framework for the protection of neurocognitive rights and the regulation of advanced neurotechnologies in Canada. It establishes fundamental neurocognitive rights for all persons in Canada, creates a regulatory framework for neurotechnology development and deployment, establishes specialized judicial mechanisms for adjudicating cases involving neurocognitive rights, and provides for criminal and civil liability for violations of neurocognitive rights.

The enactment: (a) recognizes and defines fundamental neurocognitive rights; (b) establishes the Canadian Neurotechnology Commission as an independent regulatory body; (c) creates a comprehensive classification system and regulatory framework for neurotechnology; (d) establishes special protections for neurocognitive data; (e) creates specialized Neurocognitive Rights Tribunals; (f) provides for criminal penalties and civil remedies for violations; (g) establishes educational programs and public awareness initiatives; (h) supports responsible research and development in neurotechnology; (i) ensures equitable access to therapeutic neurotechnologies; and (j) provides for implementation measures and international cooperation.

PREAMBLE

Whereas the advancement of neurotechnology presents unprecedented opportunities for human health, well-being, and development, while simultaneously creating novel risks to human autonomy, dignity, identity, and privacy;

Whereas cognitive processes represent the most intimate domain of human experience and warrant special protection;

Whereas Canada recognizes that all persons have inherent dignity and equal and inalienable rights, which includes the right to control their cognitive processes without undue external interference;

Whereas Canada is committed to protecting the mental privacy, cognitive liberty, and neural data of all persons within its jurisdiction;

Whereas the rapid development of technologies capable of monitoring, decoding, and potentially modifying neural activity necessitates proactive governance measures;

Whereas existing legal frameworks provide insufficient protection for neural data and cognitive processes in the face of emerging neurotechnologies;

Whereas Canada seeks to establish itself as a global leader in the ethical governance of neurotechnology while fostering responsible innovation;

Whereas Canada recognizes the importance of balancing individual neurocognitive rights with collective interests in advancing scientific knowledge and public health;

Whereas Canada acknowledges the particular importance of protecting vulnerable populations, including children, persons with cognitive disabilities, and elderly persons with cognitive impairments;

Whereas Canada affirms the importance of international cooperation in establishing harmonized standards for neurotechnology governance;

Now, therefore, Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

CANADIAN NEUROCOGNITIVE RIGHTS AND ADVANCED NEUROTECHNOLOGY ACT

PART 1 - PRELIMINARY PROVISIONS

Short Title

1. This Act may be cited as the *Canadian Neurocognitive Rights and Advanced Neurotechnology Act*.

Interpretation

2. (1) The following definitions apply in this Act.

"artificial intelligence system" means software that is developed with one or more techniques that enable the system to generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with. (*système d'intelligence artificielle*)

"brain-computer interface" means any technology that establishes a direct communication pathway between a brain and an external device, system, or interface. (*interface cerveau-ordinateur*)

"Canadian Neurotechnology Commission" or **"Commission"** means the Commission established under section 40. (*Commission canadienne de neurotechnologie*)

"cognitive identity integrity" means the right of individuals to maintain the continuity and authenticity of their cognitive processes and sense of self, protected from unauthorized alterations. (*intégrité de l'identité cognitive*)

"cognitive liberty" means the right of individuals to autonomous control over their own cognitive functions, mental processes, and consciousness, including the freedom to control their own cognitive processes and mental life without external intrusion, manipulation, or interference. (*liberté cognitive*)

"cognitive self-determination" means the right of individuals to make free and informed decisions regarding the use of neurotechnology to monitor, modulate, or otherwise interact with their brain and cognitive processes. (*autodétermination cognitive*)

"Commissioner" means the Commissioner of Neurocognitive Rights appointed under section 46. (*commissaire*)

"Court" means the Federal Court. (*Cour*)

"neural data" means any data obtained directly or indirectly from the measurement or monitoring of the structure or function of the brain or nervous system, or data that reflects cognitive processes or mental states. (*données neurales*)

"neural data breach" means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, neural data transmitted, stored or otherwise processed. (*violation de données neurales*)

"neural data controller" means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of neural data. (*contrôleur de données neurales*)

"neural decoding" means the process of interpreting neural data to infer mental states, cognitive processes, intentions, emotions, or other information about an individual's cognitive activity. (*décodage neural*)

"neural recording" means the measurement, monitoring, or recording of neural activity, whether through invasive or non-invasive means. (*enregistrement neural*)

"neural security" means the protection of neural data and neurotechnology systems from unauthorized access, use, disclosure, disruption, modification, or destruction. (*sécurité neurale*)

"neural state" means the configuration of brain activity at a given moment, which may correlate with mental states, cognitive processes, or emotional experiences. (*état neural*)

"Neurocognitive Rights Tribunal" means the tribunal established under section 210. (*Tribunal des droits neurocognitifs*)

"neurocognitive rights" means the rights of individuals with respect to the protection of their neural data, cognitive processes, mental privacy, cognitive liberty, and cognitive identity integrity, as established in Part 2 of this Act. (*droits neurocognitifs*)

"neurostimulation" means the application of electromagnetic, electrical, magnetic, or other energy to neural tissue for the purpose of modulating neural activity. (*neurostimulation*)

"neurotechnology" means any device, method, or system that enables direct monitoring, recording, stimulation, or modulation of neural activity, or that enables the extraction, processing, or interpretation of neural data. (*neurotechnologie*)

"neurotechnology impact assessment" means an assessment conducted in accordance with section 90. (*évaluation de l'impact de la neurotechnologie*)

"neurotechnology provider" means any person that develops a neurotechnology or has a neurotechnology developed with the intention of placing it on the market or putting it into service under their own name or trademark, whether for payment or free of charge. (*fournisseur de neurotechnologie*)

"neurotechnology user" means any person, public authority, agency or other body using neurotechnology, except where the neurotechnology is used in the course of a personal non-professional activity. (*utilisateur de neurotechnologie*)

"psychological continuity" means the continuous existence of an individual's psychological connections, including memories, beliefs, desires, and personality traits, which form the basis of personal identity over time. (*continuité psychologique*)

"mental privacy" means the right of individuals to keep their thoughts, emotions, preferences, and cognitive processes private and protected from unauthorized access, collection, or disclosure. (*vie privée mentale*)

"mental integrity" means the right of individuals to protect the physical and functional integrity of their brains and cognitive processes from harm or unauthorized interference. (*intégrité mentale*)

"substantial cognitive harm" means significant adverse effects on an individual's cognitive functions, mental states, autonomous decision-making capacity, or sense of personal identity that persists beyond a transient or temporary duration. (*préjudice cognitif substantiel*)

(2) Unless otherwise provided, words and expressions used in this Act have the same meaning as in the *Privacy Act* and the *Personal Information Protection and Electronic Documents Act*.

Purpose and Objectives

3. (1) The purpose of this Act is to establish a comprehensive legal framework for: (a) protecting neurocognitive rights; (b) regulating the development, deployment, and use of neurotechnology; (c) establishing specialized judicial mechanisms for adjudicating cases involving neurocognitive rights; and (d) ensuring that Canada is a global leader in responsible neurotechnology governance.

(2) The objectives of this Act are to: (a) protect the neurocognitive rights of individuals throughout Canada; (b) establish conditions under which neurotechnology may be developed and used in compliance with Canadian values and fundamental rights; (c) prevent potential harms arising from the misuse or unregulated use of neurotechnology; (d) foster responsible innovation in neurotechnology; (e) provide legal certainty for neurotechnology developers, providers, and users; (f) establish specialized judicial mechanisms for cases involving neurocognitive rights; (g) ensure equitable access to beneficial neurotechnologies; (h) promote public education and awareness regarding neurocognitive rights and neurotechnology; and (i) strengthen Canada's position as a global leader in ethical neurotechnology development and governance.

Application

4. (1) This Act applies to: (a) all persons in Canada; (b) federal institutions, as defined in section 3 of the *Privacy Act*; (c) every organization that engages in commercial activities, as defined in section 2(1) of the *Personal Information Protection and Electronic Documents Act*; (d) every person who develops, manufactures, sells, imports, or distributes neurotechnology in Canada; (e) every person who uses neurotechnology in Canada, whether for commercial, research, healthcare, security, or other purposes; and (f) every person who collects, uses, or discloses neural data in Canada.

(2) This Act binds Her Majesty in right of Canada.

Aboriginal and Treaty Rights

5. For greater certainty, nothing in this Act shall be construed so as to abrogate or derogate from the protection provided for the rights of the Aboriginal peoples of Canada by the recognition and affirmation of those rights in section 35 of the *Constitution Act, 1982*.

PART 2 - FUNDAMENTAL NEUROCOGNITIVE RIGHTS

Recognition of Neurocognitive Rights

6. (1) Every individual has neurocognitive rights as set out in this Part.

(2) Neurocognitive rights are complementary to, and not in substitution for, any other rights and freedoms that exist in Canada, including those recognized by the *Canadian Charter of Rights and Freedoms* and the *Canadian Human Rights Act*.

(3) Neurocognitive rights may be subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

Right to Cognitive Liberty

7. (1) Every individual has the right to cognitive liberty, which includes: (a) the right to autonomous control over their own cognitive functions, mental processes, and consciousness; (b) the freedom to control their own cognitive processes and mental life without external intrusion, manipulation, or interference; (c) the freedom to use or decline to use neurotechnology; (d) the freedom to determine which aspects of their cognitive functions may be accessed, monitored, recorded, or decoded by neurotechnology; and (e) the freedom to choose whether to disclose or withhold information about their neural activity or cognitive processes.

(2) No person shall engage in any practice that interferes with an individual's cognitive liberty without: (a) the individual's informed consent provided in accordance with section 15; or (b) express legal authorization in accordance with section 16.

Right to Mental Privacy

8. (1) Every individual has the right to mental privacy, which includes: (a) the right to keep their thoughts, emotions, preferences, and cognitive processes private and protected from unauthorized access, collection, or disclosure; (b) the right to a reasonable expectation of privacy in relation to their neural data; (c) the right to control access to information about their neural states and cognitive processes; and (d) the right to ensure the confidentiality of their neural data.

(2) No person shall: (a) intentionally access, collect, record, decode, interpret, or disclose information about an individual's neural states or cognitive processes without: (i) the individual's informed consent provided in accordance with section 15; or (ii) express legal

authorization in accordance with section 16; or (b) collect neural data beyond what is strictly necessary for the specified and legitimate purpose for which it is collected.

Right to Mental Integrity

9. (1) Every individual has the right to mental integrity, which includes: (a) the right to protection from practices that harm or disrupt the physical or functional integrity of their brain or cognitive processes; (b) the right to protection from the unauthorized modulation of their neural activity that may alter their cognitive functions, mental states, or behavior; and (c) the right to protection from neural manipulation or interference that undermines their capacity for autonomous decision-making.

(2) No person shall: (a) engage in any practice that causes or is likely to cause substantial harm to the physical or functional integrity of an individual's brain or cognitive processes without: (i) the individual's informed consent provided in accordance with section 15; or (ii) express legal authorization in accordance with section 16; or (b) use neurostimulation or other neurotechnology to modulate an individual's neural activity in a manner that substantially impairs their autonomous decision-making capacity.

Right to Psychological Continuity

10. (1) Every individual has the right to psychological continuity, which includes: (a) the right to maintain the continuity of their psychological connections, including memories, beliefs, desires, and personality traits; (b) the right to protection from substantial disruptions to their sense of personal identity resulting from interference with their neural activity; and (c) the right to prevent unauthorized modifications to their neural substrate that may significantly alter their sense of self or personal identity.

(2) No person shall: (a) engage in any practice that substantially disrupts an individual's psychological continuity without: (i) the individual's informed consent provided in accordance with section 15; or (ii) express legal authorization in accordance with section 16; or (b) use neurotechnology to make substantial alterations to an individual's neural substrate in a manner that significantly disrupts their sense of personal identity.

Right to Cognitive Equality and Non-Discrimination

11. (1) Every individual has the right to cognitive equality and non-discrimination, which includes: (a) the right to be free from discrimination based on their neural traits, states, or data; (b) the right to equal protection against discrimination based on neurocognitive characteristics; and (c) the right to be free from discriminatory applications of neurotechnology.

(2) No person shall: (a) discriminate against an individual on the basis of their neural data or neurocognitive characteristics in employment, education, healthcare, housing, financial services, or other contexts; (b) use neural data to make discriminatory decisions about an individual's access to services, opportunities, or benefits; or (c) use neurotechnology in a manner that perpetuates or reinforces existing patterns of discrimination or inequality.

Right to Cognitive Self-Determination

12. (1) Every individual has the right to cognitive self-determination, which includes: (a) the right to make free and informed decisions regarding the use of neurotechnology to monitor, modulate, or otherwise interact with their brain and cognitive processes; (b) the right to control the conditions under which they engage with neurotechnology; and (c) the right to determine whether and how to enhance their cognitive capacities through neurotechnology.

(2) No person shall: (a) coerce or unduly influence an individual to use neurotechnology; (b) deny an individual the opportunity to make free and informed decisions about their use of neurotechnology; or (c) impose neurotechnology use as a mandatory condition for accessing essential services, opportunities, or benefits, except as authorized by law and subject to the limitations in section 16.

Right to Protection from Neurotechnology-Enabled Coercion

13. (1) Every individual has the right to protection from neurotechnology-enabled coercion, which includes: (a) the right to be free from the use of neurotechnology to unduly influence their decision-making capacity; (b) the right to protection from neurotechnology-enabled practices designed to manipulate their beliefs, preferences, or behavior without their knowledge or consent; and (c) the right to be informed about any psychological or behavioral effects that may result from their interaction with neurotechnology.

(2) No person shall: (a) use neurotechnology with the intention of substantially compromising an individual's autonomous decision-making capacity; (b) employ neurotechnology to manipulate an individual's beliefs, preferences, or behavior without their knowledge and informed consent; or (c) deploy neurotechnology with the deliberate intention of inducing addiction or compulsive use patterns.

Right to Neurocognitive Rehabilitation and Enhancement Equity

14. (1) Every individual has the right to neurocognitive rehabilitation and enhancement equity, which includes: (a) the right to access appropriate neurotechnology for the treatment of neurological and psychiatric conditions; (b) the right to equal opportunity to benefit from beneficial neurotechnology, irrespective of socioeconomic status or other factors unrelated to medical necessity; and (c) the right to be free from substantial neurocognitive disparities resulting from inequitable access to neurotechnology.

(2) The Minister of Health, in consultation with the provinces and territories, shall establish programs to promote equitable access to therapeutic neurotechnologies for individuals with medical needs.

Informed Consent for Neurotechnology

15. (1) For the purposes of this Act, valid informed consent for the use of neurotechnology or the collection, use, or disclosure of neural data requires that: (a) the consent is given freely and voluntarily, without coercion, undue influence, or deception; (b) the individual has the capacity to understand the nature and consequences of the proposed use of neurotechnology or processing of neural data; (c) the individual is provided with clear, comprehensive, and understandable information about: (i) the specific purpose for which the neurotechnology will be used or the neural data will be collected, used, or disclosed; (ii) the nature, functionality, and operation of the neurotechnology; (iii) the types of neural data to be collected and how they will be processed; (iv) the potential risks, side effects, and benefits associated with the use of the neurotechnology; (v) any potential for psychological or behavioral influence; (vi) how the neural data will be protected, stored, and ultimately disposed of; (vii) any third parties who may have access to the neural data and the purposes for which they may use it; (viii) the individual's right to withdraw consent and the procedure for doing so; and (ix) any other information necessary for the individual to make an informed decision; (d) the individual has been given a reasonable opportunity to ask questions and have them answered satisfactorily; (e) the individual has expressed their consent in a clear, specific, and unambiguous manner; and (f) the consent is documented in a form appropriate to the context.

(2) For neurotechnology classified as high-risk under Part 3, consent must be: (a) explicit and affirmed through a positive action; and (b) specific to each distinct purpose for which the neurotechnology is to be used or the neural data is to be processed.

(3) An individual may withdraw their consent at any time, subject to reasonable notice requirements and legal or contractual restrictions.

(4) Consent obtained under this section must be renewed: (a) when there is a substantial change in: (i) the purpose or functionality of the neurotechnology; (ii) the type or extent of neural data collected; or (iii) the risks associated with the use of the neurotechnology; and (b) at regular intervals prescribed by regulations for ongoing or long-term use of neurotechnology.

(5) For individuals who lack the capacity to provide informed consent, the provisions of provincial and territorial laws relating to substitute decision-making apply, with the additional requirement that any decision made by a substitute decision-maker must: (a) prioritize the best interests of the individual; (b) take into account any previously expressed wishes or preferences of the individual regarding neurotechnology; and (c) be subject to review by the Neurocognitive Rights Tribunal upon application by any interested party.

Limitations on Neurocognitive Rights

16. (1) The rights established in this Part may be limited only: (a) by a law that is of general application and that: (i) is accessible and precisely formulated; (ii) serves a legitimate aim in a democratic society; (iii) is necessary and proportionate to achieve that aim; and (iv) includes adequate safeguards against abuse; or (b) where authorized by a court order issued in accordance with the requirements of procedural fairness and the specific provisions of this Act.

(2) Any limitation on neurocognitive rights in criminal investigations or national security contexts must: (a) be specifically authorized by law; (b) be subject to prior judicial authorization except in exigent circumstances; (c) be strictly necessary for a legitimate purpose and proportionate to that purpose; (d) be subject to effective oversight; and (e) include appropriate safeguards to prevent abuse.

(3) In the context of medical treatment for psychiatric or neurological conditions: (a) the use of neurotechnology without the patient's informed consent is permitted only if: (i) the patient lacks the capacity to provide informed consent; (ii) the treatment is determined to be necessary to prevent serious and imminent harm to the patient or others; (iii) the treatment is the least restrictive option available; (iv) the treatment is authorized in accordance with applicable provincial or territorial mental health legislation; and (v) the treatment is reviewed by an independent medical authority; and (b) the use of neurotechnology to modulate neural activity for therapeutic purposes must be: (i) based on

sound scientific evidence of safety and efficacy; (ii) performed by qualified medical professionals; and (iii) subject to ongoing monitoring and evaluation.

(4) In the context of scientific research: (a) the collection and analysis of neural data may be conducted without specific informed consent only if: (i) the research has been approved by a research ethics board; (ii) the data is fully anonymized and cannot reasonably be reidentified; (iii) obtaining consent would make the research impracticable; (iv) the research serves an important public interest; and (v) adequate safeguards are in place to protect the privacy and other rights of research participants.

(5) Emergency exceptions to the requirement for informed consent are permitted only when: (a) there is an immediate threat to the life or long-term health of the individual or others; (b) the individual is incapable of providing consent; (c) it is not reasonably possible to obtain consent from a substitute decision-maker in time to prevent the harm; and (d) the use of neurotechnology is reasonably expected to prevent the harm.

Government Use of Neurotechnology

17. (1) No federal government institution shall: (a) compel any individual to use neurotechnology or to submit to neural recording or stimulation, except as explicitly authorized by law; (b) make access to government services or benefits conditional upon the use of neurotechnology, except where: (i) there is a demonstrable necessity directly related to the service or benefit in question; (ii) no less intrusive alternative exists; and (iii) the condition is explicitly authorized by law; or (c) use neural data for purposes beyond those for which it was initially collected, except: (i) with the explicit informed consent of the individual concerned; (ii) when anonymized and used for statistical or research purposes in the public interest; or (iii) when authorized by law under exceptional circumstances.

(2) Any federal government institution that collects, uses, or discloses neural data shall: (a) limit collection to what is strictly necessary for an explicitly specified and legitimate purpose; (b) implement appropriate technical and organizational measures to ensure the security of the neural data; (c) retain the neural data only for as long as necessary to fulfill the purpose for which it was collected; (d) conduct and publish a privacy impact assessment before implementing any program involving the collection or use of neural data; and (e) establish oversight mechanisms to ensure compliance with these requirements.

(3) The use of neurotechnology by law enforcement agencies shall be: (a) authorized by a judicial warrant based on reasonable grounds to believe that: (i) a serious criminal offense has been, is being, or will be committed; and (ii) other investigative procedures have been tried and have failed, or are unlikely to succeed, or the urgency of the matter is such that it would be impractical to use other investigative procedures; (b) limited to what is necessary and proportionate to achieve a legitimate law enforcement objective; (c) subject to effective oversight mechanisms; and (d) conducted in accordance with protocols established by the Minister of Public Safety and Emergency Preparedness in consultation with the Privacy Commissioner and the Commissioner of Neurocognitive Rights.

(4) The use of neurotechnology for security screening or border control purposes shall be: (a) explicitly authorized by law; (b) limited to what is necessary and proportionate to identify specific security threats; (c) applied in a non-discriminatory manner; (d) subject to appropriate oversight and review mechanisms; and (e) regulated by protocols established

by the relevant Minister in consultation with the Privacy Commissioner and the Commissioner of Neurocognitive Rights.

Rights of Special Populations

18. (1) Children, defined as individuals under the age of 18 years, are entitled to enhanced protection of their neurocognitive rights, which includes: (a) a presumption against the use of neurotechnology with children except where there is a clear therapeutic benefit or educational purpose; (b) a requirement for age-appropriate information and, where the child is capable of forming their own views, respect for those views in accordance with the child's age and maturity; (c) a requirement for parental or guardian consent, except where: (i) the child is determined by a healthcare professional to be capable of making their own informed decision; or (ii) a court determines that the best interests of the child require otherwise; (d) special safeguards in educational settings to ensure that neurotechnology is used to enhance rather than restrict educational opportunities; and (e) a prohibition on marketing neurotechnology directly to children.

(2) Individuals with cognitive disabilities or impairments are entitled to: (a) accommodation in the informed consent process appropriate to their capacities; (b) protection against the use of neurotechnology in a manner that may exacerbate existing vulnerabilities or inequalities; (c) priority access to therapeutic neurotechnologies that may ameliorate their condition; and (d) representation of their interests in policy and regulatory decisions regarding neurotechnology.

(3) Individuals in institutional settings, including correctional facilities, psychiatric institutions, long-term care facilities, and similar environments, are entitled to: (a) protection against coerced or involuntary use of neurotechnology; (b) access to legal counsel before consenting to the use of neurotechnology; (c) regular review of any ongoing use of neurotechnology by an independent authority; and (d) effective remedies for violations of their neurocognitive rights.

Indigenous Rights and Neurotechnology

19. (1) In addition to the rights set out in this Part, Indigenous individuals and communities have the right to: (a) meaningful consultation regarding neurotechnology policies, regulations, and initiatives that may affect their communities; (b) protection of traditional knowledge related to mental and cognitive processes; (c) culturally appropriate application of neurotechnology in healthcare, education, and other contexts; and (d) development of community-based protocols for neurotechnology research involving Indigenous participants.

(2) The Minister, in consultation with Indigenous communities and organizations, shall establish guidelines for: (a) the respectful integration of neurotechnology with Indigenous healing traditions and practices; (b) the appropriate protection and use of neural data collected from Indigenous individuals and communities; and (c) the governance of neurotechnology research involving Indigenous participants and communities.

(3) The collection, use, and governance of neural data from Indigenous individuals and communities shall respect: (a) principles of Indigenous data sovereignty; (b) collective rights and interests in data related to Indigenous communities; and (c) existing protocols

for research involving Indigenous peoples, including OCAP® principles (Ownership, Control, Access, and Possession).

Implementation and Enforcement

20. (1) The rights established in this Part are binding on: (a) all federal institutions; (b) all provincial and territorial institutions, to the extent that they operate in areas of federal jurisdiction; (c) all private entities engaged in the development, manufacturing, distribution, or use of neurotechnology in Canada; and (d) all private entities that collect, use, or disclose neural data in Canada.

(2) Every person responsible for the development, deployment, or use of neurotechnology shall take reasonable steps to respect and protect the neurocognitive rights established in this Part.

(3) The Commissioner of Neurocognitive Rights, appointed under section 46, shall be responsible for monitoring and promoting compliance with the provisions of this Part.

(4) Violations of the rights established in this Part may give rise to: (a) complaints to the Commissioner under section 201; (b) applications to the Neurocognitive Rights Tribunal under section 215; (c) civil causes of action under section 240; and (d) criminal liability under section 235, in cases of serious or willful violations.

(5) The Governor in Council may make regulations for carrying out the purposes and provisions of this Part, including regulations: (a) prescribing additional measures for the protection of neurocognitive rights; (b) establishing detailed requirements for informed consent processes; (c) specifying further limitations and exceptions to neurocognitive rights; (d) establishing procedures for assessing capacity to consent to neurotechnology use; (e) prescribing circumstances in which neurotechnology may be used without consent; and (f) establishing additional protections for vulnerable populations.

PART 3 - NEUROTECHNOLOGY REGULATION AND OVERSIGHT

General Regulatory Framework

21. (1) No person shall: (a) place on the market neurotechnology that does not comply with the requirements of this Act and any regulations made under it; (b) put into service neurotechnology that does not comply with the requirements of this Act and any regulations made under it; or (c) use neurotechnology in a manner that contravenes this Act or any regulations made under it.

(2) The development, manufacturing, distribution, sale, and use of neurotechnology in Canada shall be governed by: (a) the classification system established in sections 24 to 29; (b) the general safety and performance requirements established in sections 30 to 36; (c) the specific requirements for each risk category established in sections 37 to 39; and (d) the additional requirements prescribed by the Commission under section 42.

(3) Subject to subsection (4), the provisions of this Part apply in addition to, and not in substitution for, any other applicable requirements under: (a) the *Food and Drugs Act* and its regulations, for neurotechnology that meets the definition of a "device" under that Act; or (b) any other federal or provincial legislation applicable to medical devices, consumer products, or research.

(4) In the event of a conflict between a provision of this Act and a provision of another Act of Parliament respecting the development, manufacture, distribution, sale, or use of neurotechnology, the provision that provides the higher level of protection for neurocognitive rights prevails to the extent of the conflict.

Multi-Stakeholder Governance

22. (1) The governance of neurotechnology in Canada shall be based on multi-stakeholder participation, including: (a) input from scientific and medical experts; (b) engagement with civil society organizations; (c) consultation with neurotechnology developers and industry representatives; (d) participation of patient and consumer advocacy groups; (e) inclusion of representatives from vulnerable or marginalized populations who may be particularly affected by neurotechnology; and (f) representation of Indigenous perspectives and knowledge systems.

(2) The Commission shall establish advisory committees that reflect the diversity of stakeholders identified in subsection (1).

(3) Prior to issuing regulations, guidelines, or standards under this Act, the Commission shall: (a) publish proposed regulations, guidelines, or standards for public comment; (b) consider and respond to submissions received during the public comment period; (c) consult with relevant advisory committees; and (d) conduct appropriate impact assessments, including assessments of the potential effects on vulnerable populations and small and medium-sized enterprises.

Risk-Based Approach

23. (1) The regulatory framework established by this Part shall apply a risk-based approach that: (a) calibrates the intensity of regulatory requirements to the level of risk posed by different types of neurotechnology; (b) provides flexibility for innovation while ensuring adequate safeguards for neurocognitive rights; (c) adapts to emerging scientific evidence and technological developments; and (d) balances individual rights with collective benefits and societal interests.

(2) In assessing the level of risk posed by neurotechnology, the following factors shall be considered: (a) the invasiveness of the technology; (b) the directness of interaction with neural tissue; (c) the depth and specificity of neural data collection; (d) the potential for modulation of neural activity; (e) the intended purpose and context of use; (f) the vulnerability of the intended user population; (g) the quality and reliability of the technology; (h) the potential for unintended effects or harms; (i) the reversibility of any effects; (j) the nature and extent of potential privacy implications; and (k) any other relevant factors prescribed by regulation.

Classification of Neurotechnology

24. (1) For the purposes of this Act, neurotechnology shall be classified into the following risk categories: (a) minimal risk neurotechnology; (b) low risk neurotechnology; (c) moderate risk neurotechnology; (d) high risk neurotechnology; and (e) unacceptable risk neurotechnology.

(2) The classification of specific neurotechnology shall be determined based on: (a) the factors listed in subsection 23(2); (b) the provisions of sections 25 to 29; and (c) any additional criteria prescribed by the Commission.

(3) Where a neurotechnology could potentially fall into more than one risk category, it shall be classified in the highest applicable risk category.

(4) The Commission shall maintain and publish a regularly updated registry of classified neurotechnologies.

(5) A provider of neurotechnology shall, before placing a neurotechnology on the market or putting it into service, determine the applicable risk category for that neurotechnology in accordance with this section.

(6) If the Commission determines that a provider has incorrectly classified a neurotechnology, it may issue a notice requiring the provider to reclassify the neurotechnology in accordance with the Commission's determination.

Minimal Risk Neurotechnology

25. (1) Neurotechnology shall be classified as minimal risk if it: (a) does not interact directly with the brain or nervous system; (b) collects only superficial or limited neural data; (c) does not have the capability to decode specific cognitive states or processes; (d) does not stimulate or modulate neural activity; (e) is intended for general wellness, educational, or recreational purposes; and (f) poses no significant risk to mental privacy, cognitive liberty, or mental integrity.

(2) Examples of minimal risk neurotechnology may include: (a) simple consumer electroencephalography (EEG) devices designed for meditation assistance or general wellness; (b) neurofeedback applications with limited data collection for relaxation or focus training; (c) educational neurotechnology that demonstrates basic principles of neuroscience without detailed neural recording; and (d) other neurotechnology prescribed by regulation as minimal risk.

Low Risk Neurotechnology

26. (1) Neurotechnology shall be classified as low risk if it: (a) interacts with the brain or nervous system only indirectly or superficially; (b) collects limited neural data without the capability of detailed neural decoding; (c) provides mild neurostimulation within established safety parameters; (d) is intended for general wellness, educational, entertainment, or basic assistive purposes; and (e) poses limited risks to mental privacy, cognitive liberty, or mental integrity.

(2) Examples of low risk neurotechnology may include: (a) consumer-grade EEG devices that collect more detailed data but without advanced decoding capabilities; (b) transcranial direct current stimulation (tDCS) devices for general cognitive enhancement within established safety parameters; (c) basic neurofeedback systems for attention training or stress management; and (d) other neurotechnology prescribed by regulation as low risk.

Moderate Risk Neurotechnology

27. (1) Neurotechnology shall be classified as moderate risk if it: (a) interacts directly with the brain or nervous system; (b) collects detailed neural data with some decoding capabilities; (c) provides moderate neurostimulation that could potentially affect cognitive processes; (d) is intended for therapeutic, significant cognitive enhancement, or advanced assistive purposes; and (e) poses moderate risks to mental privacy, cognitive liberty, or mental integrity.

(2) Examples of moderate risk neurotechnology may include: (a) advanced consumer or clinical EEG systems with neural decoding capabilities; (b) transcranial magnetic stimulation (TMS) devices for mood or cognitive modulation; (c) closed-loop neurofeedback systems that automatically adjust stimulation based on neural activity; (d) brain-computer interfaces for assistive technology applications; and (e) other neurotechnology prescribed by regulation as moderate risk.

High Risk Neurotechnology

28. (1) Neurotechnology shall be classified as high risk if it: (a) interacts directly and significantly with the brain or nervous system; (b) collects comprehensive neural data with advanced decoding capabilities; (c) provides substantial neurostimulation that could significantly modulate cognitive processes or neural activity; (d) is intended for clinical treatment of neurological or psychiatric conditions, substantial cognitive modification, or integration with artificial intelligence systems; and (e) poses significant risks to mental privacy, cognitive liberty, or mental integrity.

(2) Examples of high risk neurotechnology may include: (a) invasive brain-computer interfaces; (b) deep brain stimulation devices; (c) comprehensive neural decoding systems capable of inferring complex mental states or thought content; (d) neurotechnology that enables significant cognitive enhancement or alteration; (e) neural devices that interact with or modify memory formation or retrieval; (f) integrated neural-AI systems with autonomous capabilities; and (g) other neurotechnology prescribed by regulation as high risk.

Unacceptable Risk Neurotechnology

29. (1) Neurotechnology shall be classified as unacceptable risk if it: (a) is designed or adapted primarily to: (i) manipulate a person's thoughts, decisions, or behavior without their knowledge or informed consent; (ii) inflict pain or suffering through direct neural stimulation; or (iii) suppress or override an individual's agency or autonomy without legitimate therapeutic purpose; (b) presents risks to neurocognitive rights that: (i) cannot be mitigated through reasonable safeguards; (ii) outweigh any potential benefits; or (iii) are incompatible with Canadian values and ethical principles; or (c) is prescribed by regulation as presenting an unacceptable risk.

(2) No person shall develop, manufacture, import, export, distribute, sell, or use neurotechnology classified as unacceptable risk, except: (a) for bona fide research purposes, with appropriate research ethics approval and safeguards; or (b) under exceptional circumstances prescribed by regulation, with specific authorization from the Commission.

General Safety and Performance Requirements

30. (1) All neurotechnology placed on the market or put into service in Canada shall: (a) be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, it performs safely and effectively; (b) not compromise the clinical condition or the safety of users or, where applicable, other persons; (c) achieve the performance intended by the provider and claimed in the marketing materials; (d) be designed and manufactured in such a way that the risks associated with its use are reduced as far as possible and acceptable when weighed against the benefits; (e) include all necessary safety features, taking into account the intended purpose and the context of use; (f) be accompanied by appropriate information and instructions for safe and effective use; (g) incorporate appropriate security features to protect against unauthorized access, use, or modification; and (h) meet any additional requirements prescribed by regulation.

(2) The provider of neurotechnology shall: (a) establish, document, implement, and maintain a risk management system to identify, analyze, evaluate, control, and monitor risks associated with the neurotechnology; (b) implement appropriate risk control measures; and (c) maintain a post-market surveillance system to monitor the performance and safety of the neurotechnology after it has been placed on the market or put into service.

Technical Standards and Specifications

31. (1) The Commission shall develop and publish technical standards and specifications for neurotechnology, taking into account: (a) international standards, where appropriate; (b) the state of scientific and technical knowledge; (c) the need for interoperability; and (d) the potential risks associated with different types of neurotechnology.

(2) Technical standards and specifications shall address, as appropriate: (a) physical and electrical safety; (b) biocompatibility, for invasive neurotechnology; (c) electromagnetic compatibility; (d) accuracy and precision of neural recording; (e) reliability and stability of neurostimulation; (f) software validation and verification; (g) cybersecurity requirements; (h) data quality standards; (i) interoperability requirements; and (j) human factors and usability.

(3) Compliance with the technical standards and specifications published by the Commission shall give rise to a presumption of conformity with the corresponding requirements of this Act.

(4) The Commission shall regularly review and update technical standards and specifications to reflect technological developments and evolving scientific knowledge.

Testing and Validation Requirements

32. (1) Before placing neurotechnology on the market or putting it into service, the provider shall ensure that: (a) the neurotechnology has undergone appropriate testing and validation, commensurate with its risk classification; (b) all claims regarding the performance, functionality, or effects of the neurotechnology are substantiated by valid scientific evidence; and (c) documentation of testing and validation is maintained and available for inspection by the Commission.

(2) Testing and validation shall include, as appropriate for the risk category: (a) laboratory testing; (b) simulations or modeling; (c) usability and human factors testing; (d) clinical investigations or trials; (e) security testing; and (f) any other testing prescribed by regulation.

(3) The Commission may establish specific testing and validation requirements for different categories of neurotechnology.

Quality Management System

33. (1) Providers of moderate and high risk neurotechnology shall establish, document, implement, and maintain a quality management system that: (a) ensures compliance with the requirements of this Act; (b) covers all parts and elements of the provider's organization involved in the quality of processes, systems, and neurotechnology; (c) addresses organizational structure, management responsibility, resource management, and product realization; and (d) includes monitoring, measurement, analysis, and improvement processes.

(2) The quality management system shall be appropriate to the risk classification of the neurotechnology and the size and complexity of the provider's organization.

(3) The Commission may establish detailed requirements for quality management systems based on internationally recognized standards.

Labeling and Information Requirements

34. (1) All neurotechnology shall be accompanied by information necessary for: (a) proper identification of the neurotechnology; (b) safe and effective use by the intended user; and (c) understanding the potential risks and benefits associated with the use of the neurotechnology.

(2) Information accompanying neurotechnology shall: (a) be provided in English and French; (b) be clear, comprehensible, and accessible to the intended user; (c) include, as appropriate: (i) the name and contact information of the provider; (ii) the intended purpose, functions, and effects of the neurotechnology; (iii) instructions for proper use; (iv) any contraindications, warnings, or precautions; (v) potential side effects or adverse reactions; (vi) maintenance and cleaning instructions; (vii) information regarding neural data collection, processing, storage, and protection; (viii) any limitations or uncertainties regarding the performance or effects of the neurotechnology; and (ix) any other information prescribed by regulation.

(3) The specific information requirements shall be calibrated to the risk classification of the neurotechnology.

Post-Market Surveillance and Reporting

35. (1) Providers of neurotechnology shall: (a) establish and maintain a post-market surveillance system commensurate with the risk classification of the neurotechnology; (b) collect and analyze information about the performance and safety of the neurotechnology after it has been placed on the market or put into service; and (c) take appropriate action based on this information, including: (i) updating the risk assessment; (ii) improving the neurotechnology; (iii) updating user information; or (iv) recalling or withdrawing the neurotechnology, if necessary.

(2) Providers of moderate and high risk neurotechnology shall: (a) maintain a register of complaints and incidents; (b) report serious incidents to the Commission within the timeframe prescribed by regulation; (c) prepare and submit periodic safety update reports to the Commission; and (d) cooperate with the Commission in its market surveillance activities.

(3) A serious incident means any incident that directly or indirectly led, might have led, or might lead to: (a) temporary or permanent serious deterioration of a person's state of health

or cognitive function; (b) a violation of a person's neurocognitive rights; or (c) a serious public health concern.

Neurotechnology Impact Assessment

36. (1) Before placing high risk neurotechnology on the market or putting it into service, the provider shall conduct and document a neurotechnology impact assessment that includes: (a) a description of the neurotechnology, its intended purpose, and context of use; (b) an assessment of the potential risks to neurocognitive rights; (c) an evaluation of the potential impact on vulnerable populations; (d) an analysis of the neural data collection, processing, storage, and protection measures; (e) an assessment of security vulnerabilities and countermeasures; (f) a benefit-risk analysis; (g) documentation of risk mitigation measures; and (h) any other elements prescribed by regulation.

(2) The Commission shall provide guidance on the methodology for conducting neurotechnology impact assessments.

(3) Providers shall update the neurotechnology impact assessment: (a) when there is a significant change to the neurotechnology or its intended use; (b) when new risks or impacts are identified through post-market surveillance; or (c) at intervals prescribed by regulation.

(4) The Commission may require a provider to submit a neurotechnology impact assessment for review and may recommend or require modifications to the neurotechnology or its documentation based on its review.

Specific Requirements for Minimal Risk Neurotechnology

37. (1) Providers of minimal risk neurotechnology shall: (a) comply with the general safety and performance requirements in section 30; (b) provide clear and accurate information about the capabilities and limitations of the neurotechnology; (c) implement basic security measures to protect any neural data collected; and (d) maintain records of any adverse effects reported by users.

(2) Before placing minimal risk neurotechnology on the market, providers shall submit a notification to the Commission that includes: (a) the name and contact information of the provider; (b) a description of the neurotechnology and its intended purpose; (c) confirmation of compliance with the applicable requirements of this Act; and (d) any other information prescribed by regulation.

Specific Requirements for Low Risk Neurotechnology

38. (1) In addition to the requirements applicable to minimal risk neurotechnology, providers of low risk neurotechnology shall: (a) conduct and document basic verification and validation testing; (b) implement appropriate data protection measures for any neural data collected; (c) provide clear instructions for safe use, including any limitations or contraindications; and (d) establish a basic system for post-market surveillance and complaint handling.

(2) Before placing low risk neurotechnology on the market, providers shall submit a registration application to the Commission that includes: (a) the information required for minimal risk neurotechnology under subsection 37(2); (b) a summary of verification and validation testing results; (c) a description of the data protection measures implemented; and (d) any other information prescribed by regulation.

(3) The Commission shall review the registration application and, if satisfied that the neurotechnology complies with the applicable requirements, issue a registration certificate.

Specific Requirements for Moderate Risk Neurotechnology

39. (1) In addition to the requirements applicable to low risk neurotechnology, providers of moderate risk neurotechnology shall: (a) establish and maintain a quality management system in accordance with section 33; (b) conduct comprehensive testing and validation, including usability testing with representative users; (c) implement robust data protection measures, including encryption of neural data; (d) provide detailed user information, including potential risks and limitations; (e) establish a comprehensive post-market surveillance system; and (f) designate a qualified person responsible for regulatory compliance.

(2) Before placing moderate risk neurotechnology on the market, providers shall submit an application for authorization to the Commission that includes: (a) the information required for low risk neurotechnology under subsection 38(2); (b) documentation of the quality management system; (c) comprehensive testing and validation results; (d) a summary technical documentation file; and (e) any other information prescribed by regulation.

(3) The Commission shall review the application and, if satisfied that the neurotechnology complies with the applicable requirements, issue an authorization certificate.

Specific Requirements for High Risk Neurotechnology

40. (1) In addition to the requirements applicable to moderate risk neurotechnology, providers of high risk neurotechnology shall: (a) conduct a neurotechnology impact assessment in accordance with section 36; (b) implement state-of-the-art security measures for the protection of neural data and prevention of unauthorized access; (c) conduct clinical investigations or trials, where appropriate; (d) establish a comprehensive risk management system with ongoing monitoring and evaluation; (e) implement a system for the traceability of individual units or batches of the neurotechnology; and (f) maintain an implant card or equivalent information for invasive neurotechnology.

(2) Before placing high risk neurotechnology on the market, providers shall submit an application for certification to the Commission that includes: (a) the information required for moderate risk neurotechnology under subsection 39(2); (b) the neurotechnology impact assessment; (c) detailed documentation of clinical investigations or trials, where applicable; (d) comprehensive technical documentation, including design specifications, risk analysis, and verification and validation data; and (e) any other information prescribed by regulation.

(3) The Commission shall conduct a thorough assessment of the application, which may include: (a) review of the technical documentation and supporting evidence; (b) inspection of the provider's facilities; (c) testing or examination of samples of the neurotechnology; and (d) consultation with external experts, where appropriate.

(4) If satisfied that the neurotechnology complies with the applicable requirements, the Commission shall issue a certificate of conformity.

(5) Certificates of conformity for high risk neurotechnology shall be valid for a period prescribed by regulation and may be renewed upon application and reassessment.

PART 4 - CANADIAN NEUROTECHNOLOGY COMMISSION

Establishment of the Commission

41. (1) A commission to be known as the Canadian Neurotechnology Commission is established.

(2) The Commission is a body corporate that is an agent of Her Majesty in right of Canada.

(3) The Commission shall consist of: (a) a Chief Commissioner; (b) a Deputy Chief Commissioner; and (c) not fewer than five and not more than nine additional Commissioners.

(4) The Governor in Council shall appoint the Chief Commissioner, Deputy Chief Commissioner, and other Commissioners on the recommendation of the Minister, after consultation with relevant stakeholders.

(5) In appointing the Commissioners, the Governor in Council shall ensure that, as a group, the Commissioners possess: (a) expertise in neuroscience, neurotechnology, neuroethics, and related fields; (b) knowledge of regulatory frameworks and governance; (c) understanding of human rights, privacy, and data protection; (d) familiarity with the healthcare sector and medical device regulation; (e) knowledge of the technology sector and innovation; and (f) expertise in public policy, law, and ethics.

(6) The Governor in Council shall ensure that the composition of the Commission reflects the diversity of Canadian society, including gender balance, representation of various regions, and inclusion of Indigenous perspectives.

(7) The Commissioners shall be appointed for terms not exceeding five years, which may be renewed once.

(8) The Commission may employ such officers, employees, and agents as are necessary for the proper conduct of its work, and may establish regional offices within Canada.

Mandate and Powers of the Commission

42. (1) The Commission shall: (a) administer and enforce this Act; (b) develop and implement the regulatory framework for neurotechnology in Canada; (c) monitor and assess developments in neurotechnology and their implications for neurocognitive rights; (d) promote the protection of neurocognitive rights; (e) provide advice to the Government of Canada on matters related to neurotechnology and neurocognitive rights; (f) coordinate with other federal, provincial, and territorial authorities on matters related to neurotechnology regulation; (g) represent Canada in international forums related to neurotechnology governance; and (h) carry out any other functions assigned to it by this Act or any other Act of Parliament.

(2) The Commission may: (a) make regulations with respect to any matter that may be regulated under this Act; (b) issue guidelines, recommendations, and best practices related to neurotechnology; (c) establish registration, authorization, and certification systems for neurotechnology; (d) conduct or commission research on neurotechnology and its implications; (e) establish advisory committees on specific issues related to

neurotechnology; (f) conduct inspections and investigations to ensure compliance with this Act; (g) collect, analyze, and publish data and information related to neurotechnology and neurocognitive rights; (h) enter into agreements with provincial, territorial, foreign, or international authorities regarding matters within its mandate; (i) organize or participate in educational and awareness programs regarding neurocognitive rights and neurotechnology; and (j) exercise any other powers necessary to fulfill its mandate.

(3) The Commission shall exercise its powers in a manner that: (a) is independent, impartial, and transparent; (b) respects Canada's international obligations; (c) promotes innovation while ensuring adequate protection of neurocognitive rights; (d) is responsive to emerging technological developments; and (e) takes into account the needs and interests of diverse stakeholders.

Regulatory Functions

43. (1) The Commission shall, by regulation: (a) establish detailed requirements for each risk category of neurotechnology; (b) specify the procedures for classification, registration, authorization, and certification of neurotechnology; (c) establish performance standards and technical specifications for neurotechnology; (d) prescribe the information to be provided with neurotechnology; (e) establish post-market surveillance requirements; (f) set out the requirements for quality management systems; (g) establish procedures for investigating incidents and implementing corrective actions; (h) prescribe the content and format of notifications, applications, and reports to be submitted to the Commission; (i) establish fees for services provided by the Commission; and (j) make any other regulations necessary for carrying out the purposes and provisions of this Act.

(2) Before making regulations under this Act, the Commission shall: (a) publish proposed regulations in the Canada Gazette for a period of public comment; (b) consider the comments received during the public comment period; (c) consult with relevant stakeholders; and (d) conduct an impact analysis of the proposed regulations.

(3) The Commission shall regularly review and update its regulations to reflect technological developments, evolving scientific knowledge, and international best practices.

Registry of Neurotechnology

44. (1) The Commission shall establish and maintain a public registry of neurotechnology that has been: (a) notified to the Commission under section 37; (b) registered under section 38; (c) authorized under section 39; or (d) certified under section 40.

(2) The registry shall include, for each neurotechnology: (a) the name and contact information of the provider; (b) the name, model, and version of the neurotechnology; (c) a description of the neurotechnology and its intended purpose; (d) the risk classification of the neurotechnology; (e) the status of notification, registration, authorization, or certification; and (f) any other information prescribed by regulation.

(3) The Commission shall make the registry accessible to the public in an easily searchable format, with appropriate protection for confidential business information.

Scientific Advisory Committee

45. (1) The Commission shall establish a Scientific Advisory Committee to provide advice on scientific and technical matters related to neurotechnology and neurocognitive rights.

(2) The Scientific Advisory Committee shall consist of experts in fields including, but not limited to: (a) neuroscience; (b) neurotechnology; (c) neuroethics; (d) neuropsychology; (e) clinical neurology and psychiatry; (f) biomedical engineering; (g) artificial intelligence; (h) data science; and (i) any other field of expertise relevant to the Commission's mandate.

(3) The Commission shall appoint members of the Scientific Advisory Committee based on their expertise, ensuring a balance of scientific disciplines and perspectives.

(4) The Scientific Advisory Committee shall: (a) provide scientific and technical advice to the Commission on matters related to neurotechnology and neurocognitive rights; (b) review and evaluate scientific developments in neurotechnology; (c) assist in the development of technical standards and specifications; (d) provide input on the classification of neurotechnology; and (e) perform any other advisory functions requested by the Commission.

(5) The Scientific Advisory Committee may establish working groups to address specific scientific or technical issues.

Commissioner of Neurocognitive Rights

46. (1) The Governor in Council shall appoint a Commissioner of Neurocognitive Rights after consultation with the leader of every recognized party in the Senate and House of Commons.

(2) The Commissioner of Neurocognitive Rights shall: (a) monitor and report on compliance with the neurocognitive rights established in Part 2; (b) investigate complaints of violations of neurocognitive rights; (c) promote awareness and understanding of neurocognitive rights; (d) provide advice to government institutions, organizations, and individuals on matters related to neurocognitive rights; (e) conduct research on issues affecting neurocognitive rights; (f) collaborate with the Commission on matters related to neurocognitive rights; and (g) carry out any other functions assigned to the Commissioner by this Act or any other Act of Parliament.

(3) The Commissioner shall be appointed for a term of seven years, which may be renewed once.

(4) The Commissioner shall act independently in the exercise of their functions and shall report directly to Parliament.

(5) The Commissioner shall submit an annual report to Parliament on the state of neurocognitive rights in Canada, including any recommendations for legislative or policy changes.

Market Surveillance and Enforcement

47. (1) The Commission shall establish a market surveillance program to: (a) monitor neurotechnology placed on the market or put into service in Canada for compliance with this Act; (b) investigate reports of non-compliant neurotechnology or serious incidents; (c) assess reports submitted by providers under the post-market surveillance requirements; and (d) take appropriate enforcement action in cases of non-compliance.

(2) For the purposes of market surveillance, the Commission may: (a) inspect the premises of providers, importers, distributors, and users of neurotechnology; (b) examine and test samples of neurotechnology; (c) require the production of documents and information; (d) interview employees and other relevant persons; and (e) exercise any other powers prescribed by regulation.

(3) If the Commission determines that neurotechnology does not comply with this Act, it may: (a) require the provider to bring the neurotechnology into compliance within a specified period; (b) restrict the availability of the neurotechnology; (c) require the withdrawal of the neurotechnology from the market; (d) recall the neurotechnology; (e) suspend or revoke the registration, authorization, or certification of the neurotechnology; (f) impose administrative penalties; or (g) take any other action prescribed by regulation.

(4) The Commission shall establish procedures for: (a) receiving and investigating complaints about neurotechnology; (b) coordinating with other regulatory authorities; and (c) notifying the public about non-compliant neurotechnology or serious incidents.

International Cooperation and Harmonization

48. (1) The Commission shall: (a) monitor international developments in neurotechnology regulation and governance; (b) participate in international forums and initiatives related to neurotechnology and neurocognitive rights; (c) collaborate with regulatory authorities in other jurisdictions on matters of mutual interest; (d) work toward the harmonization of regulatory approaches for neurotechnology, where appropriate; and (e) represent Canada's interests in the development of international standards and guidelines for neurotechnology.

(2) The Commission may enter into agreements with foreign or international authorities regarding: (a) information exchange; (b) mutual recognition of conformity assessments; (c) coordination of market surveillance activities; (d) sharing of best practices; and (e) other areas of cooperation related to neurotechnology regulation.

(3) The Commission shall consider internationally recognized standards and best practices in developing its regulations, guidelines, and procedures.

Research and Innovation Support

49. (1) The Commission shall support responsible research and innovation in neurotechnology by: (a) establishing clear regulatory pathways for innovative neurotechnologies; (b) providing guidance to researchers and developers on compliance with this Act; (c) implementing regulatory sandboxes or testbeds for novel neurotechnologies; (d) identifying priority areas for neurotechnology research that address societal challenges; and (e) collaborating with research funding agencies to promote responsible innovation.

(2) The Commission shall establish a program to provide regulatory support to small and medium-sized enterprises and academic researchers working on neurotechnology, which may include: (a) pre-submission consultation; (b) guidance on regulatory requirements; (c) expedited review processes for certain types of applications; and (d) reduced fees for eligible applicants.

(3) The Commission shall collaborate with Innovation, Science and Economic Development Canada and other relevant departments and agencies to ensure that Canada's neurotechnology ecosystem remains competitive while respecting neurocognitive rights.

Public Engagement and Education

50. (1) The Commission shall promote public awareness and understanding of neurotechnology and neurocognitive rights through: (a) educational programs and materials; (b) public consultations and dialogue; (c) collaboration with educational institutions; (d) engagement with civil society organizations; and (e) communication through various media channels.

(2) The Commission shall maintain a website that provides: (a) information about neurotechnology and neurocognitive rights; (b) access to the registry of neurotechnology; (c) guidance for providers, users, and the general public; (d) procedures for submitting complaints or reports of incidents; and (e) any other information that may be useful to the public.

(3) The Commission shall establish mechanisms for ongoing public input on matters related to neurotechnology regulation and neurocognitive rights.

Annual Report and Reviews

51. (1) The Commission shall submit an annual report to Parliament through the Minister, which shall include: (a) a summary of the Commission's activities and achievements; (b) information on the state of neurotechnology in Canada; (c) data on compliance and enforcement actions; (d) emerging trends and issues in neurotechnology; (e) international developments relevant to the Commission's mandate; and (f) any recommendations for legislative or policy changes.

(2) The Commission shall conduct periodic reviews of: (a) the effectiveness of this Act in protecting neurocognitive rights and regulating neurotechnology; (b) the regulatory framework and its impact on innovation, safety, and rights protection; (c) the classification system for neurotechnology; (d) the performance of the Commission in fulfilling its mandate; and (e) emerging issues and challenges in neurotechnology governance.

(3) The first review shall be completed within five years after the coming into force of this Act, and subsequent reviews shall be conducted at intervals not exceeding five years.

(4) The Commission shall publish the results of each review and submit them to Parliament.

Funding and Financial Provisions

52. (1) The Commission shall be funded through: (a) appropriations by Parliament; (b) fees collected for services provided by the Commission; (c) administrative monetary penalties imposed under this Act; and (d) any other source of funding authorized by Parliament.

(2) The Commission shall establish a fee structure for: (a) processing notifications, registrations, authorizations, and certifications; (b) conducting inspections and assessments; (c) providing guidance and consultations; and (d) any other services provided by the Commission.

(3) The fee structure shall take into account: (a) the size and resources of the applicant organization; (b) the risk classification of the neurotechnology; (c) the complexity of the assessment required; and (d) any other relevant factors.

(4) The Commission shall publish its fee structure and ensure that it does not create undue barriers to innovation, particularly for small and medium-sized enterprises and academic researchers.

(5) The Commission shall submit an annual financial report to the Minister, including: (a) revenues from all sources; (b) expenditures by program and activity; (c) administrative costs; and (d) projected financial requirements for the next fiscal year.

Rules of Procedure

53. (1) The Commission shall establish rules of procedure for: (a) meetings of the Commission; (b) decision-making processes; (c) handling of conflicts of interest; (d) delegation of authority; (e) interactions with stakeholders and the public; and (f) any other matters necessary for the effective operation of the Commission.

(2) The rules of procedure shall be published and made available to the public.

Relationship with Other Bodies

54. (1) The Commission shall cooperate and coordinate with: (a) Health Canada and other federal departments and agencies with relevant mandates; (b) provincial and territorial authorities responsible for healthcare, privacy, consumer protection, and related areas; (c) the Privacy Commissioner of Canada; (d) the Commissioner of Neurocognitive Rights; (e) the Canadian Human Rights Commission; (f) the Standards Council of Canada; and (g) any other bodies with mandates relevant to neurotechnology and neurocognitive rights.

(2) The Commission may enter into memoranda of understanding with these bodies to clarify roles and responsibilities and establish mechanisms for cooperation.

(3) The Commission shall work to minimize regulatory duplication and ensure coherent and complementary approaches to neurotechnology governance across different authorities.

Administrative Monetary Penalties

55. (1) The Commission may impose administrative monetary penalties for: (a) placing non-compliant neurotechnology on the market; (b) providing false or misleading information to the Commission; (c) obstructing the Commission's market surveillance activities; (d) failing to comply with post-market surveillance and reporting requirements; (e) failing to take required corrective actions; or (f) any other contraventions of this Act or regulations made under it.

(2) The maximum amount of an administrative monetary penalty shall be: (a) $100,000 for violations by individuals; and (b) $500,000 for violations by corporations or other organizations.

(3) In determining the amount of a penalty, the Commission shall take into account: (a) the nature and gravity of the violation; (b) the history of compliance; (c) any benefit derived from the violation; (d) the ability to pay; (e) any harm caused by the violation; and (f) any other relevant factors.

(4) The Commission shall establish procedures for: (a) issuing notices of violation; (b) providing opportunities for the alleged violator to make representations; (c) determining whether a violation has occurred; (d) imposing penalties; and (e) reviewing and appealing decisions regarding penalties.

(5) Administrative monetary penalties are in addition to, and not in substitution for, any other remedies or sanctions available under this Act or any other Act of Parliament.

Transitional Provisions

56. (1) Neurotechnology that was legally placed on the market in Canada before the coming into force of this Act may continue to be made available on the market or put into service for a period of: (a) one year from the coming into force of this Act, for neurotechnology that would be classified as minimal or low risk; (b) two years from the coming into force of this Act, for neurotechnology that would be classified as moderate risk; and (c) three years from the coming into force of this Act, for neurotechnology that would be classified as high risk.

(2) During the transitional period, providers of existing neurotechnology shall: (a) determine the appropriate risk classification for their neurotechnology under this Act; (b) take steps to bring their neurotechnology into compliance with the applicable requirements; and (c) submit the required notifications, applications for registration, authorization, or certification to the Commission.

(3) The Commission may extend the transitional period for specific categories of neurotechnology or individual products if: (a) there are technical or practical challenges in bringing the neurotechnology into compliance within the standard transitional period; (b) the neurotechnology provides significant benefits to users; and (c) there are no known serious safety concerns or risks to neurocognitive rights.

(4) The Commission shall provide guidance and support to help providers transition to the new regulatory framework.

PART 5 - NEUROCOGNITIVE DATA PROTECTION

Classification of Neurocognitive Data

57. (1) For the purposes of this Act, neurocognitive data is classified as a special category of personal information that requires enhanced protection due to its intimate connection to an individual's cognitive processes, mental states, and personal identity.

(2) Neurocognitive data includes, but is not limited to: (a) raw neural data, such as electroencephalography (EEG) recordings, functional magnetic resonance imaging (fMRI) data, or data from invasive neural recordings; (b) processed neural data, including extracted features, patterns, or signals derived from raw neural data; (c) interpreted neural data, such as inferred mental states, cognitive processes, or intentions based on neural recordings; (d) neural profiles, which are persistent collections of neural data associated with an individual; and (e) any other data that is derived from the monitoring or recording of brain activity or neural function.

(3) Neurocognitive data shall be subject to: (a) the protections afforded to personal information under the *Privacy Act* and the *Personal Information Protection and Electronic Documents Act*; and (b) the additional protections and requirements established in this Part.

(4) In the event of any inconsistency between this Part and any other federal legislation regarding the protection of personal information, the provision that provides the higher level of protection for neurocognitive data prevails to the extent of the inconsistency.

Ownership and Control of Neurocognitive Data

58. (1) An individual has primary ownership rights over neurocognitive data derived from their brain activity, regardless of who collected the data or the means by which it was collected.

(2) The rights of ownership include: (a) the right to access one's neurocognitive data; (b) the right to control the collection, use, and disclosure of one's neurocognitive data; (c) the right to correct inaccurate neurocognitive data; (d) the right to delete or have deleted one's neurocognitive data, subject to reasonable limitations; (e) the right to port one's neurocognitive data to another service or platform; and (f) the right to limit or restrict the processing of one's neurocognitive data.

(3) Any agreement or contract that purports to transfer primary ownership rights over neurocognitive data to another party is void, except that: (a) limited licenses for specific uses may be granted through informed consent; and (b) anonymized neurocognitive data may be used for research or statistical purposes under the conditions specified in section 65.

(4) Neurocognitive data collected from an individual who lacks the capacity to provide informed consent shall be: (a) collected and used only for purposes that are in the best interests of that individual or for legitimate research purposes with appropriate ethical approval; (b) subject to the consent of a substitute decision-maker, where applicable; and (c) provided to the individual once they regain capacity, if that occurs.

Consent Requirements for Neurocognitive Data

59. (1) No person shall collect, use, or disclose neurocognitive data without the explicit, informed consent of the individual from whom the data is derived, except as provided in subsections (5) and (6).

(2) Consent for the collection, use, or disclosure of neurocognitive data must meet the requirements for informed consent specified in section 15 and must also: (a) be specific to each distinct purpose for which the neurocognitive data will be used; (b) be separate from consent for other types of data collection; (c) be provided after the individual has been informed, in clear and plain language, about: (i) the specific types of neurocognitive data to be collected; (ii) the methods used to interpret or derive information from the neural data; (iii) the level of precision or accuracy of any interpretations or inferences; (iv) the potential for unintended information to be derived from the data; (v) any potential for reidentification if the data is anonymized; (vi) the data retention period; and (vii) the data security measures in place; and (d) be recorded in a manner that allows for verification.

(3) Consent for the collection, use, or disclosure of neurocognitive data may be withdrawn at any time, subject to reasonable notice requirements and legal or contractual restrictions.

(4) Upon withdrawal of consent, the neural data controller shall: (a) cease collecting neurocognitive data from the individual; (b) stop using or disclosing the individual's neurocognitive data for the purposes covered by the withdrawn consent; and (c) delete the

individual's neurocognitive data within a reasonable time period, unless: (i) retention is required by law; (ii) the data has been irreversibly anonymized; or (iii) deletion would compromise the integrity of data that includes neurocognitive data from other individuals who have not withdrawn consent.

(5) Neurocognitive data may be collected, used, or disclosed without consent only if: (a) it is clearly in the interests of the individual and consent cannot be obtained in a timely way; (b) it is necessary for the purpose of responding to an emergency that threatens the life, health, or security of an individual; (c) the collection, use, or disclosure is authorized by a warrant, order, or other legal requirement; (d) the information is used for statistical or research purposes and meets the requirements of section 65; or (e) the information is publicly available and specified by regulation.

(6) For individuals who lack the capacity to provide informed consent, the provisions of provincial and territorial laws relating to substitute decision-making apply, with the additional requirement that any decision made by a substitute decision-maker regarding neurocognitive data must: (a) prioritize the best interests of the individual; (b) take into account any previously expressed wishes or preferences of the individual; and (c) be subject to review by the Neurocognitive Rights Tribunal upon application by any interested party.

Data Minimization and Purpose Limitation

60. (1) A neural data controller shall: (a) collect only the neurocognitive data that is necessary for the specified purpose; (b) process neurocognitive data only in ways that are compatible with the purpose for which it was collected; (c) retain neurocognitive data only for as long as necessary to fulfill the purpose for which it was collected; and (d) delete neurocognitive data when it is no longer needed for the specified purpose, unless: (i) retention is required by law; (ii) the data has been irreversibly anonymized; or (iii) the individual has provided explicit consent for longer retention.

(2) A neural data controller shall implement technical and organizational measures to ensure that, by default: (a) only the minimum necessary neurocognitive data is collected; (b) the extent of processing is limited to what is necessary; (c) the data is accessible only to those who need it for the specified purpose; and (d) the data is not made available to an indefinite number of persons without the individual's intervention.

(3) A neural data controller shall perform an assessment of the necessity and proportionality of neurocognitive data collection and processing for each distinct purpose.

Security Requirements for Neurocognitive Data

61. (1) A neural data controller shall implement appropriate technical and organizational measures to ensure a level of security appropriate to the risk presented by the processing of neurocognitive data, taking into account: (a) the state of the art; (b) the costs of implementation; (c) the nature, scope, context, and purposes of processing; and (d) the risks to the rights and freedoms of individuals.

(2) The measures referred to in subsection (1) shall include, as appropriate: (a) encryption of neurocognitive data at rest and in transit; (b) measures to ensure the ongoing confidentiality, integrity, availability, and resilience of processing systems and services; (c) measures to restore access to neurocognitive data in a timely manner in the event of a

physical or technical incident; (d) regular testing, assessment, and evaluation of the effectiveness of security measures; (e) access controls that limit access to authorized personnel; (f) authentication mechanisms proportionate to the sensitivity of the data; (g) logging and monitoring of access and processing activities; and (h) regular security audits and vulnerability assessments.

(3) Neural data controllers and processors that process neurocognitive data from a significant number of individuals, to be prescribed by regulation, shall: (a) appoint a data protection officer with expertise in neurocognitive data protection; (b) conduct regular data protection impact assessments; and (c) implement a comprehensive information security management system based on recognized standards.

(4) The Commission, in consultation with the Privacy Commissioner, shall issue guidelines on security measures appropriate for different types and volumes of neurocognitive data.

Data Breach Notification and Response

62. (1) In the event of a neural data breach that creates a real risk of significant harm to an individual, the neural data controller shall: (a) notify the affected individual and the Commission as soon as feasible after discovering the breach; (b) notify any other neural data controller or processor that may be affected by the breach; (c) take reasonable steps to mitigate the harm that could result from the breach; and (d) keep records of all neural data breaches, including details of the breach, its effects, and the remedial action taken.

(2) The notification to affected individuals shall include: (a) a description of the circumstances of the breach; (b) the date or period during which the breach occurred or the estimated date or period; (c) a description of the neurocognitive data that was compromised; (d) a description of the steps the neural data controller has taken to reduce the risk of harm; (e) a description of the steps affected individuals can take to reduce the risk of harm or mitigate the harm; (f) contact information for the neural data controller; and (g) information about the individual's right to file a complaint with the Commission.

(3) The notification to the Commission shall include the information in subsection (2) as well as: (a) the number of individuals affected by the breach; (b) a detailed description of the security measures in place at the time of the breach; (c) a description of the cause of the breach, if known; (d) a detailed description of the steps taken to prevent future breaches; and (e) any other information prescribed by regulation.

(4) The Commission may: (a) investigate the breach; (b) require the neural data controller to take additional steps to mitigate harm; (c) order the neural data controller to notify additional persons of the breach; or (d) publish information about the breach if it is in the public interest to do so.

(5) The Governor in Council may make regulations: (a) specifying what constitutes a real risk of significant harm; (b) prescribing the form and manner of notifications; (c) prescribing circumstances in which notifications are not required; and (d) prescribing additional requirements for data breach responses.

Limitations on Transfer and Secondary Use

63. (1) A neural data controller shall not transfer neurocognitive data to a third party unless: (a) the individual has provided explicit consent for the specific transfer; (b) the transfer is necessary for the performance of a contract between the individual and the neural data controller; (c) the transfer is necessary for important reasons of public interest recognized by law; (d) the transfer is necessary to protect the vital interests of the individual or another person; or (e) the transfer is authorized by a warrant, order, or other legal requirement.

(2) Before transferring neurocognitive data to a third party, the neural data controller shall: (a) ensure that the third party is capable of providing a level of protection for the neurocognitive data that is at least equivalent to that required by this Act; (b) enter into a data processing agreement that specifies the conditions for processing, including security requirements and limitations on further transfers; and (c) maintain records of all transfers, including the identity of the recipient and the purpose of the transfer.

(3) Neurocognitive data collected for one purpose shall not be used for a different purpose unless: (a) the individual has provided explicit consent for the new purpose; (b) the new purpose is compatible with the original purpose, and the individual has been informed of the new purpose and given an opportunity to object; (c) the data has been irreversibly anonymized and is used in accordance with section 65; or (d) the new use is required by law.

(4) In determining whether a new purpose is compatible with the original purpose, the neural data controller shall take into account: (a) any link between the original purpose and the new purpose; (b) the context in which the neurocognitive data was collected; (c) the nature of the neurocognitive data, particularly whether it includes sensitive inferences about mental states or cognitive processes; (d) the possible consequences of the new processing for the individual; and (e) the existence of appropriate safeguards.

(5) Neural data controllers shall maintain records of all secondary uses of neurocognitive data, including the purpose, legal basis, and any risk assessments conducted.

Cross-Border Data Transfers

64. (1) Neurocognitive data may be transferred to a recipient in a foreign jurisdiction only if: (a) the jurisdiction provides a level of protection for neurocognitive data that is comparable to that provided by this Act; (b) the neural data controller has implemented appropriate safeguards, including enforceable data subject rights and effective legal remedies; or (c) the individual has explicitly consented to the transfer after being informed of the possible risks.

(2) The Commission shall maintain and publish a list of jurisdictions that provide a comparable level of protection for neurocognitive data.

(3) Appropriate safeguards referred to in paragraph (1)(b) may include: (a) a legally binding agreement between public authorities or bodies; (b) binding corporate rules approved by the Commission; (c) standard data protection clauses adopted by the Commission; (d) an approved code of conduct; or (e) an approved certification mechanism.

(4) A neural data controller shall document the assessment of the level of protection and safeguards implemented for cross-border transfers of neurocognitive data.

(5) The Commission may prohibit or restrict transfers of neurocognitive data to specific jurisdictions or recipients if it determines that adequate protection cannot be ensured.

Research Use of Neurocognitive Data

65. (1) Neurocognitive data may be processed for scientific research purposes beyond the purpose for which it was initially collected if: (a) the individual has provided explicit consent for the research use; (b) the data has been anonymized to the extent that the individual is no longer identifiable, taking into account all reasonable means that might be used to reidentify the individual; or (c) the research has been approved by a research ethics board and meets the requirements of subsection (3).

(2) Anonymization of neurocognitive data shall take into account: (a) the unique characteristics of neural data that may make reidentification possible even after traditional anonymization techniques have been applied; (b) the potential for indirect identification through correlation with other datasets; and (c) the evolving capabilities of reidentification techniques.

(3) Research use of neurocognitive data without explicit consent must: (a) serve an important public interest; (b) be subject to appropriate safeguards to protect the rights and interests of the individual; (c) be conducted under conditions that minimize risks to privacy and other rights; (d) not involve making decisions about the individual based on the data; (e) be subject to oversight by a research ethics board; and (f) comply with any other requirements prescribed by regulation.

(4) Researchers using neurocognitive data shall: (a) implement appropriate security measures; (b) limit access to authorized personnel; (c) use the data only for the approved research purpose; (d) publish or otherwise share only aggregate results or properly anonymized data; (e) destroy or return the data when the research is complete, unless further retention is approved by a research ethics board; and (f) report any breaches or unauthorized uses to the Commission.

(5) The Commission, in consultation with research ethics boards and relevant stakeholders, shall develop detailed guidelines for the research use of neurocognitive data.

Prohibition on Discrimination

66. (1) No person shall: (a) use neurocognitive data to discriminate against an individual in a manner prohibited by the *Canadian Human Rights Act* or any other federal or provincial anti-discrimination law; (b) make decisions about access to goods, services, accommodations, employment, or other opportunities based on neurocognitive data, except where: (i) there is a demonstrable and reasonable relationship between the neurocognitive data and the decision being made; (ii) the use of the neurocognitive data is necessary to achieve a legitimate aim; and (iii) the individual has provided explicit informed consent for this use; or (c) use neurocognitive data to profile individuals in a manner that could lead to discriminatory effects.

(2) Employers shall not: (a) require job applicants or employees to undergo neural monitoring or provide neurocognitive data as a condition of employment, except where: (i) the neurocognitive data is directly relevant to an essential job function; (ii) there is no less intrusive means of assessing the relevant capacity; and (iii) the requirement is authorized by law or regulation for specific high-risk occupations; (b) use neurocognitive data to monitor employee performance, attitudes, or behavior without explicit informed consent; or (c) make employment decisions based on neurocognitive data without a clear and demonstrable relationship to job performance.

(3) Educational institutions shall not: (a) require students to undergo neural monitoring or provide neurocognitive data, except for: (i) legitimate educational research with appropriate ethical approval; (ii) therapeutic purposes for students with specific learning needs, with appropriate consent; or (iii) assessment purposes where there is a demonstrable educational necessity and no less intrusive means available; (b) use neurocognitive data to track, sort, or stream students without transparent criteria and appropriate consent; or (c) share students' neurocognitive data with third parties without explicit informed consent from the student or their parent or guardian.

(4) Insurance providers shall not: (a) require applicants to undergo neural monitoring or provide neurocognitive data as a condition of insurance coverage; (b) use neurocognitive data to determine premiums or coverage, except where explicitly authorized by provincial insurance regulations and based on actuarially sound principles; or (c) discriminate between individuals based on neurocognitive data that reveals protected characteristics or conditions.

(5) Financial institutions shall not: (a) use neurocognitive data to determine creditworthiness or eligibility for financial services; (b) require customers to undergo neural monitoring or provide neurocognitive data as a condition of service; or (c) use neurocognitive data to target vulnerable individuals with potentially harmful financial products.

Right to Explanation and Contestation

67. (1) An individual has the right to: (a) be informed when decisions significantly affecting them are based on the processing of their neurocognitive data; (b) receive a clear explanation of how neurocognitive data was used in making the decision; (c) access their neurocognitive data that was used in the decision-making process; (d) contest decisions based on neurocognitive data; and (e) request human intervention when a decision is based solely on automated processing of neurocognitive data.

(2) A neural data controller that uses neurocognitive data to make or inform significant decisions about individuals shall: (a) maintain documentation of the decision-making process; (b) ensure that the process is transparent and explainable; (c) establish procedures for individuals to contest decisions; and (d) regularly evaluate the accuracy, fairness, and effectiveness of the decision-making process.

(3) Decisions based solely on automated processing of neurocognitive data shall not be made in contexts involving: (a) employment, including hiring, promotion, and termination; (b) access to essential services; (c) educational admissions or assessments; or (d) criminal justice or security clearance determinations; unless exceptional circumstances, to be prescribed by regulation, apply.

Data Subject Rights and Access

68. (1) An individual has the right to: (a) access their neurocognitive data held by a neural data controller; (b) receive information about the processing of their neurocognitive data, including: (i) the purposes of processing; (ii) the categories of neurocognitive data processed; (iii) the recipients or categories of recipients of the data; (iv) the retention period; (v) the source of the data, if not collected directly from the individual; and (vi) the existence of automated decision-making, including profiling, and meaningful information about the logic involved; (c) obtain rectification of inaccurate neurocognitive data; (d) obtain erasure of their neurocognitive data when: (i) the data is no longer necessary for the purpose for which it was collected; (ii) the individual withdraws consent and there is no other legal basis for processing; (iii) the individual objects to the processing and there are no overriding legitimate grounds for the processing; or (iv) the data has been unlawfully processed; (e) restrict the processing of their neurocognitive data when: (i) the accuracy of the data is contested; (ii) the processing is unlawful but the individual opposes erasure; (iii) the neural data controller no longer needs the data but the individual requires it for legal claims; or (iv) the individual has objected to processing pending verification of legitimate grounds; (f) receive their neurocognitive data in a structured, commonly used, and machine-readable format and to transmit that data to another neural data controller (data portability); and (g) object to processing of their neurocognitive data for: (i) direct marketing purposes; (ii) scientific or historical research purposes or statistical purposes, unless the processing is necessary for the performance of a task carried out for reasons of public interest; or (iii) purposes based on legitimate interests pursued by the neural data controller, unless the controller demonstrates compelling legitimate grounds that override the individual's interests, rights, and freedoms.

(2) A neural data controller shall: (a) facilitate the exercise of data subject rights; (b) provide information on action taken on a request to the individual without undue delay and within one month of receipt of the request, which may be extended by two further months where necessary, taking into account the complexity and number of requests; (c) provide any information or communication in a concise, transparent, intelligible, and easily accessible form, using clear and plain language; (d) not charge a fee for providing information or carrying out requests, except where requests are manifestly unfounded or excessive; and (e) implement mechanisms to verify the identity of individuals making requests relating to their neurocognitive data.

(3) Restrictions on data subject rights may be imposed only if such restriction respects the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society to safeguard: (a) national security; (b) public safety; (c) the prevention, investigation, detection, or prosecution of criminal offences; (d) other important objectives of general public interest; or (e) the protection of the rights and freedoms of others.

Records of Processing Activities

69. (1) Each neural data controller and processor shall maintain records of their neurocognitive data processing activities, including: (a) the name and contact details of the controller or processor, any joint controllers, and, where applicable, the data protection officer; (b) the purposes of the processing; (c) a description of the categories of individuals and of the categories of neurocognitive data; (d) the categories of recipients to whom the neurocognitive data has been or will be disclosed; (e) transfers of neurocognitive data to a third country or international organization; (f) the envisaged time limits for erasure of the different categories of data; (g) a general description of the technical and organizational security measures implemented; and (h) the legal basis for each processing activity.

(2) The records shall be maintained in writing, including in electronic form.

(3) The neural data controller or processor shall make the records available to the Commission on request.

(4) The obligations referred to in subsections (1) to (3) shall not apply to an organization employing fewer than 250 persons unless: (a) the processing includes high risk neurocognitive data; (b) the processing is likely to result in a risk to the rights and freedoms of individuals; or (c) the processing is not occasional.

Accountability and Governance

70. (1) Neural data controllers shall: (a) implement appropriate technical and organizational measures to ensure and to be able to demonstrate that processing of neurocognitive data is performed in accordance with this Act; (b) review and update those measures where necessary; (c) adhere to approved codes of conduct or certification mechanisms to demonstrate compliance; (d) appoint a data protection officer when processing neurocognitive data on a large scale; and (e) conduct data protection impact assessments for high-risk processing activities.

(2) Data protection officers appointed under paragraph (1)(d) shall: (a) have expertise in neurocognitive data protection and privacy; (b) be involved in all issues relating to the protection of neurocognitive data; (c) report directly to the highest level of management; and (d) not receive any instructions regarding the exercise of their tasks.

(3) The Commission shall: (a) encourage the development of codes of conduct for the processing of neurocognitive data; (b) establish certification mechanisms and data protection seals and marks; and (c) provide guidance on accountability measures appropriate for organizations of different sizes and processing activities of varying complexity.

Enforcement and Remedies

71. (1) An individual who believes that their rights under this Part have been infringed may: (a) file a complaint with the Commission; (b) apply to the Neurocognitive Rights Tribunal for a remedy; or (c) bring a civil action in accordance with Part 9.

(2) The Commission may: (a) investigate complaints related to neurocognitive data protection; (b) conduct audits of neural data controllers and processors; (c) issue compliance orders; (d) impose administrative monetary penalties for violations; and (e) refer cases to the Neurocognitive Rights Tribunal or the Director of Public Prosecutions, as appropriate.

(3) The Neurocognitive Rights Tribunal may: (a) order a neural data controller or processor to comply with the provisions of this Part; (b) order the correction, restriction, or deletion of neurocognitive data; (c) award damages for harm suffered as a result of a violation; and (d) issue any other order it considers appropriate.

(4) Nothing in this section affects any other remedy available under any other law.

PART 6 - SPECIALIZED NEUROCOGNITIVE RIGHTS TRIBUNALS

Establishment of the Neurocognitive Rights Tribunal

72. (1) The Neurocognitive Rights Tribunal is established.

(2) The Tribunal is a court of record and shall have an official seal, which shall be judicially noticed.

(3) The Tribunal shall consist of: (a) a Chief Adjudicator; (b) a Deputy Chief Adjudicator; and (c) not fewer than seven and not more than fifteen additional Adjudicators.

(4) The Governor in Council shall appoint the Chief Adjudicator, Deputy Chief Adjudicator, and other Adjudicators on the recommendation of the Minister of Justice, after consultation with the Minister.

(5) A person is eligible to be appointed as an Adjudicator only if the person: (a) is or has been a judge of a superior court, the Federal Court, or the Federal Court of Appeal; (b) is or has been a barrister or advocate of at least ten years standing at the bar of any province; or (c) has demonstrated expertise in neurocognitive rights, neurotechnology, or related fields and meets any other requirements prescribed by regulation.

(6) In appointing Adjudicators, the Governor in Council shall ensure that, as a group, the Adjudicators possess: (a) legal expertise in human rights, privacy, and administrative law; (b) scientific knowledge related to neuroscience and neurotechnology; (c) ethical understanding of issues related to cognitive liberty and mental privacy; (d) technical knowledge about data protection and cybersecurity; and (e) expertise in healthcare law and medical technology regulation.

(7) The Governor in Council shall ensure that the composition of the Tribunal reflects the diversity of Canadian society, including gender balance, representation of various regions, and inclusion of Indigenous perspectives.

(8) The Adjudicators shall be appointed for terms not exceeding seven years, which may be renewed once.

(9) The Tribunal may employ such officers, employees, and agents as are necessary for the proper conduct of its work, and may establish regional offices within Canada.

Jurisdiction and Authority

73. (1) The Tribunal has exclusive original jurisdiction to hear and determine all applications made under this Act and all questions of law or fact in relation to those applications.

(2) The Tribunal has jurisdiction over: (a) applications alleging violations of neurocognitive rights established in Part 2; (b) applications challenging decisions or actions of the Commission; (c) applications for review of decisions made by neural data controllers regarding data subject rights under Part 5; (d) applications for compensation for harm resulting from violations of this Act; (e) applications for authorization of class proceedings related to neurocognitive rights; and (f) any other matters assigned to it by this Act or any other Act of Parliament.

(3) The Tribunal has jurisdiction over all alleged violations of neurocognitive rights in Canada, regardless of whether the violation: (a) was committed by a public or private entity; (b) occurred in the context of commercial or non-commercial activities; or (c) involved neurotechnology regulated under this Act or any other neurotechnology.

(4) The Tribunal has all the powers, rights, and privileges that are vested in a superior court of record, including the power to: (a) issue summons requiring a person to appear before the Tribunal to give evidence or produce documents; (b) administer oaths and solemn affirmations; (c) receive and accept evidence and information on oath, affidavit, or otherwise that the Tribunal considers appropriate, whether or not the evidence or

information would be admissible in a court of law; (d) enter any premises where the Tribunal believes there may be evidence relevant to an application; (e) compel witnesses to give evidence in the same manner as a superior court of record; (f) order interim measures before a final decision is rendered; (g) award costs; and (h) enforce its orders.

(5) The Tribunal is not bound by the rules of evidence applicable in judicial proceedings but shall respect principles of natural justice.

(6) The decisions of the Tribunal are binding on the parties and may be enforced in the same manner as an order of the Federal Court.

Scientific Advisory Panel

74. (1) The Tribunal shall establish a Scientific Advisory Panel to provide expert guidance on scientific and technical matters related to neurotechnology and neurocognitive rights.

(2) The Scientific Advisory Panel shall consist of experts in fields including, but not limited to: (a) neuroscience; (b) neurotechnology; (c) neuroethics; (d) neuropsychology; (e) biomedical engineering; (f) data science; (g) artificial intelligence; and (h) any other field of expertise relevant to the Tribunal's mandate.

(3) The Chief Adjudicator shall appoint members of the Scientific Advisory Panel based on their expertise, ensuring a balance of scientific disciplines and perspectives.

(4) The Scientific Advisory Panel shall: (a) provide scientific and technical advice to the Tribunal on matters related to neurotechnology and neurocognitive rights; (b) assist in the evaluation of scientific evidence presented in proceedings before the Tribunal; (c) conduct independent research or analysis at the request of the Tribunal; (d) prepare reports on scientific or technical issues relevant to cases before the Tribunal; and (e) perform any other advisory functions requested by the Tribunal.

(5) The Tribunal may, in any proceeding, consult with the Scientific Advisory Panel on any scientific or technical matter, provided that the parties are given notice of the consultation and an opportunity to make submissions.

(6) The Tribunal shall make the advice or reports of the Scientific Advisory Panel available to the parties, who shall have an opportunity to respond to or challenge the advice or reports.

Rules of Procedure

75. (1) The Tribunal may make rules governing the practice and procedure in relation to applications to the Tribunal, including rules: (a) respecting the giving of notice; (b) respecting the addition of parties to a proceeding; (c) respecting the conduct of hearings; (d) respecting the filing and service of documents; (e) respecting the examination of witnesses; (f) respecting the form and content of applications and other documents; (g) respecting the time limits for filing documents; (h) respecting the assessment and awarding of costs; (i) respecting the role and participation of interveners; (j) respecting the use of alternative dispute resolution mechanisms; and (k) generally, for carrying out the work of the Tribunal and the management of its internal affairs.

(2) The Tribunal shall adapt its rules and procedures to accommodate the unique challenges presented by cases involving neurocognitive rights and neurotechnology, including by: (a) ensuring that scientific and technical evidence is properly evaluated; (b)

protecting the privacy and neurocognitive rights of individuals involved in proceedings; (c) facilitating participation by individuals who may face challenges in accessing the Tribunal; and (d) expediting proceedings where delays could result in irreparable harm.

(3) The rules shall be published and made available to the public.

Filing an Application

76. (1) Any person who believes that their neurocognitive rights have been infringed may file an application with the Tribunal.

(2) The Commissioner of Neurocognitive Rights may file an application with the Tribunal on behalf of an individual or group of individuals.

(3) An application must: (a) be in writing in the form prescribed by the Tribunal; (b) set out the grounds for the application; (c) describe the relief sought; and (d) include any other information required by the rules of the Tribunal.

(4) An application must be filed within one year after the day on which the applicant became aware, or in the circumstances ought reasonably to have become aware, of the infringement, unless the Tribunal extends the time limit on application in accordance with subsection (5).

(5) The Tribunal may extend the time limit for filing an application if it is satisfied that: (a) there are reasonable grounds for the delay; (b) no substantial prejudice would be caused to any person by the delay; and (c) the application raises an important issue related to neurocognitive rights.

Screening of Applications

77. (1) The Tribunal shall conduct an initial screening of each application to determine whether: (a) the application is within the jurisdiction of the Tribunal; (b) the application discloses a reasonable basis for proceeding; and (c) the application has been filed within the applicable time limit or should be accepted despite being filed late.

(2) If the Tribunal determines that an application does not meet the criteria in subsection (1), it may: (a) dismiss the application; (b) return the application to the applicant with directions for amendment; or (c) refer the applicant to a more appropriate forum or process.

(3) The Tribunal shall notify the applicant in writing of its decision under subsection (2) and the reasons for the decision.

(4) A decision to dismiss an application under paragraph (2)(a) may be appealed to the Federal Court of Appeal.

Case Management

78. (1) The Tribunal shall establish a case management system to ensure that applications are dealt with as informally and expeditiously as the circumstances and considerations of fairness and natural justice permit.

(2) The Tribunal may: (a) assign one or more Adjudicators to manage the progress of an application; (b) establish timelines for different stages of the proceedings; (c) identify the issues to be determined and the evidence to be presented; (d) encourage the use of

alternative dispute resolution mechanisms; and (e) take any other measures necessary to ensure the efficient and fair resolution of the application.

(3) In complex cases involving multiple parties, technical issues, or novel legal questions, the Tribunal may hold a case management conference to: (a) clarify the issues in dispute; (b) identify the evidence required; (c) establish a timetable for the proceedings; (d) explore the potential for settlement; and (e) address any other matters that may assist in the just and expeditious disposition of the application.

Alternative Dispute Resolution

79. (1) The Tribunal shall establish alternative dispute resolution mechanisms, including mediation and conciliation, to facilitate the resolution of applications without a formal hearing.

(2) The Tribunal may, at any stage of the proceedings and with the consent of the parties, refer an application to an alternative dispute resolution process.

(3) Statements made and documents submitted in the course of an alternative dispute resolution process are confidential and shall not be disclosed in any subsequent proceedings without the consent of the parties.

(4) If the parties reach an agreement through an alternative dispute resolution process, the Tribunal may: (a) issue a consent order reflecting the terms of the agreement; (b) incorporate the agreement into a decision of the Tribunal; or (c) terminate the proceedings on terms it considers appropriate.

(5) Nothing in this section prevents the parties from attempting to settle the matter through private negotiation or other means at any time.

Hearings

80. (1) The Tribunal shall hold a hearing in respect of an application unless: (a) the parties consent to a determination without a hearing; or (b) the Tribunal determines that a hearing is not necessary for the just determination of the application.

(2) The hearing shall be open to the public, except that the Tribunal may, on application or on its own initiative, order that a hearing or any part of a hearing be held in private if it is satisfied that: (a) matters involving public security may be disclosed; (b) intimate personal or financial matters or other matters may be disclosed that are of such a nature that the privacy interests of any person outweigh the public interest in the disclosure of those matters; (c) disclosure of neurocognitive data or detailed information about neurotechnology could pose risks to individuals or public safety; or (d) the interests of justice require it.

(3) The Tribunal may receive evidence in any manner that it considers appropriate, and is not bound by the rules of evidence applicable in judicial proceedings.

(4) The Tribunal shall give the parties a reasonable opportunity to present evidence and make representations.

(5) The Tribunal may: (a) summon and enforce the attendance of witnesses and compel them to give oral or written evidence on oath in the same manner as a superior court of record; (b) administer oaths and solemn affirmations; (c) receive and accept such evidence

and information on oath, affidavit, or otherwise as the Tribunal sees fit, whether or not the evidence or information would be admissible in a court of law; (d) accept expert testimony from the Scientific Advisory Panel; and (e) take notice of facts that may be judicially noticed and of any generally recognized scientific or technical facts, information, or opinions within its specialized knowledge.

(6) The Tribunal may hold hearings in person, by videoconference, by teleconference, or through a combination of these methods, as it considers appropriate in the circumstances.

Assessment of Evidence

81. (1) In assessing scientific and technical evidence related to neurotechnology and neurocognitive rights, the Tribunal shall: (a) consider the qualifications and expertise of the source of the evidence; (b) evaluate the reliability and validity of the methods used to generate the evidence; (c) consider whether the evidence is based on established scientific principles; (d) assess whether the evidence has been peer-reviewed or otherwise subjected to critical scrutiny; (e) consider the known or potential rate of error associated with the evidence; and (f) take into account any other factors relevant to the reliability and probative value of the evidence.

(2) The Tribunal may: (a) seek advice from the Scientific Advisory Panel on the scientific validity of evidence presented; (b) appoint independent experts to evaluate technical evidence or claims; (c) require parties to provide additional information or clarification regarding scientific or technical matters; and (d) take judicial notice of well-established scientific principles and facts.

(3) Where scientific understanding is evolving or uncertain, the Tribunal shall: (a) acknowledge areas of scientific uncertainty in its decisions; (b) apply the precautionary principle where appropriate; and (c) balance the potential risks and benefits based on the best available evidence.

Remedies and Relief

82. (1) If the Tribunal finds that an infringement of neurocognitive rights has occurred, it may make one or more of the following orders: (a) an order declaring that an act or omission is an infringement of neurocognitive rights; (b) an order requiring the respondent to cease the infringing activity; (c) an order requiring the respondent to take measures to comply with this Act; (d) an order requiring the respondent to correct its practices to ensure compliance with this Act; (e) an order requiring the respondent to publish a notice of the finding and the corrective measures taken; (f) an order requiring the destruction of neural data collected, used, or disclosed in contravention of this Act; (g) an order requiring the respondent to delete or modify algorithms or other technical systems that infringe neurocognitive rights; (h) an order requiring the respondent to implement specific safeguards to protect neurocognitive rights; (i) an order requiring the respondent to provide regular reports on its compliance with the order; (j) an order awarding compensation for any loss or injury suffered as a result of the infringement, including: (i) actual damages; (ii) damages for any humiliation, psychological harm, or injury to dignity suffered by the applicant; (iii) exemplary or punitive damages in cases of particularly egregious conduct; and (iv) interest; (k) an order awarding costs; or (l) any other order that the Tribunal considers appropriate.

(2) In determining the appropriate remedy, the Tribunal shall consider: (a) the nature and severity of the infringement; (b) the vulnerability of the affected individuals; (c) whether the infringement was intentional, reckless, or negligent; (d) the respondent's history of compliance with this Act; (e) any benefit derived by the respondent from the infringement; (f) the impact of the order on the respondent's legitimate activities; and (g) any other relevant factors.

(3) The Tribunal may issue an interim order before a final decision is rendered if: (a) there is a serious question to be determined; (b) the applicant would suffer irreparable harm if the order were not issued; and (c) the balance of convenience favors issuing the order.

(4) An order of the Tribunal may be made applicable to third parties who are not parties to the proceeding if: (a) the third party has received notice of the proceeding and an opportunity to be heard; (b) the third party has a sufficient connection to the infringement; and (c) the order would not be effective without extending it to the third party.

Special Considerations for Vulnerable Populations

83. (1) In any proceeding involving a child or a person with a cognitive disability or impairment, the Tribunal shall: (a) ensure that the person's interests are properly represented; (b) adapt its procedures to accommodate the person's specific needs and capabilities; (c) consider appointing a litigation guardian or other representative if necessary; and (d) give primary consideration to the best interests of the person.

(2) Where a proceeding involves neurocognitive rights of Indigenous individuals or communities, the Tribunal shall: (a) take into account Indigenous legal traditions and customary laws; (b) consider the cultural context and potential cultural impacts; (c) respect principles of Indigenous data sovereignty; and (d) consult with Indigenous representatives or knowledge keepers where appropriate.

(3) In proceedings involving elderly persons with age-related cognitive conditions, the Tribunal shall: (a) ensure accessibility of its processes; (b) consider age-related factors in assessing capacity and consent; and (c) give special attention to potential exploitation or undue influence.

(4) The Tribunal shall develop specialized protocols for addressing applications from institutionalized individuals, including those in: (a) healthcare facilities; (b) correctional institutions; (c) mental health facilities; and (d) long-term care facilities.

Appeals and Judicial Review

84. (1) A decision of the Tribunal may be appealed to the Federal Court of Appeal on a question of law or jurisdiction, including a question of mixed fact and law of central importance to the legal system.

(2) An appeal may be brought by: (a) any party to the proceeding; (b) the Commissioner of Neurocognitive Rights; or (c) any other person granted leave to appeal by the Federal Court of Appeal.

(3) An appeal must be filed within 30 days after the day on which the decision is made, unless the Federal Court of Appeal extends the time limit.

(4) The Federal Court of Appeal may: (a) dismiss the appeal; (b) allow the appeal and set aside the decision; (c) set aside the decision and refer the matter back to the Tribunal for redetermination in accordance with any directions it considers appropriate; or (d) make any decision that the Tribunal could have made.

(5) A decision of the Tribunal that is not appealed within the time limit is final and binding on the parties.

Class Proceedings

85. (1) The Tribunal may authorize a class proceeding if: (a) the application raises common issues for a group of individuals; (b) a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues; and (c) there is an appropriate representative applicant.

(2) In deciding whether to authorize a class proceeding, the Tribunal shall consider: (a) whether the class is sufficiently numerous that proceeding individually would be impracticable; (b) whether there are questions of law or fact common to the class; (c) whether the claims of the representative applicant are typical of the claims of the class; (d) whether the representative applicant will fairly and adequately protect the interests of the class; and (e) whether a class proceeding is superior to other available methods for the fair and efficient adjudication of the controversy.

(3) If the Tribunal authorizes a class proceeding, it shall: (a) define the class; (b) appoint the representative applicant; (c) identify the common issues to be determined; (d) specify the manner of giving notice to class members; and (e) establish procedures for the conduct of the class proceeding.

(4) The Tribunal may establish specialized procedures for the management of class proceedings involving neurocognitive rights, including: (a) procedures for the protection of neurocognitive data and privacy during the proceedings; (b) methods for assessing and distributing compensation for infringements of neurocognitive rights; and (c) approaches to remedies that address both individual and collective harms.

Costs and Funding

86. (1) The Tribunal may make orders for the payment of costs in accordance with its rules and the requirements of this section.

(2) In making an order for costs, the Tribunal shall consider: (a) the outcome of the proceeding; (b) the conduct of the parties; (c) whether the application raised an important issue regarding neurocognitive rights; (d) the relative resources of the parties; and (e) any other relevant factors.

(3) The Tribunal may limit or refuse costs against an unsuccessful applicant if: (a) the application raised an important issue regarding neurocognitive rights; (b) the application was brought in the public interest; or (c) ordering costs would create a significant barrier to access to justice.

(4) The Minister shall establish a Neurocognitive Rights Access to Justice Fund to: (a) provide financial support for applicants who lack sufficient resources to bring applications before the Tribunal; (b) fund interventions in proceedings that raise important issues of

public interest; and (c) support education and outreach activities related to neurocognitive rights and the Tribunal's processes.

(5) The Fund shall be administered by an independent board of directors appointed by the Minister, which shall establish criteria and procedures for the provision of funding.

Relationship with Courts and Other Tribunals

87. (1) The jurisdiction of the Tribunal does not affect, restrict or limit the jurisdiction of any court of criminal jurisdiction or any other court of competent jurisdiction.

(2) Where an application is filed with the Tribunal and a proceeding based on the same or substantially the same facts is pending before another court or tribunal, the Tribunal may: (a) proceed with the application; (b) defer consideration of the application until the other proceeding is concluded; or (c) dismiss the application if it is satisfied that the matter would be more appropriately dealt with by the other court or tribunal.

(3) No civil action may be brought before a court for an infringement of neurocognitive rights under this Act unless: (a) an application based on the same facts has been filed with the Tribunal and: (i) the Tribunal has dismissed the application for lack of jurisdiction; (ii) the applicant has withdrawn the application with the Tribunal's consent; or (iii) the time limit for filing an application with the Tribunal has expired; or (b) the action is brought by the Commissioner of Neurocognitive Rights or the Attorney General of Canada.

(4) A decision of the Tribunal is not subject to review by a court except in accordance with section 84.

Provincial Neurocognitive Rights Tribunals

88. (1) The Minister may enter into agreements with provincial and territorial governments for the establishment of provincial or territorial neurocognitive rights tribunals.

(2) A provincial or territorial neurocognitive rights tribunal established pursuant to an agreement under subsection (1) may, in accordance with the agreement: (a) exercise any jurisdiction or powers conferred on it by provincial or territorial legislation; (b) exercise the jurisdiction and powers that would otherwise be exercised by the Tribunal in relation to matters within provincial or territorial jurisdiction; and (c) apply both this Act and provincial or territorial legislation relating to neurocognitive rights.

(3) An agreement under subsection (1) shall ensure that provincial or territorial neurocognitive rights tribunals: (a) meet minimum standards of independence, expertise, and procedural fairness; (b) apply the fundamental neurocognitive rights established in Part 2 of this Act; and (c) provide remedies at least equivalent to those available under this Act.

(4) An agreement under subsection (1) shall include provisions for: (a) appeals or judicial review of decisions of the provincial or territorial tribunal; (b) cooperation and information sharing between the Tribunal and the provincial or territorial tribunal; and (c) periodic review of the effectiveness of the arrangement.

Annual Report and Reviews

89. (1) The Tribunal shall submit an annual report to Parliament through the Minister of Justice, which shall include: (a) a summary of the Tribunal's activities and achievements; (b) statistics on applications filed, disposed of, and pending; (c) information on significant decisions and their implications; (d) emerging trends and issues in neurocognitive rights; (e) any recommendations for legislative or policy changes; and (f) any other information that the Tribunal considers relevant.

(2) The Tribunal shall conduct periodic reviews of: (a) the effectiveness of its procedures in addressing neurocognitive rights issues; (b) the adequacy of remedies available under this Act; (c) emerging challenges and opportunities related to neurocognitive rights and neurotechnology; and (d) the need for modifications to its rules, procedures, or structure.

(3) The first review shall be completed within five years after the coming into force of this Act, and subsequent reviews shall be conducted at intervals not exceeding five years.

(4) The Tribunal shall publish the results of each review and submit them to Parliament.

International Judicial Cooperation

90. (1) The Tribunal shall establish mechanisms for cooperation with courts and tribunals in other jurisdictions that address neurocognitive rights and neurotechnology issues.

(2) The cooperation may include: (a) information sharing on legal and policy developments; (b) exchange of best practices for addressing technical and scientific issues; (c) coordination in cases involving cross-border elements; and (d) participation in international networks or forums of specialized tribunals.

(3) The Tribunal may enter into memoranda of understanding with foreign courts or tribunals to facilitate cooperation.

(4) The Tribunal shall consider relevant international precedents and developments in its interpretation and application of neurocognitive rights, while ensuring consistency with Canadian legal principles and values.

PART 7 - CRIMINAL AND CIVIL LIABILITY

Criminal Offences Related to Neurocognitive Rights

91. (1) Every person who intentionally or recklessly: (a) accesses, collects, or records another person's neural data without their informed consent or lawful authorization; (b) discloses, sells, or transfers another person's neural data to a third party without their informed consent or lawful authorization; (c) uses neurotechnology to substantially alter another person's neural functioning without their informed consent or lawful authorization; (d) uses neurotechnology to covertly influence another person's thoughts, decisions, or behavior without their knowledge or informed consent; (e) uses neurotechnology to cause substantial mental suffering or psychological harm to another person; or (f) uses neurotechnology to extract information from another person against their will; is guilty of an indictable offence and liable to imprisonment for a term not exceeding five years, or is guilty of an offence punishable on summary conviction.

(2) Every person who commits an offence under subsection (1): (a) in relation to a child under the age of 18 years; (b) in relation to a person with a cognitive disability or impairment; (c) in relation to a person under the care or authority of the offender; (d) while holding a position of trust or authority; (e) for commercial gain or advantage; or (f) as part of a pattern of repeated violations; is guilty of an indictable offence and liable to imprisonment for a term not exceeding ten years, or is guilty of an offence punishable on summary conviction.

(3) Every person who commits an offence under subsection (1) that results in: (a) serious and lasting psychological harm; (b) significant alteration of the victim's sense of identity or personality; (c) substantial impairment of the victim's cognitive abilities; or (d) the victim's death or serious bodily harm, including self-harm; is guilty of an indictable offence and liable to imprisonment for a term not exceeding fourteen years.

Neural Data Breaches and Security Offences

92. (1) Every person who: (a) knowingly or recklessly fails to implement reasonable safeguards for neural data, resulting in a neural data breach; (b) intentionally causes or facilitates a neural data breach; (c) fails to notify affected individuals or the Commission of a neural data breach as required by this Act; or (d) destroys, alters, conceals, or falsifies records of neural data processing to obstruct an investigation; is guilty of an indictable offence and liable to imprisonment for a term not exceeding two years, or is guilty of an offence punishable on summary conviction.

(2) Every organization that commits an offence under subsection (1) is liable: (a) on conviction on indictment, to a fine not exceeding the greater of $10,000,000 and 3% of the organization's gross global revenue in the financial year preceding the one in which the organization is sentenced; or (b) on summary conviction, to a fine not exceeding the greater of $5,000,000 and 2% of the organization's gross global revenue in the financial year preceding the one in which the organization is sentenced.

Unauthorized Neurotechnology

93. (1) Every person who: (a) develops, manufactures, sells, imports, or distributes unacceptable risk neurotechnology as defined in section 29; (b) places on the market or puts into service high risk neurotechnology without the required certification under section 40; (c) intentionally misclassifies neurotechnology to evade regulatory requirements; or (d) uses neurotechnology for a purpose expressly prohibited by regulation; is guilty of an indictable offence and liable to imprisonment for a term not exceeding three years, or is guilty of an offence punishable on summary conviction.

(2) Every organization that commits an offence under subsection (1) is liable: (a) on conviction on indictment, to a fine not exceeding the greater of $5,000,000 and 2% of the organization's gross global revenue in the financial year preceding the one in which the organization is sentenced; or (b) on summary conviction, to a fine not exceeding the greater of $2,500,000 and 1% of the organization's gross global revenue in the financial year preceding the one in which the organization is sentenced.

Obstruction and False Information

94. (1) Every person who: (a) obstructs, hinders, or makes a false or misleading statement to the Commission, an inspector, the Commissioner of Neurocognitive Rights, or the Tribunal in the exercise of their powers or the performance of their duties; (b) destroys or alters any document or information required to be kept under this Act; (c) falsifies or conceals material facts in relation to any matter under this Act; or (d) retaliates against a person for reporting a violation of this Act or cooperating with an investigation; is guilty of an indictable offence and liable to imprisonment for a term not exceeding two years, or is guilty of an offence punishable on summary conviction.

(2) Every organization that commits an offence under subsection (1) is liable: (a) on conviction on indictment, to a fine not exceeding $2,000,000; or (b) on summary conviction, to a fine not exceeding $1,000,000.

Corporate Liability

95. (1) Where an organization commits an offence under this Act, any director, officer, agent, mandatary, or authorized representative of the organization who directed, authorized, assented to, acquiesced in, or participated in the commission of the offence is a party to and guilty of the offence and is liable to the punishment provided for the offence, whether or not the organization has been prosecuted or convicted.

(2) In determining the appropriate sentence for an organization convicted of an offence under this Act, the court shall consider the following factors: (a) the size and revenue of the organization; (b) the degree to which senior management of the organization was involved in the commission of the offence; (c) whether the organization had implemented adequate measures to prevent the offence; (d) whether the organization has previously been found guilty of a similar offence; (e) whether the organization reported the offence to authorities; (f) whether the organization has taken steps to remediate the harm caused by the offence; (g) the impact of the sentence on the economic viability of the organization; and (h) any other relevant factor.

(3) In addition to any other penalty, the court may order an organization convicted of an offence under this Act to: (a) implement specific measures to prevent future offences; (b) publish the facts relating to the commission of the offence; (c) provide redress to victims of the offence; (d) establish a compliance program or enhance an existing one; (e) submit to inspections or audits; or (f) perform community service related to neurocognitive rights awareness.

Due Diligence Defence

96. (1) No person shall be convicted of an offence under this Act if the person establishes that they exercised due diligence to prevent the commission of the offence.

(2) In determining whether a person exercised due diligence, the court shall consider: (a) the nature and context of the alleged offence; (b) the foreseeability of the harm; (c) the existence and implementation of relevant policies, procedures, and training; (d) the response to any previous incidents or warning signs; (e) industry standards and best practices; and (f) any other relevant factors.

(3) An organization that seeks to rely on the due diligence defence must establish that it took all reasonable steps to: (a) identify and mitigate risks related to neurocognitive rights and neurotechnology; (b) implement appropriate technical and organizational measures to protect neural data and prevent violations; (c) provide adequate training and supervision to employees and agents; (d) establish effective monitoring and compliance systems; and (e) respond promptly and effectively to any incidents or warning signs.

Limitation Period

97. (1) No proceedings by way of summary conviction may be instituted more than two years after the time when the subject matter of the proceedings arose.

(2) No proceedings by way of indictment may be instituted more than five years after the time when the subject matter of the proceedings arose.

(3) Notwithstanding subsections (1) and (2), in the case of offences involving neural data of children or persons with cognitive disabilities or impairments, no limitation period shall apply.

Civil Liability and Causes of Action

98. (1) Any person who suffers damage by reason of an act or omission that constitutes a contravention of this Act may, in addition to any other right or remedy available under law, bring a civil action against the person who committed the act or omission.

(2) Without limiting the generality of subsection (1), the following constitute specific causes of action under this Act: (a) unauthorized neural data collection, use, or disclosure; (b) neural data breach resulting from failure to implement reasonable security measures; (c) use of neurotechnology without informed consent; (d) neural manipulation or interference that harms cognitive integrity; (e) neural privacy invasion; (f) discriminatory use of neural data or neurotechnology; (g) failure to provide required information about neurotechnology or neural data processing; and (h) any other violation of a neurocognitive right established in Part 2.

(3) In an action under this section, a plaintiff may claim: (a) actual damages, including: (i) monetary losses; (ii) costs of remediation; (iii) medical or therapeutic expenses; and (iv) lost income or opportunity; (b) damages for pain, suffering, and loss of enjoyment of life; (c) damages for humiliation, loss of dignity, or psychological harm; (d) damages for injury to identity or autonomy; (e) punitive or exemplary damages in cases of particularly egregious conduct; (f) injunctive relief; (g) an accounting of profits made by the defendant as a result of the contravention; and (h) any other relief that the court considers appropriate.

(4) In assessing damages under subsection (3), the court shall take into account: (a) the nature, severity, and duration of the harm suffered; (b) the vulnerability of the plaintiff; (c) the relationship between the plaintiff and the defendant; (d) whether the defendant acted intentionally, recklessly, or negligently; (e) any benefit derived by the defendant from the contravention; (f) any steps taken by the defendant to mitigate harm; and (g) any other relevant factors.

Standard of Liability

99. (1) For civil liability under this Act: (a) a neural data controller is strictly liable for: (i) unauthorized disclosure of neural data; (ii) neural data breaches resulting from inadequate security measures; and (iii) use of neural data beyond the scope of consent; (b) a neurotechnology provider is liable for harm caused by defects in design, manufacturing, or instructions for use, unless they can establish that: (i) the defect could not have been discovered given the state of scientific and technical knowledge at the time the neurotechnology was placed on the market; or (ii) the user was adequately warned of the risk and chose to assume it; and (c) in all other cases, liability shall be based on a fault standard, requiring proof that the defendant failed to meet the standard of care that a reasonable person would observe in the circumstances.

(2) The standard of care for professionals working with neurotechnology shall be that of a reasonably competent professional in the same field, taking into account: (a) established

professional standards and best practices; (b) the state of knowledge regarding the neurotechnology in question; (c) the potential risks associated with the neurotechnology; and (d) the vulnerability of the individuals affected.

(3) The burden of proving that harm resulted from a violation of this Act rests with the plaintiff, except that: (a) where a neural data breach has occurred, there shall be a rebuttable presumption that any harm to the plaintiff's neurocognitive rights was caused by the breach; and (b) where neurotechnology has been used without proper informed consent, there shall be a rebuttable presumption that any subsequent neural or cognitive harm was caused by the use of the neurotechnology.

Vicarious Liability

100. (1) An employer is vicariously liable for violations of this Act committed by its employees in the course of their employment, regardless of whether the specific acts were authorized by the employer.

(2) A principal is vicariously liable for violations of this Act committed by its agent within the scope of the agency relationship.

(3) The liability imposed by this section is joint and several with that of the primary wrongdoer.

(4) An employer or principal who is found vicariously liable under this section has a right of indemnity against the employee or agent who committed the violation, except where the violation resulted from: (a) inadequate training or supervision by the employer or principal; (b) compliance with instructions or policies of the employer or principal; or (c) conditions of work that made compliance with this Act difficult or impossible.

Joint and Several Liability

101. (1) Where harm results from violations of this Act by multiple defendants, the defendants are jointly and severally liable for the damage caused.

(2) Where it is not reasonably possible to determine the extent to which the damage suffered by the plaintiff was caused by each defendant, a defendant who seeks to limit their liability bears the burden of proving the extent of the damage not attributable to them.

(3) A defendant who is jointly and severally liable has a right of contribution from any other defendant who is liable for the same damage, in proportion to the degree to which each defendant's conduct contributed to the damage.

Class Actions

102. (1) A person who has a cause of action under this Act may commence proceedings on behalf of a class of persons who have similar causes of action, in accordance with the applicable rules of civil procedure in the jurisdiction where the proceedings are commenced.

(2) In assessing whether a class action is the preferable procedure for the resolution of common issues related to neurocognitive rights, the court shall consider: (a) the nature of the violations alleged; (b) the commonality of harm suffered by class members; (c) the efficiency of addressing widespread violations through a single proceeding; (d) the potential

for a class action to address systemic issues relating to neurocognitive rights; and (e) the power imbalance between individual plaintiffs and organizational defendants.

(3) In a class action relating to violations of neurocognitive rights, the court may: (a) order aggregate damages to be paid to the class as a whole; (b) establish a mechanism for individual assessment of damages where necessary; (c) order cy-près distribution of unclaimed damages to organizations working on neurocognitive rights or neurotechnology ethics; and (d) make any other order appropriate to provide effective relief to the class.

Statutory Remedies Not Exclusive

103. The civil cause of action established by this Act is in addition to, and not in substitution for, any other rights or remedies available under any other law, including: (a) actions in tort, such as negligence, trespass, invasion of privacy, assault, or battery; (b) actions for breach of contract; (c) actions under provincial or territorial privacy legislation; (d) actions under human rights legislation; or (e) any other applicable cause of action.

Burden of Proof and Evidentiary Matters

104. (1) In any civil proceeding under this Act, the plaintiff bears the burden of proving, on a balance of probabilities, that: (a) the defendant engaged in conduct that contravened this Act; (b) the plaintiff suffered damage or harm; and (c) the contravention caused or contributed to the damage or harm.

(2) A certified copy of a finding by the Tribunal that a person has engaged in conduct that contravenes this Act is admissible in evidence in a civil proceeding and is proof, in the absence of evidence to the contrary, that the person engaged in that conduct.

(3) In a civil proceeding against a neural data controller relating to a neural data breach, evidence that the controller did not comply with the security requirements established in section 61 constitutes proof, in the absence of evidence to the contrary, that the controller failed to implement reasonable safeguards.

(4) In a civil proceeding relating to informed consent for neurotechnology, evidence that the defendant did not comply with the requirements established in section 15 constitutes proof, in the absence of evidence to the contrary, that valid informed consent was not obtained.

Limitation Period for Civil Actions

105. (1) Subject to subsections (2) and (3), an action under section 98 must be brought within two years after the day on which the plaintiff became aware, or in the circumstances ought reasonably to have become aware: (a) of the conduct that allegedly contravenes this Act; (b) that the conduct caused or contributed to damage to the plaintiff; and (c) that the defendant was the person who engaged in the conduct.

(2) In the case of an action relating to neural data of children or persons with cognitive disabilities or impairments, the limitation period does not begin to run until: (a) in the case of a child, the day on which the person reaches the age of 18 years; or (b) in the case of a person with a cognitive disability or impairment, the day on which the person regains capacity or, if that never occurs, the limitation period does not apply.

(3) The court may extend the limitation period if it is satisfied that: (a) there are reasonable grounds for the delay; (b) the delay was due to factors beyond the plaintiff's control; (c) the defendant would not be substantially prejudiced by the extension; or (d) the nature of the harm is such that its full effects only became apparent after the expiry of the limitation period.

Whistleblower Protections

106. (1) No employer or person acting on behalf of an employer shall: (a) dismiss, suspend, demote, discipline, harass, or otherwise disadvantage an employee; (b) deny an employee a benefit of employment; or (c) threaten to take any action referred to in paragraph (a) or (b) against an employee; because the employee, acting in good faith and on the basis of reasonable belief: (d) has disclosed or stated an intention to disclose to the Commission, the Commissioner of Neurocognitive Rights, the Tribunal, a law enforcement agency, or other appropriate authority that the employer or another person has contravened or intends to contravene this Act; (e) has refused or stated an intention to refuse to do anything that is a contravention of this Act; (f) has done or stated an intention to do anything to prevent a contravention of this Act; or (g) has testified or otherwise participated in a proceeding under this Act.

(2) An employee who alleges that an employer has contravened subsection (1) may: (a) file a complaint with the Commission, which shall investigate the complaint in accordance with procedures established by regulation; (b) file a complaint with the Tribunal; or (c) bring a civil action against the employer.

(3) In a proceeding relating to a complaint or action under subsection (2), if the employee establishes that they took an action described in paragraphs (1)(d) to (g) and subsequently experienced a measure described in paragraphs (1)(a) to (c), there is a presumption that the measure was taken because of the employee's action, unless the employer establishes that it was taken for a legitimate reason.

(4) If a complaint or action under subsection (2) is successful, the Commission, Tribunal, or court may order: (a) the reinstatement of the employee; (b) the payment of compensation for lost wages and benefits; (c) the removal of any disciplinary action from the employee's record; (d) the payment of damages for pain and suffering or humiliation; and (e) any other remedy that is just and reasonable in the circumstances.

(5) The protections in this section apply, with necessary modifications, to: (a) contractors who provide goods or services to an organization; (b) students or trainees working with an organization; and (c) volunteers working with an organization.

(6) Any agreement or contractual provision that purports to prevent a person from making a disclosure described in paragraph (1)(d) is void to the extent that it does so.

Provincial Attorneys General

107. (1) The Attorney General of a province in which a contravention of this Act is alleged to have occurred may commence and conduct proceedings in respect of the contravention.

(2) The Attorney General of a province may exercise all the powers and perform all the duties and functions of the Director of Public Prosecutions under the *Criminal Code* in respect of an offence under this Act.

(3) Nothing in this section affects the jurisdiction of the Attorney General of Canada.

Application to Federal Court

108. (1) The Attorney General of Canada or the Commissioner of Neurocognitive Rights may apply to the Federal Court for a declaration that a person has contravened or is likely to contravene this Act, or for an order directing the person to cease the contravention or take corrective measures.

(2) An application under subsection (1) may be made regardless of whether: (a) the person has been charged with an offence under this Act; or (b) proceedings have been commenced before the Tribunal in respect of the same matter.

(3) In an application under subsection (1), the Federal Court may: (a) declare that the person has contravened or is likely to contravene this Act; (b) order the person to cease the contravention; (c) order the person to take corrective measures; (d) order the person to comply with any other conditions the Court considers appropriate; and (e) make any other order it considers appropriate.

(4) The Federal Court may, on application by the Attorney General of Canada or the Commissioner of Neurocognitive Rights, grant an interim injunction ordering a person to cease an activity that is alleged to be in contravention of this Act if the Court is satisfied that: (a) there is a serious issue to be tried; (b) irreparable harm will result if the injunction is not granted; and (c) the balance of convenience favours granting the injunction.

Alternative Dispute Resolution

109. (1) The Minister shall establish or designate a body to provide alternative dispute resolution services for conflicts relating to alleged violations of neurocognitive rights.

(2) The services provided by the body referred to in subsection (1) may include: (a) facilitation; (b) mediation; (c) arbitration; and (d) other forms of dispute resolution that the Minister considers appropriate.

(3) The alternative dispute resolution process shall be: (a) voluntary; (b) accessible; (c) timely; (d) confidential, except as required by law; and (e) conducted by neutral third parties with expertise in neurocognitive rights and neurotechnology.

(4) A settlement agreement reached through alternative dispute resolution: (a) is binding on the parties to the agreement; (b) may be filed with the Tribunal and, once filed, is enforceable as an order of the Tribunal; and (c) does not preclude further regulatory action by the Commission or the Commissioner of Neurocognitive Rights to address systemic issues identified in the dispute.

(5) Statements made and documents submitted in the course of alternative dispute resolution are confidential and shall not be disclosed in any subsequent proceedings without the consent of the parties, except: (a) where disclosure is required by law; (b) where disclosure is necessary to prevent a serious and imminent threat to public health or safety; or (c) to the extent that the information is publicly available.

Compensation Fund

110. (1) The Governor in Council may, by regulation, establish a Neurocognitive Harm Compensation Fund for the purpose of providing compensation to individuals who have suffered harm as a result of contraventions of this Act but who are unable to obtain adequate compensation through other means.

(2) The Fund shall be financed by: (a) contributions from providers of neurotechnology, in amounts proportional to the risk classification of their products and their market share; (b) administrative monetary penalties imposed under this Act; (c) a portion of the fines imposed for offences under this Act; and (d) any other sources prescribed by regulation.

(3) The regulations establishing the Fund shall address: (a) criteria for eligibility for compensation; (b) procedures for making claims; (c) methods for assessing the amount of compensation; (d) maximum amounts that may be paid to a claimant; (e) governance and administration of the Fund; and (f) any other matter necessary for the operation of the Fund.

(4) The Fund shall be administered by an independent board of directors appointed by the Governor in Council on the recommendation of the Minister.

(5) The board of directors shall submit an annual report to the Minister on the activities and financial affairs of the Fund.

PART 8 - EDUCATION AND PUBLIC AWARENESS

National Neurocognitive Rights Education Program

111. (1) The Minister, in collaboration with the Minister of Education, provincial and territorial governments, and other relevant stakeholders, shall establish a National Neurocognitive Rights Education Program.

(2) The purpose of the Program is to: (a) promote awareness and understanding of neurocognitive rights; (b) educate Canadians about neurotechnology and its implications; (c) build capacity for informed decision-making regarding neurotechnology; and (d) foster a culture of respect for neurocognitive rights.

(3) The Program shall include: (a) development of educational materials for different audiences and contexts; (b) support for curriculum development for schools and higher education institutions; (c) training programs for professionals working with neurotechnology; (d) public awareness campaigns; (e) community engagement initiatives; and (f) research on effective educational approaches for neurocognitive rights literacy.

(4) The Minister shall establish an advisory committee to guide the development and implementation of the Program, with representation from: (a) neuroscience and neurotechnology experts; (b) educators and curriculum specialists; (c) ethicists and policy experts; (d) representatives of vulnerable populations; (e) Indigenous knowledge keepers; and (f) other relevant stakeholders.

(5) The Minister shall submit a report to Parliament on the activities and outcomes of the Program every three years.

Educational Materials Development

112. (1) The Commission, in collaboration with the Commissioner of Neurocognitive Rights, shall develop and distribute educational materials about neurocognitive rights and neurotechnology, including: (a) general information resources for the public; (b) specialized materials for different age groups and educational levels; (c) guidance for specific sectors, including healthcare, education, workplace, and consumer contexts; (d) resources for vulnerable populations, including materials in accessible formats; and (e) materials reflecting diverse cultural perspectives, including Indigenous perspectives.

(2) All educational materials shall: (a) be available in both official languages; (b) be provided in accessible formats for persons with disabilities; (c) be culturally appropriate and inclusive; (d) be based on current scientific evidence and legal standards; and (e) be regularly updated to reflect technological developments and evolving understanding.

(3) The Commission shall make all educational materials freely available through: (a) a dedicated website; (b) social media platforms; (c) partnerships with educational institutions, libraries, and community organizations; and (d) any other distribution channels that may effectively reach diverse audiences.

(4) The Commission shall collaborate with relevant stakeholders, including educational institutions, professional associations, consumer groups, and civil society organizations, in the development and distribution of educational materials.

Public Awareness Campaigns

113. (1) The Commission shall develop and implement national public awareness campaigns to: (a) inform Canadians about their neurocognitive rights; (b) promote understanding of the benefits and risks of neurotechnology; (c) raise awareness about the regulatory framework established by this Act; (d) provide guidance on how to exercise rights under this Act; and (e) highlight available resources and support for addressing neurocognitive rights concerns.

(2) Public awareness campaigns shall utilize diverse media and communication channels, including: (a) traditional media (television, radio, print); (b) digital and social media platforms; (c) public presentations and community forums; (d) partnerships with community organizations and institutions; and (e) innovative outreach approaches designed to engage diverse audiences.

(3) The Commission shall develop targeted awareness campaigns for: (a) vulnerable populations, including children, elderly persons, and persons with cognitive disabilities; (b) Indigenous communities, with culturally appropriate messaging and delivery methods; (c) professionals who work with neurotechnology or neural data; and (d) specific contexts where neurocognitive rights may be at particular risk.

(4) The Commission shall evaluate the effectiveness of public awareness campaigns and adapt strategies based on evaluation results.

School Curriculum

114. (1) The Minister, in cooperation with provincial and territorial ministers of education, shall support the development of curriculum materials related to neurocognitive rights and neurotechnology for integration into K-12 education.

(2) Curriculum materials shall be age-appropriate and may address: (a) basic neuroscience concepts; (b) introduction to neurotechnology and its applications; (c) understanding of cognitive liberty and mental privacy; (d) ethical considerations related to neurotechnology; (e) critical thinking about neurotechnology in society; and (f) personal decision-making regarding neurotechnology.

(3) The Minister shall establish a grant program to support: (a) development of innovative teaching resources; (b) teacher training on neurocognitive rights education; (c) school-based initiatives that promote neurocognitive rights awareness; and (d) research on effective pedagogical approaches for neurocognitive rights education.

(4) Curriculum development shall involve input from: (a) education specialists; (b) neuroscience and neurotechnology experts; (c) ethicists and legal experts; (d) child development specialists; and (e) representatives of diverse communities, including Indigenous educational authorities.

Higher Education Programs

115. (1) The Minister, in cooperation with the Minister of Employment and Social Development, shall establish a program to support the development and enhancement of higher education programs related to neurocognitive rights and neurotechnology.

(2) The program shall support: (a) development of courses and programs on neurocognitive rights, neuroethics, and neurotechnology governance; (b) interdisciplinary initiatives that bring together perspectives from neuroscience, law, ethics, engineering, social sciences, and humanities; (c) research on neurocognitive rights and neurotechnology governance; (d) training of graduate students and early career researchers in fields related to neurocognitive rights; and (e) partnerships between academic institutions, industry, civil society, and government.

(3) The Minister shall establish a Neurocognitive Rights Research Network to: (a) connect researchers across disciplines and institutions; (b) facilitate knowledge mobilization and translation; (c) identify research priorities and gaps; (d) support collaborative research initiatives; and (e) promote international research cooperation.

(4) The Minister shall establish a scholarship and fellowship program to support: (a) graduate students pursuing studies related to neurocognitive rights and neurotechnology governance; (b) postdoctoral researchers contributing to the field; and (c) early career faculty developing research programs in relevant areas.

Professional Training

116. (1) The Commission, in collaboration with relevant professional bodies, shall develop training programs for professionals who work with neurotechnology or neural data, including: (a) healthcare professionals; (b) researchers and scientists; (c) engineers and technology developers; (d) legal professionals; (e) privacy and data protection officers; (f) educators and educational administrators; and (g) policy-makers and regulators.

(2) Training programs shall address: (a) the legal framework for neurocognitive rights and neurotechnology; (b) ethical principles and considerations; (c) best practices for protecting neurocognitive rights; (d) informed consent procedures; (e) neural data protection; and (f) sector-specific applications and challenges.

(3) The Commission shall work with professional regulatory bodies to: (a) integrate neurocognitive rights into professional standards and codes of ethics; (b) develop certification or credentialing programs for specialized roles related to neurotechnology; and (c) incorporate neurocognitive rights into continuing education requirements.

(4) The Commission shall establish a registry of approved training programs and maintain a database of certified professionals in specialized neurotechnology roles.

Community Engagement

117. (1) The Commission shall establish a community engagement program to: (a) foster dialogue about neurocognitive rights and neurotechnology in diverse communities; (b) ensure that the perspectives of various communities inform the implementation of this Act; (c) address concerns and misconceptions about neurotechnology; and (d) build capacity within communities to engage with neurotechnology issues.

(2) The community engagement program shall include: (a) community forums and town halls; (b) participatory workshops and dialogue sessions; (c) citizen panels and deliberative processes; (d) partnerships with community organizations and institutions; and (e) digital engagement platforms.

(3) The Commission shall provide resources and support for community-led initiatives related to neurocognitive rights, including: (a) grants for community projects; (b) training for community advocates; (c) networking opportunities for community leaders; and (d) access to expertise and informational resources.

(4) The Commission shall establish a dedicated Indigenous engagement strategy, developed in collaboration with Indigenous organizations and communities, that: (a) respects Indigenous governance and decision-making processes; (b) acknowledges the unique concerns and perspectives of Indigenous communities regarding neurotechnology; (c) supports Indigenous-led initiatives; and (d) incorporates traditional knowledge and practices.

Digital Media Resources

118. (1) The Commission shall develop and maintain comprehensive digital resources on neurocognitive rights and neurotechnology, including: (a) a dedicated website with information for different audiences and purposes; (b) social media presence and content; (c) interactive tools and applications; (d) webinars and online learning modules; (e) podcasts, videos, and other multimedia content; and (f) curated resources and links to reliable information sources.

(2) Digital resources shall: (a) be accessible to persons with disabilities; (b) be available in both official languages and, where appropriate, in other languages spoken in Canada; (c) be designed for different levels of technical knowledge and literacy; (d) be regularly updated to reflect current information and developments; and (e) incorporate user feedback and evaluation.

(3) The Commission shall develop interactive tools to help individuals: (a) understand their neurocognitive rights; (b) assess risks associated with specific neurotechnologies; (c) navigate the process of providing informed consent; (d) exercise their rights under this Act; and (e) access resources and support if they believe their rights have been infringed.

(4) The Commission shall establish a digital reporting system that allows individuals to: (a) report concerns about potential violations of neurocognitive rights; (b) provide feedback on experiences with neurotechnology; and (c) contribute to monitoring and evaluation of the implementation of this Act.

Support for Civil Society Organizations

119. (1) The Minister shall establish a program to support civil society organizations engaged in neurocognitive rights advocacy, education, and monitoring.

(2) The program shall provide: (a) funding for projects and initiatives related to neurocognitive rights; (b) capacity-building support for organizations working in the field; (c) opportunities for networking and collaboration; and (d) access to expertise, information, and resources.

(3) The Minister shall give particular attention to supporting: (a) organizations representing vulnerable populations; (b) Indigenous organizations; (c) patient and disability advocacy groups; (d) organizations focused on digital rights and technological justice; and (e) community-based and grassroots initiatives.

(4) The Minister shall establish a Civil Society Advisory Council on Neurocognitive Rights to: (a) provide input on the implementation of this Act; (b) identify emerging issues and concerns; (c) advise on priorities for education and awareness initiatives; and (d) foster collaboration among civil society organizations.

Media Engagement Strategy

120. (1) The Commission shall develop a media engagement strategy to: (a) promote accurate and responsible reporting on neurotechnology and neurocognitive rights; (b) build relationships with journalists and media outlets; (c) provide timely and reliable information to the media; and (d) respond to misinformation or sensationalism.

(2) The media engagement strategy shall include: (a) media briefings and background materials; (b) training for journalists on neurotechnology and neurocognitive rights; (c) a rapid response mechanism for addressing inaccurate reporting; and (d) proactive outreach to diverse media outlets, including ethnic media and alternative media platforms.

(3) The Commission shall develop specialized resources for media professionals, including: (a) a style guide for reporting on neurotechnology and neurocognitive rights; (b) fact sheets and backgrounders on key topics; (c) a database of experts available for media interviews; and (d) case studies that illustrate important principles and issues.

(4) The Commission shall monitor media coverage of neurotechnology and neurocognitive rights and produce an annual analysis of trends, gaps, and opportunities in media representation of these issues.

Public Consultations

121. (1) The Commission shall conduct regular public consultations on matters related to neurocognitive rights and neurotechnology, including: (a) the implementation and effectiveness of this Act; (b) emerging issues and challenges; (c) proposed regulatory changes; and (d) priorities for education and awareness initiatives.

(2) Public consultations shall: (a) be accessible to diverse participants; (b) employ a variety of methods and formats; (c) actively seek input from marginalized and vulnerable populations; (d) be transparent in process and outcomes; and (e) meaningfully incorporate public input into decision-making.

(3) The Commission shall publish reports on the results of public consultations, including how public input has been considered and incorporated into decisions and actions.

(4) The Commission shall establish a permanent public participation mechanism, such as a citizens' assembly or reference panel, to provide ongoing input on neurocognitive rights and neurotechnology governance.

Evaluation and Reporting

122. (1) The Minister shall establish a framework for evaluating the effectiveness of education and public awareness initiatives under this Part.

(2) The evaluation framework shall include: (a) indicators and metrics for assessing outcomes and impact; (b) methods for collecting and analyzing data; (c) processes for incorporating evaluation findings into program improvement; and (d) mechanisms for transparency and accountability in reporting.

(3) The Minister shall conduct or commission: (a) regular surveys of public knowledge, attitudes, and behaviors related to neurocognitive rights and neurotechnology; (b) assessments of the reach and effectiveness of specific programs and initiatives; (c) studies of best practices in neurocognitive rights education; and (d) research on emerging educational needs and challenges.

(4) The Minister shall submit a comprehensive report to Parliament every three years on the state of neurocognitive rights education and awareness in Canada, including: (a) an overview of programs and initiatives; (b) evidence of outcomes and impact; (c) challenges and gaps identified; and (d) recommendations for enhancement and improvement.

International Cooperation

123. (1) The Minister, in collaboration with the Minister of Foreign Affairs, shall promote international cooperation on neurocognitive rights education and awareness, including: (a) participation in international forums and initiatives related to neurocognitive rights and neurotechnology governance; (b) exchange of best practices, educational materials, and resources with other countries; (c) support for global capacity-building in neurocognitive rights education; (d) collaboration on research and knowledge development; and (e) promotion of harmonized approaches to neurocognitive rights education across jurisdictions.

(2) The Minister shall support Canadian participation in the development of international standards and guidelines for neurocognitive rights education.

(3) The Minister shall establish an international visitors program to: (a) facilitate knowledge exchange with experts and practitioners from other countries; (b) showcase Canadian approaches and innovations; and (c) build global networks of educators and advocates.

(4) The Minister shall work with international development agencies and organizations to support neurocognitive rights education and awareness in developing countries, with particular attention to: (a) building local capacity; (b) respecting cultural contexts and perspectives; (c) addressing equity considerations; and (d) promoting sustainable approaches.

Funding and Resources

124. (1) The Minister shall establish a Neurocognitive Rights Education and Awareness Fund to support initiatives under this Part.

(2) The Fund shall provide financial support for: (a) development and distribution of educational materials; (b) public awareness campaigns; (c) curriculum development and implementation; (d) professional training programs; (e) community engagement initiatives; (f) research and evaluation; and (g) other activities that promote understanding of neurocognitive rights and neurotechnology.

(3) The Fund shall be administered by the Commission, which shall establish: (a) criteria and procedures for funding applications; (b) mechanisms for ensuring equitable distribution of resources; (c) accountability measures for funded initiatives; and (d) processes for evaluating the impact of funded projects.

(4) The Minister shall report annually to Parliament on the activities and expenditures of the Fund.

(5) In addition to the Fund, the Minister shall ensure that adequate resources are allocated for: (a) staffing and operational costs related to education and awareness initiatives; (b) development and maintenance of digital infrastructure; (c) research and evaluation activities; and (d) coordination and collaboration with partners and stakeholders.

PART 9 - RESEARCH AND DEVELOPMENT

National Neurotechnology Research Initiative

125. (1) The Minister, in collaboration with the Minister of Innovation, Science and Industry, shall establish a National Neurotechnology Research Initiative.

(2) The purpose of the Initiative is to: (a) advance scientific knowledge in neuroscience and neurotechnology; (b) develop innovative and beneficial neurotechnologies; (c) ensure that neurotechnology research and development respects neurocognitive rights; (d) build Canadian capacity and leadership in neurotechnology; and (e) address societal challenges through responsible neurotechnology innovation.

(3) The Initiative shall: (a) establish research priorities based on scientific opportunities and societal needs; (b) provide funding for research projects, research networks, and research infrastructure; (c) support multidisciplinary and collaborative approaches; (d) foster partnerships among academic institutions, industry, healthcare providers, and civil society; (e) facilitate knowledge mobilization and technology transfer; and (f) promote international research cooperation.

(4) The Minister shall establish a Neurotechnology Research Advisory Board to guide the implementation of the Initiative, with representation from: (a) neuroscience and neurotechnology researchers; (b) ethicists and social scientists; (c) healthcare professionals; (d) patient and public representatives; (e) industry representatives; and (f) policy experts.

(5) The Minister shall report to Parliament on the activities and outcomes of the Initiative every three years.

Research Ethics Framework

126. (1) The Commission, in collaboration with the Canadian Institutes of Health Research and other relevant bodies, shall establish a comprehensive research ethics framework for neurotechnology research.

(2) The framework shall address: (a) protection of research participants' neurocognitive rights; (b) informed consent processes for neurotechnology research; (c) privacy and confidentiality of neural data; (d) management of incidental findings; (e) special protections for vulnerable populations; (f) community engagement and consultation; (g) responsible research practices; and (h) anticipation and mitigation of potential harms.

(3) All neurotechnology research involving human participants conducted in Canada, whether publicly or privately funded, shall comply with the framework.

(4) The Commission shall work with research ethics boards and institutional review boards to: (a) develop specialized guidelines and procedures for reviewing neurotechnology research; (b) provide training on neurocognitive rights and ethical issues in neurotechnology; (c) establish mechanisms for ongoing monitoring and oversight of approved research; and (d) facilitate sharing of best practices and case studies.

(5) The Commission shall establish a specialized Ethics Advisory Committee for Neurotechnology Research to: (a) provide guidance on complex or novel ethical issues; (b) review and respond to emerging ethical challenges; (c) develop recommendations for addressing gaps in the ethical framework; and (d) promote dialogue about ethical dimensions of neurotechnology research.

Responsible Innovation Principles

127. (1) All neurotechnology research and development conducted in Canada shall adhere to the following principles of responsible innovation: (a) Inclusion: engaging diverse stakeholders in research priority-setting, design, and governance; (b) Anticipation: systematically considering potential impacts, risks, and uncertainties; (c) Reflexivity: critically examining one's own activities, commitments, and assumptions; (d) Responsiveness: adapting direction in response to stakeholder and public values and changing circumstances; (e) Transparency: communicating methods, findings, implications, and limitations openly and accessibly; (f) Accountability: taking responsibility for one's actions and their consequences; and (g) Sustainability: considering long-term social, environmental, and economic implications.

(2) Researchers and developers shall: (a) integrate these principles throughout the research and development process; (b) document how they have applied these principles in their work; (c) engage with affected stakeholders and communities; and (d) adjust their approaches based on ongoing reflection and feedback.

(3) Research funders shall: (a) require adherence to these principles as a condition of funding; (b) provide resources and guidance to support implementation of the principles; (c) evaluate proposals and projects partly on the basis of how well they embody these principles; and (d) support research on effective methods for implementing responsible innovation in neurotechnology.

(4) The Commission shall develop detailed guidelines, tools, and metrics for the implementation and evaluation of these principles in neurotechnology research and development.

Safety and Security Research

128. (1) The Minister shall establish a dedicated program to support research on safety and security aspects of neurotechnology, including: (a) physical safety of neurotechnology devices and applications; (b) neural data security and privacy; (c) protection against unauthorized access or manipulation; (d) resilience against malfunction or misuse; (e) methods for detecting and preventing harmful applications; and (f) approaches to governance and oversight that enhance safety and security.

(2) The program shall support: (a) fundamental research on safety and security challenges; (b) development and testing of technical solutions; (c) creation of standards, benchmarks, and evaluation methods; (d) establishment of best practices for risk assessment and management; and (e) interdisciplinary approaches that integrate technical, social, and ethical perspectives.

(3) The Minister shall establish specialized research facilities and testbeds for evaluating the safety and security of neurotechnologies under controlled conditions.

(4) The Minister shall establish mechanisms for sharing safety and security research findings with researchers, developers, regulators, and other stakeholders, while respecting legitimate confidentiality concerns.

Accessible Neurotechnology Development

129. (1) The Minister shall establish a program to support the development of accessible neurotechnologies that: (a) address the needs of persons with disabilities or medical conditions; (b) are affordable and available to those who need them; (c) incorporate universal design principles; (d) respect user autonomy and dignity; and (e) provide meaningful benefits while minimizing risks.

(2) The program shall: (a) provide funding for research and development projects; (b) facilitate collaboration among researchers, developers, healthcare providers, and potential users; (c) support user-centered design processes that engage potential users throughout development; (d) address barriers to adoption and implementation; and (e) promote knowledge translation and commercialization.

(3) The Minister shall establish an Accessible Neurotechnology Challenge program to: (a) identify priority needs and opportunities; (b) incentivize innovative solutions through competitions and prizes; (c) support prototype development and testing; and (d) facilitate scaling and dissemination of successful innovations.

(4) The program shall give particular attention to neurotechnologies that address: (a) conditions for which effective treatments are currently limited; (b) needs of underserved populations; (c) enhancement of independence and quality of life; and (d) reduction of health inequities.

Open Science and Collaborative Research

130. (1) The Minister shall promote open science and collaborative approaches in neurotechnology research by: (a) requiring open access publication of publicly funded research results; (b) supporting the development and maintenance of open datasets, tools, and resources; (c) encouraging pre-registration of research studies and transparent reporting of methods and results; (d) facilitating data sharing while respecting privacy and confidentiality; and (e) recognizing and rewarding open and collaborative research practices.

(2) The Minister shall establish a Canadian Neurotechnology Research Commons to: (a) provide infrastructure for sharing data, code, protocols, and resources; (b) establish standards and best practices for interoperability and documentation; (c) support collaborative projects that span institutions and sectors; and (d) facilitate community building among neurotechnology researchers and developers.

(3) The Minister shall work with research institutions, funding agencies, and publishers to align incentives, policies, and practices to support open science and collaborative research in neurotechnology.

(4) The Minister shall establish mechanisms to ensure that open science practices respect: (a) privacy and confidentiality of personal information; (b) intellectual property rights, where appropriate; (c) security considerations; and (d) ethical standards and community norms.

Clinical Translation Pathways

131. (1) The Minister, in collaboration with the Minister of Health, shall establish clear and efficient pathways for the clinical translation of neurotechnology research, including: (a) guidelines for preclinical studies and early-phase clinical trials; (b) protocols for safety and efficacy evaluation; (c) frameworks for benefit-risk assessment; (d) mechanisms for expedited review of promising technologies for serious conditions; and (e) support for implementation and dissemination of evidence-based neurotechnologies.

(2) The Minister shall establish a Neurotechnology Clinical Trials Network to: (a) coordinate and support clinical trials of new neurotechnologies; (b) develop standardized protocols and outcome measures; (c) facilitate recruitment and participation; (d) build capacity for neurotechnology clinical research; and (e) disseminate results and best practices.

(3) The Minister shall establish a program to support: (a) translational research that bridges the gap between laboratory discoveries and clinical applications; (b) early-phase clinical studies to establish safety and proof-of-concept; (c) later-phase clinical trials to establish efficacy and effectiveness; (d) health services research to optimize implementation and delivery; and (e) post-market studies to monitor long-term outcomes and effects.

(4) The Minister shall work with health technology assessment bodies, healthcare payers, and healthcare providers to facilitate the adoption and appropriate use of evidence-based neurotechnologies in clinical practice.

Public Interest Neurotechnology

132. (1) The Minister shall establish a program to support the development of public interest neurotechnology that: (a) addresses societal challenges and public needs; (b) prioritizes public benefit over private profit; (c) embodies values of equity, inclusion, and justice; and (d) employs governance models that include meaningful public participation.

(2) The program shall support: (a) research and development of neurotechnologies that address public priorities; (b) public-private partnerships that align commercial incentives with public interest; (c) community-based and participatory research approaches; (d) alternative intellectual property models that promote access and sharing; and (e) governance frameworks that ensure public accountability and oversight.

(3) The Minister shall establish a Public Interest Technology Fund to: (a) provide grants for public interest neurotechnology projects; (b) support non-profit organizations developing public interest neurotechnologies; (c) fund fellowships for researchers and developers working on public interest applications; and (d) invest in infrastructure and resources that facilitate public interest innovation.

(4) The Minister shall establish a Civil Society Neurotechnology Innovation Lab to: (a) bring together civil society organizations, researchers, and developers; (b) identify needs and opportunities for public interest neurotechnology; (c) prototype and test solutions; and (d) build capacity within civil society to engage with neurotechnology.

Neuroethics Research

133. (1) The Minister shall establish a dedicated program to support research in neuroethics, including: (a) philosophical and conceptual analysis of neurotechnology and its implications; (b) empirical studies of societal, ethical, legal, and policy issues; (c) normative inquiry into appropriate principles, values, and frameworks; (d) development of methods and approaches for addressing ethical challenges; and (e) integration of ethical considerations into neurotechnology research, development, and governance.

(2) The program shall support: (a) individual research projects on neuroethics topics; (b) interdisciplinary research teams and networks; (c) integration of neuroethics into neurotechnology research projects; (d) training and career development in neuroethics; and (e) knowledge mobilization and public engagement.

(3) The Minister shall establish a Canadian Neuroethics Network to: (a) connect researchers, practitioners, policy-makers, and stakeholders; (b) facilitate collaboration and knowledge sharing; (c) identify research priorities and emerging issues; (d) develop best practices and guidelines; and (e) promote Canadian leadership in neuroethics globally.

(4) The Minister shall ensure that neuroethics research: (a) engages with diverse cultural, social, and philosophical perspectives; (b) includes voices and experiences of affected communities; (c) considers implications for different populations and contexts; and (d) produces insights that inform policy, practice, and public understanding.

Indigenous Knowledge and Neurotechnology

134. (1) The Minister, in consultation with Indigenous governments, organizations, and knowledge keepers, shall establish a program to: (a) support research that respectfully integrates Indigenous knowledge and Western scientific approaches to understanding the brain, mind, and consciousness; (b) facilitate dialogue and knowledge exchange between Indigenous knowledge systems and neuroscience; (c) develop approaches to neurotechnology research, development, and governance that respect Indigenous values, traditions, and rights; and (d) address the specific needs, priorities, and concerns of Indigenous communities regarding neurotechnology.

(2) The program shall: (a) be co-developed and co-governed with Indigenous partners; (b) respect principles of Indigenous data sovereignty; (c) support Indigenous-led research initiatives; (d) build capacity for Indigenous participation in neurotechnology research and governance; and (e) ensure that benefits from research are shared equitably with Indigenous communities.

(3) The Minister shall establish an Indigenous Neuroscience and Technology Council to: (a) provide guidance on research priorities and approaches; (b) develop protocols for respectful research partnerships; (c) advise on the protection of Indigenous knowledge related to the brain, mind, and consciousness; and (d) facilitate knowledge mobilization that respects cultural protocols and contexts.

(4) All neurotechnology research involving Indigenous peoples or communities shall: (a) adhere to principles of free, prior, and informed consent at both individual and community levels; (b) respect Indigenous governance and decision-making processes; (c) acknowledge and incorporate relevant Indigenous knowledge, with appropriate permission and attribution; (d) ensure mutually beneficial outcomes; and (e) comply with any additional requirements established by relevant Indigenous governments or organizations.

International Research Cooperation

135. (1) The Minister, in collaboration with the Minister of Foreign Affairs, shall promote international cooperation in neurotechnology research, including: (a) participation in multinational research initiatives and consortia; (b) bilateral and multilateral research agreements and partnerships; (c) exchange programs for researchers and students; (d) shared research infrastructure and resources; and (e) harmonization of research standards and protocols.

(2) The Minister shall establish a Global Neurotechnology Research Alliance to: (a) coordinate research efforts across countries; (b) address global challenges that require collaborative approaches; (c) share knowledge, data, and resources; (d) develop common standards and benchmarks; and (e) build research capacity, particularly in low- and middle-income countries.

(3) In promoting international research cooperation, the Minister shall ensure that: (a) Canadian values and standards regarding neurocognitive rights are respected; (b) benefits and burdens of research are equitably shared; (c) capacity building and knowledge transfer are prioritized; and (d) global disparities in access to neurotechnology research and its benefits are addressed.

(4) The Minister shall establish mechanisms for: (a) coordinating Canadian participation in international research initiatives; (b) facilitating international research partnerships and collaborations; (c) supporting Canadian researchers engaging in international projects; and (d) promoting Canadian approaches and contributions on the global stage.

Research Integrity and Accountability

136. (1) All neurotechnology research conducted in Canada shall adhere to the highest standards of research integrity, including: (a) honesty in the design, conduct, and reporting of research; (b) reliability in performing research and reporting results; (c) objectivity in experimental design, data analysis, interpretation, peer review, and other aspects of research; (d) impartiality in conducting research and avoiding bias; (e) openness in sharing data, results, methods, and tools; (f) respect for intellectual property, confidentiality, and research participants; and (g) accountability for research conduct and adherence to regulations and guidelines.

(2) Research institutions shall: (a) establish clear policies and procedures for promoting research integrity and addressing misconduct; (b) provide training on research integrity for

all researchers and staff; (c) create an environment that encourages ethical behavior and discourages misconduct; and (d) promptly investigate allegations of research misconduct.

(3) The Minister shall establish a Neurotechnology Research Integrity Office to: (a) develop guidelines and best practices for research integrity in neurotechnology; (b) provide advice and resources to researchers, institutions, and funders; (c) oversee investigations of serious or complex cases of alleged misconduct; and (d) coordinate with international partners on research integrity issues.

(4) Research funders shall: (a) require adherence to research integrity standards as a condition of funding; (b) verify that funded institutions have appropriate policies and procedures in place; (c) respond appropriately to findings of research misconduct; and (d) support education and training on research integrity.

Research Capacity Building

137. (1) The Minister shall establish a program to build Canadian research capacity in neurotechnology, including: (a) support for training and education at all levels; (b) career development opportunities for researchers; (c) infrastructure and equipment for cutting-edge research; (d) institutional support for neurotechnology research programs; and (e) initiatives to attract and retain talented researchers.

(2) The program shall include: (a) scholarships and fellowships for students and early-career researchers; (b) research chairs and professorships in priority areas; (c) grants for establishing new research groups and programs; (d) funding for specialized research facilities and equipment; and (e) support for networks and collaborative platforms.

(3) The Minister shall establish targeted initiatives to: (a) increase diversity in the neurotechnology research workforce; (b) support underrepresented groups in pursuing neurotechnology research careers; (c) build research capacity in historically underserved regions and institutions; and (d) develop research leadership in priority areas.

(4) The Minister shall establish a Neurotechnology Skills Strategy to: (a) identify current and future skills needs in the neurotechnology sector; (b) develop and implement training programs to address skills gaps; (c) facilitate partnerships between educational institutions and employers; and (d) promote neurotechnology careers and pathways.

Evaluation and Impact Assessment

138. (1) The Minister shall establish a framework for evaluating and assessing the impacts of neurotechnology research and development, including: (a) scientific and technological outcomes; (b) economic impacts and benefits; (c) health and clinical impacts; (d) social and ethical implications; (e) environmental considerations; and (f) effects on neurocognitive rights and well-being.

(2) The framework shall: (a) employ diverse methods and approaches appropriate to different types of impacts; (b) consider both short-term and long-term impacts; (c) assess both intended and unintended consequences; (d) engage stakeholders in defining relevant impacts and metrics; and (e) provide meaningful information for decision-making and improvement.

(3) The Minister shall conduct or commission: (a) regular evaluations of major research programs and initiatives; (b) studies of emerging trends and developments in

neurotechnology research; (c) assessments of the state of Canadian neurotechnology research capacity; and (d) analyses of the broader impacts of neurotechnology research on society.

(4) The Minister shall report to Parliament every three years on the state of neurotechnology research in Canada, including: (a) major accomplishments and developments; (b) challenges and opportunities; (c) international standing and competitiveness; (d) alignment with Canadian priorities and values; and (e) recommendations for enhancing research performance and impact.

PART 10 - ACCESSIBILITY AND EQUITY

Universal Access to Therapeutic Neurotechnologies

139. (1) The Minister, in collaboration with the Minister of Health and provincial and territorial ministers of health, shall develop and implement a strategy to ensure universal access to therapeutic neurotechnologies for Canadians who need them.

(2) The strategy shall address: (a) coverage of therapeutic neurotechnologies under public health insurance plans; (b) coordination of federal, provincial, and territorial programs and policies; (c) affordability and cost containment measures; (d) equitable geographical access, including in rural and remote communities; (e) timeliness of access to new and emerging neurotechnologies; and (f) sustainability of funding and delivery systems.

(3) In developing and implementing the strategy, the Minister shall: (a) consult with patients, healthcare providers, neurotechnology developers, and other stakeholders; (b) consider the unique needs and circumstances of different populations and regions; (c) respect provincial and territorial jurisdiction over healthcare delivery; (d) promote evidence-based decision-making; and (e) establish mechanisms for monitoring and evaluation.

(4) The Minister shall report to Parliament on the implementation and outcomes of the strategy every three years.

Public Health Insurance Coverage

140. (1) The Minister shall work with provincial and territorial governments to: (a) establish criteria and processes for determining which therapeutic neurotechnologies should be covered under public health insurance plans; (b) develop harmonized approaches to health technology assessment for neurotechnologies; (c) implement risk-sharing arrangements and innovative pricing models to facilitate coverage of high-cost neurotechnologies; and (d) ensure timely updates to coverage policies in response to emerging evidence and technologies.

(2) The criteria for coverage decisions shall include: (a) clinical effectiveness and safety; (b) cost-effectiveness and value for money; (c) population health impact; (d) alignment with patient values and preferences; (e) ethical, legal, and social implications; and (f) feasibility of implementation.

(3) The Minister shall establish a Neurotechnology Advisory Committee to provide recommendations on coverage decisions, with representation from: (a) clinical experts in relevant specialties; (b) health technology assessment specialists; (c) patient representatives; (d) health economists; (e) ethicists; and (f) health system administrators.

(4) The Minister shall establish a Rare Neurological Conditions Fund to support access to neurotechnologies for rare conditions that may not meet traditional cost-effectiveness thresholds but address significant unmet needs.

Private Insurance Regulations

141. (1) The Superintendent of Financial Institutions, in consultation with the Minister, shall develop regulations for private health insurance coverage of neurotechnologies, including: (a) minimum coverage requirements for therapeutic neurotechnologies; (b) prohibitions on discrimination based on genetic or neural information; (c) transparency requirements for coverage decisions and policies; (d) processes for appealing coverage denials; and (e) coordination of benefits with public insurance plans.

(2) No insurer shall: (a) require an individual to undergo neural monitoring or provide neural data as a condition of insurance eligibility or coverage; (b) use neural data to determine premiums or coverage unless specifically authorized by provincial insurance regulations and based on actuarially sound principles; or (c) discriminate between individuals based on neural data that reveals protected characteristics or conditions.

(3) Insurers shall: (a) clearly disclose to policyholders the extent of coverage for neurotechnologies; (b) establish transparent and evidence-based criteria for coverage decisions; (c) provide timely and accessible appeals processes for coverage denials; and (d) report annually to the Superintendent on neurotechnology coverage and claims.

(4) The Superintendent shall monitor insurance market practices related to neurotechnology coverage and issue regular reports on trends, issues, and recommendations.

Assistive Neurotechnology Program

142. (1) The Minister shall establish a National Assistive Neurotechnology Program to ensure access to neurotechnologies that enhance functioning, independence, and quality of life for persons with disabilities or medical conditions.

(2) The Program shall: (a) provide funding for the acquisition, maintenance, and upgrading of assistive neurotechnologies; (b) establish assessment and eligibility processes that are person-centered and responsive to individual needs; (c) ensure coordination with other assistive technology and disability support programs; (d) provide training and support for effective use of assistive neurotechnologies; and (e) promote innovation and continuous improvement in assistive neurotechnology.

(3) The Program shall be administered in collaboration with provincial and territorial governments and shall complement existing assistive device programs.

(4) In implementing the Program, the Minister shall ensure: (a) respect for the autonomy and dignity of persons with disabilities; (b) meaningful involvement of persons with disabilities in program design and governance; (c) responsiveness to diverse needs and preferences; and (d) sustainability and equity of access.

(5) The Minister shall establish an advisory committee for the Program, with representation from: (a) persons with disabilities who use assistive neurotechnology; (b) disability rights organizations; (c) healthcare providers and rehabilitation specialists; (d) assistive technology experts; and (e) provincial and territorial program representatives.

Rural and Remote Access

143. (1) The Minister, in collaboration with provincial and territorial governments, shall develop and implement a strategy to ensure equitable access to neurotechnology for Canadians living in rural and remote communities.

(2) The strategy shall address: (a) distribution and availability of neurotechnology services and expertise; (b) virtual care and telehealth approaches for neurotechnology assessment and support; (c) transportation and accommodation support for accessing specialized services; (d) community-based delivery models and capacity building; (e) training and support for local healthcare providers; and (f) infrastructure and connectivity requirements.

(3) The Minister shall establish a Rural and Remote Neurotechnology Access Fund to support: (a) outreach clinics and mobile service delivery; (b) telehealth infrastructure and services; (c) training programs for local providers; (d) patient travel and accommodation subsidies; and (e) community-based neurotechnology support programs.

(4) The Minister shall work with First Nations, Inuit, and Métis communities to develop and implement approaches that: (a) respect Indigenous rights and self-determination; (b) integrate traditional healing practices with neurotechnology, where appropriate; (c) build capacity within communities; and (d) address the unique geographical, cultural, and historical contexts of Indigenous communities.

Disability Rights and Accommodations

144. (1) No person shall be denied access to services, opportunities, or benefits because they: (a) use assistive neurotechnology; (b) require accommodations related to neurotechnology use; or (c) choose not to use neurotechnology that would alter or mask their natural neurological functioning.

(2) Employers, service providers, educational institutions, and other organizations shall: (a) provide reasonable accommodations for individuals who use neurotechnology; (b) ensure that digital and physical environments are compatible with common assistive neurotechnologies; (c) develop and implement policies that respect neurodiversity and different ways of cognitive functioning; and (d) train staff on neurotechnology accommodations and inclusive practices.

(3) The Canadian Human Rights Commission, in consultation with the Commission, shall develop guidelines for: (a) accommodations related to neurotechnology in various contexts; (b) addressing potential conflicts between different accommodation needs; (c) determining when accommodations would constitute undue hardship; and (d) balancing accommodations with safety and security considerations.

(4) The Minister shall establish a program to support organizations in implementing neurotechnology accommodations, including: (a) technical assistance and consultation; (b) funding for accommodation-related costs; (c) training and educational resources; and (d) sharing of best practices and success stories.

Addressing Neurocognitive Disparities

145. (1) The Minister shall establish a program to identify, monitor, and address disparities in access to neurotechnology and protection of neurocognitive rights among different population groups.

(2) The program shall: (a) collect and analyze data on neurotechnology access, use, and outcomes across demographic groups; (b) identify barriers and factors contributing to disparities; (c) develop and implement targeted interventions to reduce disparities; (d) support research on effective approaches to promoting equity; and (e) monitor progress and adjust strategies based on evidence.

(3) The Minister shall give particular attention to disparities affecting: (a) Indigenous peoples; (b) racialized communities; (c) persons with disabilities; (d) lower-income individuals and families; (e) older adults; (f) linguistic minorities; and (g) rural and remote communities.

(4) The Minister shall establish a Neurotechnology Equity Task Force to: (a) provide advice on strategies for addressing disparities; (b) engage with affected communities; (c) monitor trends and developments; and (d) report on progress and challenges.

Community-Based Initiatives

146. (1) The Minister shall establish a program to support community-based initiatives that promote equitable access to neurotechnology and protection of neurocognitive rights.

(2) The program shall provide funding and support for: (a) community needs assessments and planning; (b) locally-designed and implemented projects; (c) capacity building and skill development; (d) peer support and navigation programs; (e) community education and awareness; and (f) evaluation and knowledge sharing.

(3) The program shall emphasize: (a) community leadership and ownership; (b) cultural appropriateness and responsiveness; (c) building on existing community strengths and assets; (d) addressing social determinants of health and well-being; and (e) sustainability and long-term impact.

(4) The Minister shall establish mechanisms for: (a) coordinating community-based initiatives with broader policies and programs; (b) facilitating learning and exchange among communities; (c) scaling up successful approaches; and (d) addressing systemic barriers identified through community work.

Workforce Development and Training

147. (1) The Minister, in collaboration with the Minister of Employment and Social Development, shall establish a Neurotechnology Workforce Development Strategy to: (a) ensure an adequate supply of qualified professionals to support equitable access to neurotechnology; (b) promote diversity in the neurotechnology workforce; (c) address geographic distribution and shortages; and (d) support ongoing professional development and specialization.

(2) The Strategy shall address the needs of various professional groups involved in neurotechnology, including: (a) neuroscientists and researchers; (b) engineers and technical specialists; (c) healthcare providers, including physicians, nurses, and allied health professionals; (d) rehabilitation specialists; (e) technicians and support personnel; (f) ethical and legal specialists; and (g) educators and trainers.

(3) The Strategy shall include: (a) support for educational programs at undergraduate, graduate, and professional levels; (b) scholarships and bursaries for students pursuing careers in neurotechnology; (c) incentives for practicing in underserved communities; (d)

continuing education programs and requirements; (e) mentorship and career development initiatives; and (f) retraining programs for workers affected by technological changes.

(4) The Minister shall establish a Neurotechnology Skills Certification Framework to: (a) define competencies and standards for various roles; (b) establish certification processes that recognize knowledge and skills; (c) promote recognition and portability of qualifications across jurisdictions; and (d) ensure that training and certification requirements do not create unnecessary barriers to workforce entry and mobility.

Financial Assistance Programs

148. (1) The Minister, in collaboration with the Minister of Finance, shall establish financial assistance programs to help individuals access needed neurotechnology, including: (a) means-tested subsidies for the purchase or lease of therapeutic or assistive neurotechnology; (b) tax credits for eligible neurotechnology expenses; (c) low-interest loans for high-cost neurotechnology; and (d) special financial assistance for emergency or temporary needs.

(2) Financial assistance programs shall: (a) be coordinated with existing programs at federal, provincial, and territorial levels; (b) use simple and accessible application processes; (c) respond to individual circumstances and needs; (d) ensure timeliness of assistance; and (e) include mechanisms for appeals and exceptional circumstances.

(3) The Minister shall work with financial institutions to: (a) develop specialized financing products for neurotechnology; (b) ensure fair and non-discriminatory lending practices; (c) provide financial literacy education related to neurotechnology costs and financing; and (d) establish programs to support individuals with limited credit history or financial resources.

(4) The Minister shall establish a Compassionate Access Program to provide immediate assistance to individuals with urgent needs who face financial barriers to accessing essential neurotechnology.

Affordable Neurotechnology Initiative

149. (1) The Minister shall establish an Affordable Neurotechnology Initiative to: (a) promote the development of cost-effective neurotechnologies; (b) implement strategies to reduce costs of existing neurotechnologies; (c) facilitate sustainable access to neurotechnology for individuals with limited financial resources; and (d) address price barriers to equitable access.

(2) The Initiative shall include: (a) research and development grants for low-cost neurotechnology solutions; (b) innovation challenges and prizes for affordable designs; (c) volume purchasing and procurement strategies; (d) price negotiation and reference pricing mechanisms; and (e) support for not-for-profit and social enterprise models of production and distribution.

(3) The Minister shall establish an Affordable Neurotechnology Advisory Committee, with representation from: (a) patient and consumer advocates; (b) healthcare providers and administrators; (c) neurotechnology developers and manufacturers; (d) health economists and policy experts; and (e) representatives of vulnerable populations.

(4) The Minister shall report to Parliament every three years on the state of neurotechnology affordability in Canada, including: (a) trends in prices and costs; (b) impact of affordability

initiatives; (c) remaining barriers and challenges; and (d) recommendations for further action.

Culturally Appropriate Neurotechnology

150. (1) The Minister shall establish a program to promote the development and implementation of culturally appropriate approaches to neurotechnology for diverse populations in Canada.

(2) The program shall support: (a) research on cultural factors that influence neurotechnology acceptance, use, and effectiveness; (b) adaptation of neurotechnology design, implementation, and support to diverse cultural contexts; (c) development of culturally specific protocols and approaches; (d) training for professionals on cultural competence in neurotechnology; and (e) community engagement in design and implementation.

(3) The Minister shall give particular attention to ensuring culturally appropriate neurotechnology for: (a) Indigenous peoples, respecting traditional knowledge and healing practices; (b) immigrant and refugee communities; (c) linguistic minorities; and (d) religious and cultural groups with specific values or practices relevant to neurotechnology.

(4) The Minister shall establish a Cultural Appropriateness Review Process to: (a) assess neurotechnology for cultural appropriateness; (b) provide recommendations for adaptation or modification; (c) identify potential cultural barriers or concerns; and (d) promote sharing of best practices for culturally appropriate implementation.

Gender-Based Analysis

151. (1) The Minister shall ensure that gender-based analysis plus (GBA+) is applied to all policies, programs, and initiatives related to neurotechnology, including: (a) research priorities and funding; (b) design and development of neurotechnology; (c) clinical trials and testing; (d) regulatory frameworks and processes; (e) coverage and access policies; and (f) education and training programs.

(2) The Minister shall establish guidelines for the application of GBA+ to neurotechnology research, development, and implementation, addressing: (a) consideration of sex and gender differences in brain structure and function; (b) inclusion of diverse gender identities in research and design; (c) assessment of differential impacts across genders and other identity factors; (d) addressing gender-based barriers to access and use; and (e) monitoring for gender-based disparities in outcomes and benefits.

(3) The Minister shall require that all federal programs and initiatives related to neurotechnology include: (a) explicit consideration of gender and intersectional factors; (b) sex- and gender-disaggregated data collection and analysis; (c) measures to address identified disparities; and (d) evaluation of gender-based outcomes and impacts.

(4) The Minister shall report to Parliament every three years on gender-based considerations and impacts in neurotechnology policy and programs.

Global Equity and Capacity Building

152. (1) The Minister, in collaboration with the Minister of Foreign Affairs and the Minister of International Development, shall establish a program to promote global equity in neurotechnology access and neurocognitive rights protection.

(2) The program shall support: (a) capacity building in low- and middle-income countries; (b) technology transfer and knowledge sharing; (c) development of context-appropriate neurotechnology solutions; (d) establishment of legal and regulatory frameworks for neurocognitive rights; and (e) strengthening of healthcare systems to deliver neurotechnology services.

(3) The Minister shall establish a Global Neurotechnology Equity Fund to: (a) provide financial and technical assistance to eligible countries and organizations; (b) support south-south cooperation and regional initiatives; (c) fund fellowships and training opportunities; and (d) promote research collaboration addressing global neurotechnology challenges.

(4) In implementing the program, the Minister shall ensure: (a) respect for national sovereignty and local priorities; (b) sustainability and long-term impact; (c) alignment with broader development goals and approaches; and (d) meaningful participation of local stakeholders and communities.

Intergenerational Equity

153. (1) The Minister shall establish mechanisms to ensure that neurotechnology development and governance consider the interests of future generations, including: (a) long-term assessment of impacts and implications; (b) precautionary approaches to risks with potential long-term consequences; (c) sustainable models of development and access; and (d) preservation of cognitive diversity and autonomy.

(2) The Minister shall establish a Future Generations Advisory Council to: (a) provide a voice for the interests of future generations in neurotechnology policy; (b) conduct forward-looking analysis of trends and developments; (c) identify potential long-term concerns and opportunities; and (d) recommend approaches that balance current needs with future well-being.

(3) The Council shall include members with expertise in: (a) futures studies and forecasting; (b) sustainable development and intergenerational ethics; (c) long-term technology assessment; (d) environmental and social sustainability; and (e) youth perspectives and advocacy.

(4) The Minister shall require that significant policy decisions related to neurotechnology include an Intergenerational Impact Assessment that: (a) identifies potential impacts on future generations; (b) evaluates sustainability and long-term implications; (c) considers options for preserving future choices and opportunities; and (d) recommends approaches that protect the interests of those not yet born.

Monitoring and Evaluation

154. (1) The Minister shall establish a comprehensive framework for monitoring and evaluating equity and accessibility in neurotechnology, including: (a) indicators and metrics for key dimensions of equity and access; (b) data collection and analysis systems; (c) periodic assessments and reports; and (d) mechanisms for using evidence to inform policy and program improvements.

(2) The monitoring and evaluation framework shall address: (a) availability and distribution of neurotechnology services and resources; (b) affordability and financial barriers; (c) physical and geographical accessibility; (d) cultural appropriateness and acceptability; (e) quality and effectiveness across population groups; and (f) outcomes and impacts for different communities and individuals.

(3) The Minister shall publish an annual report on the state of equity and accessibility in neurotechnology in Canada, including: (a) current status and trends; (b) progress on addressing disparities; (c) persistent challenges and barriers; and (d) recommendations for action.

(4) The Minister shall establish an independent Neurotechnology Equity and Access Review Panel to: (a) provide external assessment of progress and challenges; (b) conduct in-depth reviews of specific issues or concerns; (c) engage with affected communities and stakeholders; and (d) make recommendations for policy and program improvements.

PART 11 - IMPLEMENTATION AND ADMINISTRATION

Federal Agency Responsibilities

155. (1) The Minister shall be responsible for the overall administration of this Act and shall: (a) provide leadership and coordination for the implementation of this Act; (b) establish policies, guidelines, and standards as required by this Act; (c) monitor and evaluate the effectiveness of this Act; (d) report to Parliament on the implementation and outcomes of this Act; and (e) represent Canada in international forums related to neurocognitive rights and neurotechnology.

(2) The following ministers shall have specific responsibilities in relation to this Act: (a) the Minister of Health shall be responsible for matters related to therapeutic neurotechnologies, healthcare access, and health-related research; (b) the Minister of Innovation, Science and Industry shall be responsible for matters related to research, development, innovation, and commercial applications of neurotechnology; (c) the Minister of Justice shall be responsible for matters related to the Neurocognitive Rights Tribunal, law enforcement aspects, and coordination with the justice system; (d) the Minister of Employment and Social Development shall be responsible for matters related to workforce development, accessibility, and social programs; (e) the Minister of Public Safety and Emergency Preparedness shall be responsible for matters related to security applications and oversight of law enforcement use of neurotechnology; (f) the Minister of Foreign Affairs shall be responsible for international cooperation and agreements related to neurocognitive rights and neurotechnology; and (g) the Minister of Crown-Indigenous Relations and Northern Affairs shall be responsible for matters related to Indigenous rights and neurotechnology in Indigenous contexts.

(3) The Minister shall establish an Interdepartmental Coordination Committee, comprising representatives from all relevant federal departments and agencies, to: (a) ensure coherent and complementary approaches across the federal government; (b) identify and address gaps, overlaps, or inconsistencies in implementation; (c) coordinate reporting and information sharing; and (d) develop joint initiatives and approaches where appropriate.

(4) The Minister shall establish mechanisms for regular consultation with provinces, territories, Indigenous governments, and other key stakeholders to ensure coordinated and collaborative implementation.

Federal-Provincial-Territorial Coordination

156. (1) The Minister shall work with provincial and territorial governments to develop a framework for coordinated implementation of neurocognitive rights protection and neurotechnology regulation across jurisdictions.

(2) The framework shall address: (a) clear delineation of roles and responsibilities; (b) mechanisms for harmonization of standards and approaches; (c) information sharing and joint data collection; (d) cooperative enforcement and compliance activities; (e) conflict resolution processes; and (f) coordinated reporting and evaluation.

(3) The Minister may enter into agreements with provinces and territories regarding: (a) delegation of specific functions or responsibilities; (b) funding arrangements for implementation activities; (c) joint programs or initiatives; and (d) coordination of regulatory activities.

(4) The Minister shall convene an annual Federal-Provincial-Territorial Neurocognitive Rights and Neurotechnology Conference to: (a) review progress on implementation; (b) address emerging issues and challenges; (c) share best practices and innovations; and (d) plan coordinated responses to developments in neurotechnology.

Indigenous Government Coordination

157. (1) The Minister shall work with First Nations, Inuit, and Métis governments and representative organizations to develop and implement approaches to neurocognitive rights protection and neurotechnology regulation that: (a) respect Indigenous rights, treaties, and self-government agreements; (b) recognize Indigenous jurisdiction and authority in relevant areas; (c) incorporate Indigenous legal traditions and knowledge systems; (d) address the specific historical, cultural, and social contexts of Indigenous communities; and (e) support Indigenous-led initiatives and capacity building.

(2) The Minister shall establish an Indigenous Neurocognitive Rights Advisory Council, with representation from diverse Indigenous nations, communities, and perspectives, to: (a) provide advice on the implementation of this Act in Indigenous contexts; (b) identify issues and concerns specific to Indigenous peoples; (c) recommend approaches that respect Indigenous sovereignty and self-determination; and (d) monitor the impacts of this Act on Indigenous communities.

(3) The Minister shall provide support for: (a) Indigenous governments and organizations to develop their own laws, policies, and programs related to neurocognitive rights and neurotechnology; (b) capacity building within Indigenous governments and organizations; (c) community-based initiatives and pilot projects; and (d) Indigenous-led research and knowledge development.

(4) The Minister shall ensure that all implementation activities related to Indigenous peoples are conducted in a manner consistent with: (a) the United Nations Declaration on the Rights of Indigenous Peoples; (b) the Truth and Reconciliation Commission's Calls to

Action; (c) the National Inquiry into Missing and Murdered Indigenous Women and Girls' Calls for Justice; and (d) relevant treaties, agreements, and constitutional provisions.

Implementation Timeline

158. (1) This Act shall come into force in phases according to the following timeline: (a) Phase 1, which shall come into force on the day that is six months after the day on which this Act receives royal assent, shall include: (i) the general provisions in Part 1; (ii) the fundamental neurocognitive rights in Part 2; (iii) the provisions establishing the Commission in Part 4; and (iv) the provisions for the development of regulations and standards; (b) Phase 2, which shall come into force on the day that is one year after the day on which this Act receives royal assent, shall include: (i) the regulatory framework for minimal and low risk neurotechnology in Part 3; (ii) the basic provisions for neurocognitive data protection in Part 5; (iii) the provisions establishing the Neurocognitive Rights Tribunal in Part 6; and (iv) the education and public awareness provisions in Part 8; (c) Phase 3, which shall come into force on the day that is eighteen months after the day on which this Act receives royal assent, shall include: (i) the regulatory framework for moderate and high risk neurotechnology in Part 3; (ii) the remaining provisions for neurocognitive data protection in Part 5; (iii) the criminal and civil liability provisions in Part 7; and (iv) the research and development provisions in Part 9; and (d) Phase 4, which shall come into force on the day that is two years after the day on which this Act receives royal assent, shall include: (i) the accessibility and equity provisions in Part 10; and (ii) any remaining provisions not included in previous phases.

(2) The Governor in Council may, by order, extend any implementation timeline specified in subsection (1) by up to six months if necessary to ensure effective implementation.

(3) The Minister shall develop and publish a detailed implementation plan for each phase, including: (a) key milestones and deliverables; (b) responsible agencies and offices; (c) resource allocations and requirements; and (d) performance indicators and targets.

(4) The Minister shall report to Parliament on the progress of implementation at the conclusion of each phase.

Transitional Provisions

159. (1) Neurotechnology that was legally placed on the market in Canada before the coming into force of the regulatory provisions in Part 3 may continue to be made available on the market or put into service for a transitional period of: (a) one year from the coming into force of the relevant provisions, for neurotechnology that would be classified as minimal or low risk; (b) two years from the coming into force of the relevant provisions, for neurotechnology that would be classified as moderate risk; and (c) three years from the coming into force of the relevant provisions, for neurotechnology that would be classified as high risk.

(2) During the transitional period, providers of existing neurotechnology shall: (a) determine the appropriate risk classification for their neurotechnology under this Act; (b) take steps to bring their neurotechnology into compliance with the applicable requirements; and (c) submit the required notifications, applications for registration, authorization, or certification to the Commission.

(3) Neural data collected before the coming into force of the data protection provisions in Part 5 may continue to be processed for: (a) the same purpose for which it was originally collected, provided that: (i) the original collection was lawful under the laws in force at the time; (ii) the data controller implements the security requirements specified in section 61 within six months of the coming into force of that section; and (iii) the data controller provides notice to the individuals concerned about the continued processing and their rights under this Act; or (b) research or statistical purposes, if the data is anonymized in accordance with the requirements of section 65 within six months of the coming into force of that section.

(4) The Commission may extend the transitional period for specific categories of neurotechnology or neural data if: (a) there are technical or practical challenges in bringing the neurotechnology or data processing into compliance within the standard transitional period; (b) the neurotechnology provides significant benefits to users; and (c) there are no known serious safety concerns or risks to neurocognitive rights.

(5) The Minister shall establish a Transition Support Office to: (a) provide guidance and assistance to organizations in transitioning to compliance with this Act; (b) develop tools, templates, and resources to facilitate compliance; (c) offer training and educational programs; and (d) respond to inquiries and requests for clarification.

Regulatory Authority

160. (1) The Governor in Council may make regulations for carrying out the purposes and provisions of this Act, including regulations: (a) prescribing anything that by this Act is to be prescribed; (b) defining terms for the purposes of this Act; (c) establishing additional requirements or restrictions related to neurocognitive rights; (d) specifying detailed requirements for each risk category of neurotechnology; (e) establishing procedures for classification, registration, authorization, and certification of neurotechnology; (f) prescribing technical standards and specifications for neurotechnology; (g) establishing detailed requirements for neurocognitive data protection; (h) prescribing procedures for the Neurocognitive Rights Tribunal; (i) establishing administrative monetary penalties for violations of this Act; (j) prescribing requirements for education, training, and certification of professionals; (k) establishing reporting and documentation requirements; and (l) generally, providing for any other matter necessary for the administration of this Act.

(2) The Commission may, with the approval of the Governor in Council, make regulations: (a) prescribing technical specifications and standards for neurotechnology; (b) establishing detailed procedures for the regulatory processes under Part 3; (c) prescribing formats and content for notifications, applications, and reports; (d) establishing fees for services provided by the Commission; (e) prescribing security standards for neural data and neurotechnology; and (f) establishing detailed requirements for informed consent processes.

(3) Before making regulations under this Act, the Governor in Council or the Commission, as the case may be, shall: (a) publish the proposed regulations in the Canada Gazette for a period of public comment of at least 60 days; (b) consider the comments received during the public comment period; (c) consult with relevant stakeholders; and (d) conduct an impact analysis of the proposed regulations.

(4) Regulations made under this Act may incorporate by reference standards, guidelines, or similar documents, as they exist on a particular date or as amended from time to time, with such adaptations as the circumstances require.

Budgetary Provisions

161. (1) There is established in the accounts of Canada an account to be known as the Neurocognitive Rights and Neurotechnology Account.

(2) There shall be credited to the Account: (a) all amounts appropriated by Parliament for the purposes of the Account; (b) fees collected by the Commission; (c) administrative monetary penalties imposed under this Act; (d) amounts received for services provided by the Commission or the Tribunal; and (e) any other amounts required by this Act to be credited to the Account.

(3) Subject to the other provisions of this Act, amounts may be paid out of the Account for: (a) the administration and enforcement of this Act; (b) grants and contributions made for purposes related to this Act; (c) the costs of the Commission and the Tribunal; and (d) any other expenditure authorized by this Act.

(4) The Minister shall, in consultation with other relevant ministers, prepare an annual budget for the implementation of this Act, which shall be submitted as part of the Main Estimates.

(5) The Minister shall report annually to Parliament on the expenditures and financial operations related to this Act.

Implementation Support for Organizations

162. (1) The Minister shall establish a Neurocognitive Rights and Neurotechnology Compliance Support Program to assist organizations in implementing the requirements of this Act.

(2) The Program shall provide: (a) guidance documents, toolkits, and templates; (b) training and educational resources; (c) technical assistance and consultation; (d) financial support for compliance activities; and (e) recognition for exemplary practices and innovation in compliance.

(3) The Program shall give particular attention to the needs of: (a) small and medium-sized enterprises; (b) not-for-profit organizations; (c) healthcare providers and institutions; (d) educational institutions; and (e) community-based organizations.

(4) The Minister shall establish a Compliance Resource Center to: (a) develop and disseminate compliance resources; (b) provide expert consultation on complex compliance issues; (c) facilitate peer learning and exchange of best practices; and (d) track emerging challenges and develop targeted resources.

Performance Measurement and Reporting

163. (1) The Minister shall establish a comprehensive performance measurement framework for this Act, including: (a) clear objectives and expected outcomes; (b) indicators and metrics for assessing performance; (c) data collection and analysis methods; (d) regular evaluation processes; and (e) mechanisms for reporting on results and using performance information to improve implementation.

(2) The performance measurement framework shall address: (a) the effectiveness of neurocognitive rights protection; (b) the efficiency and effectiveness of the regulatory system; (c) the performance of the Commission and the Tribunal; (d) the impacts on innovation and development of neurotechnology; (e) progress on education and awareness; and (f) achievements in promoting accessibility and equity.

(3) The Minister shall submit an annual report to Parliament on the implementation and performance of this Act, including: (a) major activities and accomplishments; (b) performance data and analysis; (c) challenges and issues encountered; (d) planned improvements and adjustments; and (e) resource utilization and requirements.

(4) The Minister shall commission an independent comprehensive evaluation of this Act every five years, with the first evaluation to be completed within five years after the full implementation of the Act.

International Cooperation

164. (1) The Minister, in collaboration with the Minister of Foreign Affairs, shall promote international cooperation on neurocognitive rights protection and neurotechnology regulation, including: (a) participation in international forums and initiatives; (b) negotiation of bilateral and multilateral agreements; (c) harmonization of standards and approaches, where appropriate; (d) information sharing and collaboration with counterpart agencies in other jurisdictions; and (e) capacity building and technical assistance for developing countries.

(2) The Minister shall establish a strategy for positioning Canada as a global leader in ethical neurotechnology governance, including: (a) promotion of Canadian approaches and standards in international contexts; (b) engagement with international standard-setting bodies; (c) leadership in developing international frameworks and agreements; and (d) showcasing Canadian innovations and best practices.

(3) The Commission shall be authorized to enter into agreements with counterpart regulatory authorities in other jurisdictions regarding: (a) mutual recognition of conformity assessments; (b) coordination of regulatory activities; (c) information sharing and joint investigations; and (d) collaboration on emerging issues and challenges.

(4) The Minister shall report to Parliament annually on international activities and developments related to neurocognitive rights and neurotechnology governance.

Periodic Review and Updates

165. (1) The Minister shall conduct a comprehensive review of this Act and its administration and operation: (a) within five years after the full implementation of this Act; and (b) every five years thereafter.

(2) The review shall include: (a) assessment of the effectiveness of the Act in protecting neurocognitive rights and regulating neurotechnology; (b) evaluation of the performance of the Commission, the Tribunal, and other implementing entities; (c) consideration of scientific and technological developments and their implications for the Act; (d) examination of emerging issues and challenges; (e) review of international developments and best practices; and (f) consultation with a wide range of stakeholders and the public.

(3) Following each review, the Minister shall submit a report to Parliament that includes: (a) findings and conclusions from the review; (b) identified issues and areas for improvement; (c) recommendations for amendments to the Act or changes in its implementation; and (d) a response plan addressing the findings and recommendations.

(4) The Minister shall establish a continuous monitoring mechanism to track scientific, technological, social, and legal developments relevant to this Act, in order to identify the need for updates or adjustments between formal reviews.

Interagency Coordination

166. (1) The Minister shall establish a Neurotechnology Regulatory Coordination Council to ensure coherent and complementary approaches among federal regulatory bodies with responsibilities related to neurotechnology.

(2) The Council shall include representatives from: (a) the Commission; (b) Health Canada; (c) the Office of the Privacy Commissioner; (d) the Canadian Human Rights Commission; (e) the Canadian Radio-television and Telecommunications Commission; (f) the Competition Bureau; (g) the Office of the Superintendent of Financial Institutions; (h) the Canadian Security Intelligence Service; (i) the Royal Canadian Mounted Police; and (j) any other federal agency with relevant regulatory responsibilities.

(3) The Council shall: (a) identify areas of potential regulatory overlap, gaps, or conflicts; (b) develop coordinated approaches to emerging issues; (c) establish mechanisms for information sharing and collaboration; (d) coordinate enforcement activities where appropriate; and (e) develop joint guidance where multiple regulatory frameworks apply.

(4) The Council shall meet at least quarterly and shall report annually to the Minister on its activities and recommendations.

Preemption and Federalism

167. (1) This Act does not affect the jurisdiction of provincial and territorial governments in areas of their exclusive jurisdiction, and is to be interpreted and applied in a manner that respects the division of powers established by the Constitution Acts, 1867 to 1982.

(2) Where a provision of this Act addresses a matter that falls within federal jurisdiction, that provision operates to the exclusion of provincial or territorial law to the extent of any inconsistency.

(3) Where a provision of this Act addresses a matter that falls within an area of concurrent jurisdiction, that provision is paramount to provincial or territorial law to the extent of any inconsistency, but only if compliance with both laws is impossible.

(4) Nothing in this Act prevents a province or territory from enacting legislation that: (a) provides additional protections for neurocognitive rights, provided such legislation does not conflict with this Act; (b) establishes complementary regulatory frameworks for neurotechnology in areas of provincial or territorial jurisdiction; or (c) addresses aspects of neurocognitive rights or neurotechnology not covered by this Act.

(5) The Minister shall work with provincial and territorial governments to promote harmonized approaches to neurocognitive rights protection and neurotechnology regulation across Canada.

Non-Derogation of Rights

168. (1) Nothing in this Act shall be construed so as to abrogate or derogate from: (a) any rights of the Aboriginal peoples of Canada recognized and affirmed by section 35 of the Constitution Act, 1982; (b) any rights or freedoms guaranteed by the Canadian Charter of Rights and Freedoms; (c) any rights protected by the Canadian Human Rights Act or provincial or territorial human rights legislation; or (d) any other rights established by law.

(2) The neurocognitive rights established in this Act are in addition to, and not in substitution for, any other rights that exist in Canada.

Consequential Amendments

169. The Privacy Act is amended by adding the following after section 76:

"**Neural Data Protection**

77. For greater certainty, neural data, as defined in the Canadian Neurocognitive Rights and Advanced Neurotechnology Act, is personal information for the purposes of this Act and is subject to the additional protections specified in that Act."

170. The Personal Information Protection and Electronic Documents Act is amended by adding the following after section 30:

"**Neural Data Protection**

30.1 For greater certainty, neural data, as defined in the Canadian Neurocognitive Rights and Advanced Neurotechnology Act, is personal information for the purposes of this Act and is subject to the additional protections specified in that Act."

Severability

171. If any provision of this Act or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.

Coming into Force

172. The provisions of this Act come into force on a day or days to be fixed by order of the Governor in Council, in accordance with the implementation timeline established in section 158.

SCHEDULES

SCHEDULE 1

(Section 15)

INFORMATION TO BE PROVIDED FOR INFORMED CONSENT FOR NEUROTECHNOLOGY

1. **General Information About the Neurotechnology** (a) Name and type of neurotechnology (b) Purpose and intended use of the neurotechnology (c) Manufacturer or provider information (d) Regulatory status and classification under this Act (e) General description of how the neurotechnology works

2. **Specific Functionality and Operation** (continued) (f) Integration with other technologies or systems (g) Accessibility features and limitations (h) Customization options and settings (i) Methods for stopping or interrupting operation
3. **Neural Data Collection and Processing** (a) Types of neural data collected (b) Sampling rate and resolution of data collection (c) Processing methods applied to raw neural data (d) Algorithms or models used for analysis or interpretation (e) Inferences or interpretations made from neural data (f) Accuracy, reliability, and limitations of interpretations (g) Storage duration and location of neural data (h) Security measures for protecting neural data (i) Third parties who may access the neural data (j) Secondary uses of neural data, if any
4. **Potential Benefits** (a) Expected outcomes and benefits for the individual (b) Evidence supporting claimed benefits (c) Likelihood and timeline for experiencing benefits (d) Factors that may influence effectiveness (e) Limitations to expected benefits (f) Comparison with alternative approaches or treatments
5. **Potential Risks and Side Effects** (a) Common side effects (b) Rare but serious risks (c) Long-term risks and uncertainties (d) Psychological or cognitive effects (e) Potential for dependence or habituation (f) Potential impacts on identity or sense of self (g) Environmental or contextual risks (h) Contraindications and warning signs (i) Interactions with medications, substances, or other technologies (j) Potential for malfunction or failure
6. **Psychological or Behavioral Influence** (a) Potential for direct or indirect influence on thoughts, emotions, or behavior (b) Nature and extent of any potential influence (c) Mechanisms of influence (d) Persistence of effects after discontinuation (e) Measures to mitigate unwanted influence
7. **Privacy and Data Protection** (a) Privacy policy and terms of service (b) Types of data collected beyond neural data (c) Purposes for which data will be used (d) Parties with whom data may be shared (e) Data retention policies (f) Rights regarding data access, correction, and deletion (g) Process for exercising data rights (h) Jurisdiction and applicable law for data protection (i) Potential for reidentification of anonymized data (j) Data breach notification procedures
8. **Rights and Responsibilities** (a) Right to withdraw consent at any time (b) Procedure for withdrawing consent (c) Consequences of withdrawing consent (d) Responsibilities of the user for safe operation (e) Support and assistance available (f) Complaint and dispute resolution processes (g) Liability and compensation provisions (h) Warranty information (i) Updates and changes to terms (j) Process for receiving notices about changes
9. **Additional Information for Specific Categories** (a) For therapeutic neurotechnology: (i) Regulatory approval status (ii) Treatment alternatives (iii) What happens if treatment is declined (iv) Follow-up and monitoring requirements (v) Coverage and cost information (b) For research neurotechnology: (i) Research protocol overview (ii) Institutional review board or research ethics board approval (iii) Compensation for participation (iv) Rights as a research participant (v) Process for withdrawing from the research (c) For educational neurotechnology: (i) Learning objectives and pedagogical approach (ii) Integration with curriculum (iii)

Assessment and evaluation practices (iv) Parental access to data (v) Alternatives for students who opt out (d) For workplace neurotechnology: (i) Purpose and scope of workplace use (ii) Impact on job evaluation or performance assessment (iii) Employee rights regarding collected data (iv) Alternatives for employees who opt out (v) Collective agreement provisions, if applicable

SCHEDULE 2

(Sections 42 and 90)

NEUROTECHNOLOGY IMPACT ASSESSMENT FRAMEWORK

PART A - GENERAL INFORMATION

1. **Description of the Neurotechnology** (a) Name and version (b) Provider information (c) General function and purpose (d) Target user population (e) Intended use context (f) Development history and status (g) Regulatory classification

2. **Scope of Assessment** (a) Parameters and boundaries of the assessment (b) Time frame considered (c) Geographical scope (d) Populations included (e) Use scenarios evaluated (f) Methodology overview

PART B - NEUROCOGNITIVE RIGHTS IMPACT ASSESSMENT

3. **Impact on Cognitive Liberty** (a) Potential restrictions on cognitive autonomy (b) Measures to preserve user control over cognitive processes (c) Freedom to use or decline use (d) User control over data collection and processing (e) Potential for coercion or undue influence (f) Safeguards for voluntary use

4. **Impact on Mental Privacy** (a) Types and sensitivity of neural data collected (b) Depth of access to cognitive processes (c) Potential for revealing unexpressed thoughts or emotions (d) Privacy by design features (e) Data minimization approaches (f) Anonymization and de-identification methods (g) Privacy risk mitigation measures

5. **Impact on Mental Integrity** (a) Potential for harm to brain function (b) Effects on cognitive processes (c) Neuroplasticity considerations (d) Safety features and protections (e) Monitoring for adverse effects (f) Reversibility of effects

6. **Impact on Psychological Continuity** (a) Potential effects on memory, personality, or identity (b) Duration and persistence of effects (c) User awareness of changes (d) Gradual vs. abrupt changes (e) Measures to preserve psychological continuity (f) Recovery or reversal options

7. **Impact on Cognitive Equality and Non-Discrimination** (a) Potential for creating or exacerbating cognitive disparities (b) Accessibility across diverse populations (c) Differential impacts on various groups (d) Algorithmic bias assessment (e) Testing across diverse populations (f) Measures to promote inclusive design and use

8. **Impact on Cognitive Self-Determination** (a) User control over neurotechnology parameters (b) Information provided for decision-making (c) Consent processes and mechanisms (d) Options for customization and personalization (e) User autonomy in determining enhancement goals (f) Supports for informed choice

9. **Protection from Neurotechnology-Enabled Coercion** (a) Potential for manipulation or undue influence (b) Transparency about psychological effects (c) Measures to prevent addictive use patterns (d) Safeguards against unauthorized use (e) Detection of coercive applications (f) User control mechanisms

PART C - TECHNICAL AND SECURITY ASSESSMENT

10. **Neural Data Management** (a) Data collection processes (b) Data storage methods and location (c) Data retention periods (d) Data sharing practices (e) Data deletion procedures (f) Data portability options (g) Compliance with data protection standards

11. **Security Assessment** (a) Threat model and risk assessment (b) Authentication and access controls (c) Encryption and data protection measures (d) Vulnerability testing results (e) Security incident response plan (f) Update and patch management (g) Third-party security assessments (h) Physical security considerations

12. **Technical Reliability and Safety** (a) Hardware reliability assessment (b) Software reliability assessment (c) Accuracy and precision measurements (d) Performance across different conditions (e) Failure modes and effects analysis (f) Fault tolerance mechanisms (g) Emergency shutdown procedures (h) Maintenance and calibration requirements

PART D - INDIVIDUAL AND SOCIETAL IMPACT ASSESSMENT

13. **Impact on Individuals** (a) Benefits to users (b) Risks to users (c) Impact on user agency and autonomy (d) Psychological and emotional effects (e) Impacts on relationships and social interactions (f) Long-term effects on development and functioning (g) Quality of life considerations

14. **Impact on Vulnerable Populations** (a) Effects on children and youth (b) Effects on elderly individuals (c) Effects on persons with disabilities (d) Effects on persons with mental health conditions (e) Effects on other vulnerable groups (f) Specialized safeguards for vulnerable populations (g) Equitable access considerations

15. **Social and Ethical Implications** (a) Potential changes to social norms and practices (b) Implications for social equality and justice (c) Cultural and religious considerations (d) Economic implications and access disparities (e) Potential dual-use concerns (f) Alignment with human rights frameworks (g) Intergenerational implications

16. **Governance and Oversight Mechanisms** (a) Internal governance structures (b) External oversight arrangements (c) Stakeholder engagement processes (d) Transparency and accountability measures (e) Complaint and redress mechanisms (f) Ongoing monitoring and evaluation (g) Adaptive governance approaches

PART E - RISK MITIGATION AND MANAGEMENT

17. **Risk Mitigation Measures** (a) Identified risks and potential harms (b) Probability and severity assessments (c) Mitigation strategies for each risk (d) Residual risks after mitigation (e) Plan for addressing residual risks (f) Monitoring and reassessment procedures (g) Responsibility assignments for mitigation

18. **Informed Consent Implementation** (a) Consent materials and processes (b) Comprehension assessment methods (c) Approaches for complex or technical information (d) Accommodations for diverse users (e) Ongoing consent and withdrawal mechanisms (f) Documentation and verification procedures (g) Specialized consent procedures for vulnerable users

19. **Training and Support** (a) User training requirements and resources (b) Professional training for implementers (c) Technical support provisions (d) Resources for troubleshooting (e) Updates on new information or risks (f) Community education and awareness (g) Specialized support for vulnerable users

20. **Monitoring and Evaluation Plan** (a) Key performance indicators (b) Monitoring mechanisms and schedule (c) User feedback collection methods (d) Adverse event reporting system (e) Periodic reassessment process (f) Criteria for intervention or discontinuation (g) Continuous improvement approach

SCHEDULE 3

(Section 149)

NEUROTECHNOLOGY AFFORDABILITY EVALUATION FRAMEWORK

1. **Acquisition Costs** (a) Purchase price (b) Leasing or subscription options (c) Required accessories or peripherals (d) Installation costs (e) Comparison with similar technologies (f) Price trends and projections

2. **Operational Costs** (a) Consumable supplies (b) Energy consumption (c) Maintenance requirements (d) Upgrades and updates (e) Technical support fees (f) Training expenses (g) Insurance costs

3. **Lifecycle Considerations** (a) Expected lifespan (b) Depreciation rate (c) Replacement schedule (d) End-of-life disposal costs (e) Scalability and expansion options (f) Backward and forward compatibility

4. **Financial Accessibility** (a) Affordability for different income groups (b) Financing options (c) Insurance coverage (d) Public funding or subsidies (e) Tax implications (f) Charitable programs (g) Second-hand market

5. **Value Assessment** (a) Cost-effectiveness analysis (b) Quality-adjusted life year calculations (c) Alternative technology comparisons (d) Indirect economic benefits (e) Productivity impacts (f) Healthcare system cost offsets (g) Societal return on investment

6. **Equity Considerations** (a) Distribution of benefits across socioeconomic groups (b) Geographic accessibility (c) Cultural and linguistic accessibility (d) Disability accommodations (e) Gender-based analysis (f) Indigenous perspectives (g) Intergenerational equity

7. **Sustainability Factors** (a) Environmental impact (b) Resource efficiency (c) Long-term funding models (d) Market competition effects (e) Supply chain reliability (f) Workforce implications (g) System integration costs

8. **Cost Reduction Strategies** (a) Bulk purchasing options (b) Reference pricing mechanisms (c) Value-based procurement (d) Risk-sharing arrangements (e)

Technology transfer opportunities (f) Open source or open hardware approaches (g) Local manufacturing potential (h) Regulatory pathway optimization

SCHEDULE 4

(Section 163)

PERFORMANCE MEASUREMENT FRAMEWORK

PART A - NEUROCOGNITIVE RIGHTS PROTECTION

1. **Awareness and Understanding** (a) Public awareness of neurocognitive rights (b) Professional understanding of obligations (c) Organizational policy development (d) Educational program reach and effectiveness (e) Media coverage and discourse
2. **Implementation and Compliance** (a) Integration into organizational practices (b) Compliance rates across sectors (c) Reported violations by type (d) Remediation and corrective actions (e) Best practice adoption rates
3. **Enforcement Effectiveness** (a) Complaint resolution rates (b) Investigation timeliness (c) Enforcement action outcomes (d) Deterrent effects (e) Recidivism rates
4. **Individual Experience** (a) Perceived protection of rights (b) Confidence in exercising rights (c) Satisfaction with redress mechanisms (d) Reported barriers to rights protection (e) Effects on technology acceptance and use

PART B - REGULATORY SYSTEM PERFORMANCE

5. **Regulatory Process Efficiency** (a) Registration and certification timelines (b) Consistency of decisions (c) Administrative burden measures (d) Fee structure appropriateness (e) Resource utilization metrics
6. **Regulatory Outcomes** (a) Safety incidents by risk category (b) Data breach occurrences (c) Compliance with post-market requirements (d) Recall rates and timeliness (e) Quality of regulated products and services
7. **Innovation Support** (a) Time to market for new technologies (b) Regulatory predictability measures (c) Guidance utilization and effectiveness (d) Support program participation (e) International regulatory alignment
8. **Institutional Performance** (a) Commission operational metrics (b) Tribunal case management efficiency (c) Stakeholder satisfaction measures (d) Transparency and accountability indicators (e) Resource allocation effectiveness

PART C - SOCIETAL OUTCOMES

9. **Neurotechnology Development** (a) Research and development activity (b) Investment trends (c) Patent and intellectual property metrics (d) Innovation ecosystem indicators (e) International competitiveness measures
10. **Access and Adoption** (a) Availability of beneficial neurotechnology (b) Adoption rates across populations (c) Geographic distribution of access (d) Affordability metrics (e) Barriers to access and use

11. **Health and Wellbeing Impacts** (a) Health outcomes for users (b) Quality of life measures (c) Functional improvement indicators (d) Side effects and adverse outcomes (e) Healthcare system impacts

12. **Societal Impact** (a) Public trust in neurotechnology (b) Social acceptance indicators (c) Ethical discourse quality (d) Equity and inclusion measures (e) Long-term societal implications monitoring

PART D - INTERNATIONAL LEADERSHIP

13. **Global Influence** (a) Adoption of Canadian approaches by other jurisdictions (b) Participation in international standard-setting (c) International collaboration metrics (d) Global perception of Canadian leadership (e) Export of Canadian expertise and technology

14. **International Cooperation** (a) Agreement negotiation and implementation (b) Harmonization progress (c) Information sharing effectiveness (d) Joint enforcement actions (e) Capacity building activities

PART E - IMPLEMENTATION PROCESS

15. **Implementation Progress** (a) Milestone achievement (b) Timeline adherence (c) Resource allocation and utilization (d) Stakeholder engagement effectiveness (e) Implementation challenges and responses

16. **Continuous Improvement** (a) Lesson identification and application (b) Policy and procedure updates (c) Stakeholder feedback incorporation (d) Adaptation to emerging issues (e) Innovation in implementation approaches

São Paulo, Brazil

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3:45am