

TECHETHOS

FUTURE ○ TECHNOLOGY ○ ETHICS

Annex 9.6 National Legal Case Study: Neurotechnologies in the United States of America (USA)

D4.2 Comparative analysis of national legal case studies

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D4.2 National legal case studies: Annex 9.6 - Neurotechnologies in United States of America (USA)

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The TechEthos Project

TechEthos is an EU-funded project that deals with the ethics of the new and emerging technologies anticipated to have high socio-economic impact. The project involves ten scientific partners and six science engagement organisations and runs from January 2021 to the end of 2023.

TechEthos aims to facilitate “ethics by design”, namely, to bring ethical and societal values into the design and development of new and emerging technologies from the very beginning of the process. The project will produce operational ethics guidelines for three technologies for users such as researchers, research ethics committees and policy makers. To reconcile the needs of research and innovation and the concerns of society, the project will explore the awareness, acceptance and aspirations of academia, industry and the general public alike and reflect them in the guidelines.

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Definitions and abbreviations

Table 1: List of Definitions

Term	Explanation
Neurotechnology	Devices and procedures used to access, monitor, investigate, manipulate, and/or emulate the structure and function of the neural systems of natural persons. ¹

Table 2: List of Abbreviations

Term	Explanation
ACHR	American Convention on Human Rights
ADA	Americans with Disabilities Act
ALI	American Law Institute
BCI	Brain computer interface
BIPA	Biometric Information Privacy Act
BMI	Brain machine interface
BRAIN	Brain Research Through Advancing Innovative Neurotechnologies
CAT	Convention against Torture and Other Cruel, Inhuman or Degrading Treatment

¹ OECD. (2019) *Recommendation of the Council on Responsible Innovation in Neurotechnology*, OECD/LEGAL/0457.

CCPA	California Consumer Privacy Act
CED	Convention for the Protection of All Persons from Enforced Disappearance
CEDAW	Convention on the Elimination of All Forms of Racial Discrimination
COPPA	Children's Online Privacy Protection Act
CRC	Convention on the Rights of the Child
CRDH	Centre for Devices and Radiological Health
CRPD	Convention on the Rights of Persons with Disabilities
CST	Competency to stand for trial
DARPA	Defense Advanced Research Projects Agency
DBS	Deep brain stimulation
DoA	Description of Action
EEG	Electroencephalograph
EU	European Union
FD&C	Federal Food, Drug and Cosmetic Act
FDA	Food and Drug Administration
FERPA	Family Educational Rights and Privacy Act
fMRI	Functional magnetic resonance imaging
FTC	Federal Trade Commission
GINA	Genetic Information Nondiscrimination Act
HIPAA	Health Insurance Portability and Accountability Act
HSS	Department of Health and Human Services
IACtHR	Inter-American Court of Human Rights
ICCPR	International Covenant on Civil and Political Rights (ICCPR)
ICERD	International Convention on the Elimination of All Forms of Racial Discrimination

ICESCR	International Covenant on Economic, Social and Cultural Rights
ICRMW	Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families
IDE	Investigational Device Exemption
MPC	Model Penal Code
MRI	Magnetic resonance imaging
N ³	Next-Generation Nonsurgical Neurotechnology
NESD	Neural Engineering System Design
NIH	National Institute of Health
NSF	National Science Foundation
OAS	Organisation of American States
PC	Project Coordinator
PET	Positron Emissions Topography
qEEG	Quantitative electroencephalography
R&D	Research and Development
RUD	Reservation, understanding and declaration
SPECT	Single photon emissions computerized tomography
UAV	Unmanned aerial vehicle
UCC	Uniform Commercial Code
USA	United States of America
WP	Work Package
XR	Digital extended reality

Abstract

The objective of this study is to review the current state of the law on and legal responses to neurotechnologies in the United States of America (USA), as evidenced in legislation (including, where applicable, the existence of proposals to create new law or adapt existing law in response to those neurotechnological developments), case law, regulation and policy. It focuses on those issues affecting and/or contributing to fundamental human rights and freedoms, socio-economic inequalities, and stimulation of innovation within the domains of human rights law, privacy and data protection law, the use of neurotechnologies in criminal and civil law proceedings, and liability for harms under tort, contract and criminal law. The study sets out the extent to which these legal domains already regulate neurotechnologies, before highlighting the gaps and challenges in the existing legal frameworks.

A summary overview of the main findings and legal issues surrounding neurotechnologies in the US is provided in Section 4.1.3 of the TechEthos Deliverable 4.2 summary comparative overview, to which this individual national legal case study report is annexed. In conjunction with the other national legal case studies on neurotechnologies and the other two technology families, namely climate engineering and digital extended reality (XR) technologies, this report provides the basis for the various neurotechnology-specific and cross-cutting regulatory challenges outlined in the summary comparative overview. This report is primarily aimed at informing relevant stakeholders, including US policymakers and regulators, of the main regulatory gaps and challenges applicable to neurotechnologies in the US.



1. Introduction

Neurotechnologies present many significant legal issues that impact socio-economic equality and fundamental rights in the United States of America (USA). This study provides an overview of those legal issues and challenges.

This study analyses relevant laws and policies from the U.S. legal system in relation to neurotechnologies. There is no comprehensive or dedicated legislation in the U.S. governing this technology family, but many elements of existing laws and policies would apply to the use of such technologies. For the purpose of the TechEthos project and this national legal case study, we have used the following definition for neurotechnologies:

Neurotechnologies refers to devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons.²

The definition for this technology family is based on the TechEthos factsheets, as developed by work package 1 team members as part of the initial horizon scan.³ For more information about the three TechEthos technology families and their innovation ecosystems, visit: <https://www.techethos.eu/resources/>.

1.1 Purpose of the U.S. legal case study

The objective of this study is to review the current state of the law on and legal responses to neurotechnologies in the U.S., as evidenced in policy, legislation, case law and regulation. Whilst there are no specific laws on neurotechnologies in the U.S., many existing laws (including human rights law, privacy and data protection law, use in criminal, civil and evidence law) are relevant and likely to apply to the use of such technologies, including any harms resulting from them (covering tort, contract and criminal law in relation to liability for harms). Particularly relevant legal developments in the U.S. include the existence of case law on the use and admissibility in legal proceedings of neuroscientific evidence obtained through the use of neurotechnologies, as well as the ongoing debate in legal academic discourse around whether the enactment by various state legislatures of comprehensive data privacy laws may lead to similar legislative developments at the federal level, with potential implications for the regulation of brain and other neural data. At the policy level, various federal agencies are involved in the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative, which seeks

² OECD. (2019) *Recommendation of the Council on Responsible Innovation in Neurotechnology*, OECD/LEGAL/0457.

³ TechEthos (2022) *Technology Factsheet: Climate Engineering / TechEthos*, [Online]. Available at: https://www.techethos.eu/wp-content/uploads/2022/05/TechEthos_factsheet_Climate-Engineering_website.pdf; TechEthos (2022) *Technology Factsheet: Neurotechnologies / TechEthos*, [Online]. Available at: https://www.techethos.eu/wp-content/uploads/2022/05/TechEthos_factsheet_Neurotechnologies_website.pdf; TechEthos (2022) *Technology Factsheet: Digital Extended Reality / TechEthos*, [Online]. Available at: https://www.techethos.eu/wp-content/uploads/2022/05/TechEthos_factsheet_Digital-Extended-Reality_website.pdf.

to advance neuroscientific understanding by developing and applying neurotechnologies for various research purposes.⁴

In addition to the reasons mentioned above, the selection of the U.S. as a national legal case study is intended to complement the other national legal case studies on neurotechnologies, specifically, and the other technology families, more generally. For the purposes of this deliverable, at least one common law jurisdiction and at least one civil law jurisdiction was selected for each of the three technologies families, to ensure a full range of legal frameworks would inform the comparative analysis. As an extensive study of EU law (and international law) in relation to the three technology families has been conducted for Deliverable 4.1, it was decided that it would be beneficial to represent both EU and non-EU jurisdictions in the national legal case studies, in order to explore both how EU law is operationalised at a national level, as well as how non-EU frameworks differ from the approaches of EU Member States.

This study was prepared through desk research, using legal academic literature and legislation tracker databases, such as the Library of Congress⁵ and Open States.⁶ It is part of a series of national legal case studies prepared in the TechEthos project covering three technology families, namely: climate engineering, neurotechnologies, and digital extended reality (XR). A complementary report covers the international and European Union law dimensions of the three technology families (D4.1 of the TechEthos project).⁷ The following table provides an overview of the nine country studies conducted as part of the *Analysis of national legal case studies* (D4.2 of the TechEthos project):

Table 3: Overview of nine national legal case studies (TechEthos WP4)

Climate Engineering	Neurotechnologies	Digital Extended Reality
Australia	Germany	France
Austria	Ireland	Italy
United Kingdom	United States	United Kingdom

1.2 Structure of the case study

Section II explores the existing and proposed laws and policies in the U.S. that specifically address neurotechnologies. **Section III** explores the legal implications of neurotechnologies in relation to four specific legal domains, specifically human rights law (Section 3.1), privacy and data protection law (Section 3.2), use in criminal and civil legal proceedings (Section 3.3), and liability for harms (Section 3.4). **Section IV** provides an overview of the gaps and challenges in relation to the regulation of neurotechnologies. **Section V** concludes the case study, followed by a reference list at the end.

⁴ Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Working Group Report to the Advisory Committee to the Director, NIH. (2014) *Brain 2025 – A Scientific Vision*, p.5-6. Available at: https://braininitiative.nih.gov/sites/default/files/pdfs/brain2025_508c.pdf

⁵ Available at: <https://www.congress.gov/>

⁶ Available at: <https://openstates.org/>

⁷ Santiago, N., et al. (2022). TechEthos D4.1: *Analysis of international and EU law and policy*. TechEthos Project Deliverable. Available at: www.techethos.eu.

1.3 Scope and Limitations

This national legal case study was prepared as part of TechEthos Work Package 4 on policy, legal and regulatory analysis of the three identified families of technologies, namely climate engineering technologies, neurotechnologies and digital extended reality (XR) technologies. The scope of this study is demarcated by the project task's workplan. The U.S. legal system is comprised of both federal law and state law of fifty states, as well as separate but overlapping federal and state court systems. It is thus beyond the scope defined in the workplan to conduct a comprehensive study of all U.S. law and case law with relevance to neurotechnologies. Instead, the aim of this national legal case study is to provide a high-level overview of the legal implications related to the development and use of neurotechnologies, focusing primarily on federal law and referring to selected examples of state law in order to highlight significant and relevant differences. The analysis is structured around four legal frameworks, namely: human rights law, privacy and data protection law, use in criminal and civil law proceedings, and liability for harms. This defined scope allows for a comparative analysis with the other national legal case studies on neurotechnologies in Ireland and Germany, as well as between cross-cutting legal frameworks, such as human rights law, which are applicable to at least two of the three technology families analysed.

1.4 Overview of the U.S. legal system

The U.S. is a federal republic comprised of fifty states plus the District of Columbia, each of which has its own codified Constitution based on the overarching U.S. Constitution. As part of the Anglosphere, its legal system is based on the common law tradition, meaning the ratio decidendi of contemporary and higher court judgements create authoritative precedents which are binding on the decisions of subsequent and lower courts through the doctrine of stare decisis. Such precedents can be traced back to the English common law.⁸ The exception to this is the state of Louisiana, which has a civil law character as a legacy of its colonial past under the jurisdiction of two civil law jurisdictions in Spain and France.⁹

The U.S. Constitution, domestic laws and international treaties are “the supreme Law of the Land”¹⁰ and pre-empt state law, including state constitutions, with the U.S. Constitution also establishing the framework for and power-sharing arrangement between the three branches of government, namely: the legislature, the executive and the judiciary.

The powers of the legislative branch are “vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.”¹¹ The legislative model thus established is bicameral, with the United States Congress, the federal legislative body, being comprised of an upper body, the Senate, consisting of 100 senators, 2 for each state, and a lower body, the House of Representatives, consisting of 435 elected members as “divided among the 50 states in proportion to their total population.”¹²

The powers of the executive branch are “vested in a President of the United States of America”, who is elected as head of state alongside a Vice President to serve office for a four-year term,¹³ which can be

⁸ Pope, H. (1910) ‘The English Common Law in the United States’, *Harvard Law Review*, Vol.24:1, pp.6-30. DOI: <https://doi.org/10.2307/1324643>

⁹ See generally, Ward, R.K. (1997) ‘The French Language in Louisiana Law and Legal Education: A Requiem’, *Louisiana Law Review*, Vol.57:4, pp.1283-1324. Available at: <https://digitalcommons.law.lsu.edu/lalrev/vol57/iss4/7>

¹⁰ U.S. Const. Art.VI §2.

¹¹ U.S. Const. Art.I §1.

¹² The White House. *The Legislative Branch* / [Online]. Available at: <https://www.whitehouse.gov/about-the-white-house/our-government/the-legislative-branch/>

¹³ U.S. Const. Art. II §1.



renewed for a maximum of one extra term.¹⁴ Eligibility requirements for the presidency include being “a natural born Citizen, or a Citizen of the United States”, at least thirty-five years old and a United States resident for fourteen years.¹⁵ The explicit powers of the President include the “Power, by and with the Advice and Consent of the Senate, to make Treaties”, to “appoint Ambassadors, other public Ministers and Consuls, Judges of the Supreme Court, and all other Officers of the United States”, and to “Grant Reprieves and Pardons for Offences against the United States, except in Cases of Impeachment.”¹⁶

The powers of the judicial branch are “vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish.”¹⁷ Federal courts are courts of limited jurisdiction, meaning they may only hear the types of “Cases” and “Controversies” listed in the Constitution.¹⁸ Although not provided for in the text of the U.S. Constitution itself, the Supreme Court and other federal courts have the power of judicial review, which means that legislative and executive acts can be struck down if found to be in violation of the U.S. Constitution.¹⁹

The U.S. Constitution:

The U.S. legal system is comprised of a network of both federal and state laws and institutions, at the apex of which is the codified U.S. Constitution. This foundational text inaugurates the U.S. Federal Government, the powers of which, in accordance with the separation of powers doctrine, are divided between three separate branches: legislative powers vested in Congress (the House of Representatives and the Senate),²⁰ executive power granted to the President,²¹ and judicial power conferred to a singular Supreme Court and any such “inferior Courts as the Congress may from time to time ordain and establish.”²² The U.S. Constitution also establishes an elaborate system of checks and balances throughout the U.S. government in order to avoid the concentration of power in any one branch. By way of example, the President as the head of the executive branch is “Commander in Chief of the Army and Navy”,²³ yet it is in the power of Congress to “provide and maintain a [n]avy” and “[t]o declare [w]ar”.²⁴

Since its drafting in 1787 and entry into force in 1789, there have been 27 amendments to the U.S. Constitution, the most recent of which was in 1992.²⁵ The first 10 amendments to the U.S. Constitution encompass the Bill of Rights,²⁶ which establishes various constitutional limits to the exercise of governmental power in order to protect civil liberties, including that “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances.”²⁷ In addition to the protection of individual rights, the Bill of Rights Amendment also establishes the division of power arrangement between the national government and individual state governments pursuant to the principle of federalism. Specifically, it provides that “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”²⁸ Whilst the legislative powers

¹⁴ U.S. Const. Amend XXII §1.

¹⁵ U.S. Const. Art. II §1.

¹⁶ U.S. Const. Art. II §2.

¹⁷ U.S. Const. Art. III §1.

¹⁸ U.S. Const. Art. III §2.

¹⁹ *Marbury v. Madison*, 5 U.S. 137 (1803).

²⁰ U.S. Const. Art. I §1.

²¹ U.S. Const. Art. II §1.

²² U.S. Const. Art. III §1.

²³ U.S. Const. Art. III §2.

²⁴ U.S. Const. Art. I §VIII.

²⁵ U.S. Const. Amend. XXVII.

²⁶ U.S. Const. Amends. I – X.

²⁷ U.S. Const. Amend I.

²⁸ U.S. Const. Amend. X.



of Congress are enumerated in and delimited by the Constitution, the valid exercise of such powers entails that, in accordance with the Supremacy Clause,²⁹ conflicting state law is pre-empted by the Constitution and federal statutory law.³⁰

International law:

The Supremacy Clause of the U.S. Constitution provides that “all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme law of the Land”.³¹ As one of the primary sources of international law, the three-stage process by which the U.S. assumes treaty obligations is initiated by the President or another representative of the executive negotiating and signing a treaty and then seeking the formal advice and consent of two-thirds of the Senate,³² the attainment of which enables the President to affirm ratification.³³ However, the status of treaty law as a matter of domestic law is variable. Textually, whilst the Supremacy Clause supports a form of monism through which international law is directly effective as domestic law, the requirement for the advice and consent of the Senate implies that international law is effective as domestic law once transposed into the domestic legal order.³⁴ Addressing this tension, a majority of the Supreme Court observed in *Medellín v. Texas* that “[w]hile a treaty may constitute an international commitment, it is not binding domestic law unless Congress has enacted statutes implementing it or the treaty itself conveys an intention that it be “self-executing” and is ratified on that basis.”³⁵ Although critiqued, particularly for the potential uncertainty around whether a treaty is “self-executing” or not,³⁶ this signals a primarily dualist approach to the status of international law within the domestic legal order, whereby non self-executing treaties require express incorporation through implementing legislation in order to be judicially enforceable in the U.S.³⁷

Some of the core United Nations (UN) treaties to which the U.S. is a state party, and which are relevant to this national legal case study, are situated within the field of international human rights law and include the International Convention on the Elimination of All Forms of Racial Discrimination (ICERD), the International Covenant on Civil and Political Rights (ICCPR), the Convention against Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment (CAT), and two Optional Protocols to the Convention on the Rights of the Child (CRC) pertaining to the involvement of children in armed conflict and the sale of children, child prostitution and child pornography.³⁸ The U.S. is also a signatory to, but has not ratified, the International Covenant on Economic, Social and Cultural Rights (ICESCR), the

²⁹ U.S. Const. Art VI.

³⁰ Segall, E.J. (2013) ‘Constitutional Change and the Supreme Court: The Article V Problem’, *University of Pennsylvania Journal of Constitutional Law*, Vol.16:2, pp.443-451. Available at: <https://scholarship.law.upenn.edu/jcl/vol16/iss2/5/>

³¹ U.S. Const. Art.VI §2.

³² Ibid.

³³ Telman, D.A.J. (2013) ‘A Monist Supremacy Clause and a Dualistic Supreme Court: The Status of Treaty Law as U.S. Law’, *Valparaiso University Legal Studies Research Paper No.13-6*. Available at: https://scholar.valpo.edu/law_fac_pubs/300/

³⁴ Ibid.

³⁵ *Medellín v. Texas*, 552 U.S. 491 (2008), 505 (citing *Igartúa-De La Rosa v. United States*, 417 F. 3d 145, 150 (CA1 2005) (en banc) (Boudin, C.J.)).

³⁶ See, e.g., *Medellín v. Texas*, 552 U.S. 491 (2008), 538-567 (Breyer, J., dissenting).

³⁷ Congressional Research Service. (2018) *International Law and Agreements: Their Effect upon U.S. Law*. RL32528. Available at: <https://sgp.fas.org/crs/misc/RL32528.pdf>

³⁸ International Convention on the Elimination of All Forms of Racial Discrimination (entered into force 4 January 1969) G.A. Res. 2106 (XX); International Covenant on Civil and Political Rights (entered into force 23 March 1976), G.A. Res 2200A (XXI); Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (entered into force 26 June 1987) G.A. Res. 39/46; Optional Protocol to the Convention on the Rights of the Child on the involvement of children in armed conflict (entered into force 12 February 2002) G.A. Res. A/RES/54/263; Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography (entered into force 18 January 2002) G.A. Res. A/RES/54/263.




Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), the Convention on the Rights of the Child (CRC) and the Convention on the Rights of Persons with Disabilities (CRPD).³⁹

U.S. court system:

The U.S. court system is comprised of both a federal court system and court systems in each of the 50 states. In relation to the former, the U.S. Constitution provides that “[t]he judicial power of the United States, shall be vested in one supreme Court, and in such inferior courts as the Congress may from time to time ordain and establish.”⁴⁰ The federal court system consists of three hierarchical levels, namely: district courts (the trial court, of which there are 94), circuit courts (first appeal court, of which there are 13) and the Supreme Court of the U.S. – the highest court in the U.S. legal system and the final court of appeal in the federal court system.⁴¹ The state court systems, as established by the constitution and laws of each of the 50 states, mirror the structure of the federal court system, from which they are mostly separate, except where the U.S. Supreme Court exercises its authority to review the decisions of state courts concerning federal law.⁴² Whereas the federal courts are courts of limited jurisdiction determined by the “Cases” and “Controversies” listed in the Constitution,⁴³ state courts are courts of general jurisdiction that can in principle hear all types of cases, whether based on state or federal law.⁴⁴

Table 4: Overview of court structure in the U.S.

	Federal and State Court Hierarchies in the U.S.
Higher  Lower	<ul style="list-style-type: none"> • Supreme Court • Circuit courts • District courts

³⁹ International Covenant on Economic, Social and Cultural Rights (entered into force 3 January 1976), G.A. Res 2200A (XXI), 993 U.N.T.S. 3; Convention on the Elimination of All Forms of Discrimination against Women (entered into force 3 September 1981), 1249 U.N.T.S. 13; Convention on the Rights of the Child (entered into force 2 September 1990) GA Res. 44/25, 1577 U.N.T.S. 3; Convention on the Rights of Persons with Disabilities (entered into force 3 May 2008), GA Res. A/61/106.

⁴⁰ U.S. Const. Art. III §1.

⁴¹ Office of the United States Attorneys. *Introduction To The Federal Court System* / U.S. Department of Justice [Online]. Available at: <https://www.justice.gov/usao/justice-101/federal-courts>

⁴² Bradley, C.A. (2020) *International law in the US legal system*. 3rd edn. New York: Oxford University Press, pp.3.

⁴³ U.S. Const., Art.III §2.

⁴⁴ Bradley, C.A. (2020) *International law in the US legal system*. 3rd edn. New York: Oxford University Press, pp.2-3.

1.5 Current state of neurotechnologies in the U.S.

Through the various programs carried out as part of the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) initiative (see Section 2), which involves partners such as the National Institute of Health (NIH), the U.S. Food and Drug Administration (FDA) and the Defense Advanced Research Projects Agency (DARPA), neurotechnologies are widely used for a variety of research and development (R&D) purposes. At the time of writing, the most significant advancements in neurotechnology R&D relate to brain computer or brain-machine interfaces (BCI/BMI), a type of neurotechnological device enabling direct and occasionally bidirectional communication between the brain and an external computer-based system.⁴⁵ Although most commercially available BCIs are non-invasive, most recent R&D efforts have increasingly focused on more invasive implanted BCIs, with Synchron announcing it had received FDA approval to conduct the first human clinical trial of such technology following the granting of \$10 million from the NIH Neural Interfaces Program,⁴⁶ and Neuralink also seeking regulatory clearance from the FDA to begin human trials for its own brain chip implant.⁴⁷ Whilst both are primarily intended to be used as medical devices to restore motor and other functions, as well as to treat neurological disorders, Neuralink has indicated its long-term strategy is to eventually make its BCIs more widely available to the general population.⁴⁸ Paralleling this is the general and significantly increasing trend towards the use of and reliance upon neuroscientific evidence, both in the form of brain scans and expert testimony, for civil and, in particular, criminal legal proceedings.⁴⁹

2. Neurotechnology-specific legal developments

This section presents an overview of the legal developments pertaining to neurotechnologies in the U.S. It examines relevant policies and laws in relation to neurotechnologies and identifies the national authorities involved in the implementation and enforcement of such laws and policies.

U.S. policy on neurotechnologies

The centrepiece of U.S. policy in relation to neurotechnologies is the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative. Launched in 2013, it involves a collaborative partnership between public and private sector bodies, with funding for research provided by various federal governmental agencies, including those connected to the U.S. Department of Health and Human Services (HHS), such as the National Institute of Health (NIH) and the Food and Drug Administration

⁴⁵ Saha, S. et al. (2021) 'Progress in Brain Computer Interface: Challenges and Opportunities', *Frontiers in Systems Neuroscience*, Vol.15. DOI: <https://doi.org/10.3389/fnsys.2021.578875>

⁴⁶ Park, A. (2022) *Sci-fi no more: Synchron implants mind-reading device in first US patient in paralysis trial* / Fierce Biotech [Online]. Available at: <https://www.fiercebiotech.com/medtech/synchron-implants-brain-computer-interface-first-us-patient-paralysis-trial>

⁴⁷ Levy, R. (2022) *Musk approaches brain chip start-up Synchron about deal amid Neuralink delays* / Reuters [Online]. Available at: <https://www.reuters.com/technology/musk-approaches-brain-chip-startup-synchron-about-deal-amid-neuralink-delays-2022-08-19/>

⁴⁸ See, e.g., Neuralink (no date) *Applications* / [Online]. Available at: <https://neuralink.com/applications/>

⁴⁹ Aono, D., Yaffe, G., and Kober, H. (2019) 'Neuroscientific evidence in the courtroom: a review', *Cognitive Research: Principles and Implications*, Vol.4:40. DOI: <https://doi.org/10.1186/s41235-019-0179-y>



(FDA), as well as the National Science Foundation (NSF) and the Defense Advanced Research Projects Agency (DARPA). In response to this “Grand Challenge”, the NIH established a BRAIN Working Group of the Advisory Committee to the Director, NIH, whose report entitled “BRAIN 2025: A Scientific Vision” sets out a 10-year plan for achieving the seven main goals of the BRAIN initiative.⁵⁰ The overall aim can be summarised as “the development and use of tools for acquiring fundamental insight about how the nervous system functions in health and disease.”⁵¹ A follow-up report at the midway point of the initiative in 2019 by the Working Group 2.0 reviewed the progress made in relation to the strategic priorities laid down in the 2025 Report and identified opportunities for the second phase of the initiative.⁵² One of the key overall aims of the BRAIN initiative is the closer integration between neuroscience and neuroethics, in accordance with which the BRAIN Neuroethics Subgroup has developed a Neuroethics Roadmap focusing on the “potential neuroethics implications of new tools and neurotechnologies and their use.”⁵³

As part of its role in the BRAIN initiative, the FDA works with the developers of medical devices to ensure the transparency of the applicable regulatory framework and assist in the bringing of safe and effective products to market.⁵⁴ The Centre for Devices and Radiological Health (CDRH), an entity connected to the FDA, has issued “leapfrog guidance” relating to non-clinical testing and clinical use of implanted brain computer interfaces (BCIs) for patients with paralysis or amputation.⁵⁵ This guidance document provides a series of non-binding recommendations for Q-Submissions and Investigational Device Exemptions (IDEs) intended to inform relevant technology developers and other stakeholders of the process by which medical devices can achieve regulatory approval and enter the healthcare market.⁵⁶ The issuing of guidance relating to implanted BCIs reflects the rapid progress in relation to the development of this technology specifically, and the growing interest in the availability of medical consumer neurotechnology, more generally.⁵⁷ This follows the approval given by the FDA for the use of similar though potentially less invasive deep brain stimulation (DBS) applications, such as Percept PC by Medtronic and the NeuroPace RNS System, to treat movement disorders including Parkinson’s disease, as well as severe epilepsy.⁵⁸ Since the issuing of this guidance document, New York-based Synchron announced that as part of its COMMAND trial it was the first company in the U.S. to implant a BCI into a human patient following the awarding of IDE status by the FDA.⁵⁹ These developments, coupled with

⁵⁰ Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Working Group Report to the Advisory Committee to the Director, NIH. (2014) *Brain 2025 – A Scientific Vision*, p.5. Available at: https://braininitiative.nih.gov/sites/default/files/pdfs/brain2025_508c.pdf

⁵¹ Ibid.

⁵² Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Working Group 2.0 Report to the Advisory Committee to the Director, NIH. (2019) *The Brain Initiative 2.0: From Cells to Circuits, Towards Cures*. Available at: https://braininitiative.nih.gov/sites/default/files/images/brain_2.0_6-6-19-final_revised10302019_508c.pdf

⁵³ Advisory Committee to the Director Working Group on BRAIN 2.0 Neuroethics Subgroup. (2019) *The BRAIN Initiative and Neuroethics: Enabling and Enhancing Neuroscience Advances for Society*. Available at: https://braininitiative.nih.gov/sites/default/files/images/bns_roadmap_11_october_2019_sent_to_acd_for_oct_2019_revised_10282019_508c.pdf

⁵⁴ Food and Drug Administration & The BRAIN Initiative / Food and Drug Administration [Online]. Available at: <https://www.braininitiative.org/alliance/food-and-drug-administration/>

⁵⁵ U.S Department of Health and Human Services Food and Drug Administration Centre for Devices and Radiological Health. (2021) *Implanted Brain-Computer Interfaces for Patients with Paralysis or Amputation – Non-clinical Testing and Clinical Considerations*. FDA-2014-N-1130.

⁵⁶ Ibid.

⁵⁷ Ibid.

⁵⁸ Shein, E. (2022) ‘Neurotechnology and the Law’, *Communications of the ACM*, Vol.65:8, pp.16-18. DOI: 10.1145/3542816.

⁵⁹ Ha, K., and Hubin, T. (2022) *Synchron Announces First Human U.S. Brain-Computer Interface Implant* / Businesswire [Online]. Available at: <https://www.businesswire.com/news/home/20220719005248/en/Synchron-Announces-First-Human-U.S.-Brain-Computer-Interface-Implant>



the growing potential for dual-use (i.e., for both civilian and military applications),⁶⁰ have led the Congressional Research Service to include BCIs in the category of emerging and foundational technology the sale of which may be restricted by export controls, such as licensing agreements.⁶¹

The research and development body of the U.S. Department of Defense, DARPA, has been involved in the scientific research and technological development of neurotechnologies, particularly BCIs, since the 1970s.⁶² It supports the BRAIN initiative through its funding of various research and development (R&D) programs into medical and military applications of neurotechnologies.⁶³ Such programs include the Neural Engineering System Design (NESD) program, which seeks to develop implantable neural interfaces to alleviate damage caused by injury or disease to the visual and auditory systems of military personnel,⁶⁴ and the Next-Generation Nonsurgical Neurotechnology (N³) program, which aims to develop non-invasive brain-machine interfaces for a variety of national security applications, including controlling unmanned aerial vehicles (UAVs).⁶⁵

Paralleling this, at the level of civil society in the US there exists the Neurorights Foundation, the primary aim of which is to advocate for the incorporation of five specific so-called “neurorights” into “international human rights law, national legal and regulatory frameworks, and ethical guidelines.”⁶⁶ Its work with national governments, as well as other civil society stakeholders in both the public and private sector, has been particularly influential in proposed and actual legislative reforms recognising so-called “neurorights” in the Republic of Chile.

U.S. laws explicitly covering neurotechnologies

There are currently no known dedicated U.S. laws on neurotechnologies at the federal or state level.

However, medical device legislation, such as the Federal Food, Drug, and Cosmetic Act (1938) (FD&C Act), the Medical Device Amendments to the FD&C Act (1976), and the 21st Century Cures Act (2016), is applicable to neurotechnologies classified as such. The FD&C Act (1938) is the primary statutory authority for the FDA’s regulatory oversight of medical devices,⁶⁷ while the Medical Device Amendments to the FD&C Act (1976) creates a three-tiered risk-based classification system designed to ensure the safety and effectiveness of all medical devices intended for human use.⁶⁸ For devices classified as Class III, there exists “insufficient information” that neither the general controls applicable to Class I devices, nor the performance standards applicable to Class II devices, “are sufficient to provide reasonable assurance of the safety and effectiveness of the device”, with the effect that such devices are subject to premarket approval requirements.⁶⁹ A potential challenge here relates to direct-to-

⁶⁰ European Commission. (2020) *Guidance note – Research with an exclusive focus on civil applications*. Available at: https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-civil-apps_en.pdf

⁶¹ Congressional Research Service. (2021) *Export Controls: Key Challenges*. IF11154. Available at: <https://crsreports.congress.gov/product/pdf/IF/IF11154>

⁶² Miranda, R.A., et al. (2015) ‘DARPA-funded efforts in the development of novel brain-computer interface technologies’, *Journal of Neuroscience Methods*, vol.244, pp.52-67. DOI: <https://doi.org/10.1016/j.jneumeth.2014.07.019>

⁶³ See, e.g., *DARPA and the Brain Initiative* [Online]. Available at: <https://www.darpa.mil/program/our-research/darpa-and-the-brain-initiative>

⁶⁴ Arthur, J. *Neural Engineering System Design* / DARPA [Online]. Available at: <https://www.darpa.mil/program/neural-engineering-system-design>

⁶⁵ Sarma, G. *Next-Generational Nonsurgical Neurotechnology* / DARPA [Online]. Available at: <https://www.darpa.mil/program/next-generation-nonsurgical-neurotechnology>

⁶⁶ *Mission* / The Neurorights Foundation [Online]. Available at: <https://neurorightsfoundation.org/mission>

⁶⁷ 21 U.S.C §372.

⁶⁸ 21 U.S.C §360c.

⁶⁹ 21 U.S.C §360c(a)(1)(c).



consumer neurotechnologies that purport to serve health-related purposes, such as improving cognition, but which do not claim to serve a therapeutic benefit, for which the classification as low-risk devices that do not require FDA regulatory approval may represent a regulatory oversight.⁷⁰ More recently, the 21st Century Cures Act has clarified the types of digital health technologies regulated as medical devices within the meaning of the legislation, specifically by excluding those with a software function intended, inter alia, for administrative support of a healthcare facility, the maintenance of a healthy lifestyle, or to serve as electronic patient records.⁷¹

At the state level, a study of bills proposed in U.S. state legislatures between 1992 and 2009 identified nearly 1000 bills for so-called “neurolegislation”, defined as “legislation that explicitly mentions the brain or brain sciences”, of which 290 were enacted into law.⁷² The main categories to which the bills related were (i) brain injury and brain trauma, (ii) health care provision and insurance coverage, (iii) mental health and mental disabilities, (iv) education, early childhood education and special education, and (v) combat veterans and posttraumatic stress disorder.⁷³ Whilst not related to neurotechnologies, specifically, this reflects the gradual transposition of neuroscience into a legislative form or framework.

Proposals for dedicated law on neurotechnologies

There are no active proposals at the federal or state level for dedicated legislation in relation to neurotechnologies. Previously, however, a bill for a National Neurotechnology Initiative Act of Congress was put before the House of Representatives (e.g., H.R.1483⁷⁴) and the Senate (e.g., S.2989⁷⁵). The proposal sought to increase investment in federal neurotechnology research and development,⁷⁶ “coordinate and promote the study of the social, ethical and legal aspects of neurotechnology”,⁷⁷ and establish a National Neurotechnology Coordination Office to be responsible for overseeing implementation of the initiative.⁷⁸ At the state level, a bill introduced to the State of Minnesota House of Representatives in 2021 sought to establish neurodata rights,⁷⁹ such as a right to mental privacy, a right to cognitive liberty, and a right to psychological continuity, as well as a prohibition on the use of BCIs to bypass conscious decision-making,⁸⁰ with resultant civil and criminal penalties for failure to comply.⁸¹ Whereas the establishment of the BRAIN initiative soon after the introduction of the National Neurotechnology Initiative Act is the most likely reason for its limited further progression, it is unclear whether the Minnesota Bill will proceed any further in the legislative process during the 22-23 session.

Responsibility for enforcement

The FDA, the predecessor to which was established by the Pure Food and Drugs Act (1906), is responsible for regulating medical devices, including neurotechnologies classified as such. Its regulatory

⁷⁰ Altimus, C. Helmers-Wegman, E. and Raver, S. (2021) *Neurotechnology – A Giving Smarter Guide*. Milken Institute Center for Strategic Philanthropy. Available at:

<https://milkeninstitute.org/report/neurotechnology-giving-smarter-guide>

⁷¹ 21 U.S.C §360j(o)(1)(A)-(E).

⁷² Shen, F.X. (2016) ‘Neurolegislation: How U.S. Legislators Are Using Brain Science’, *Harvard Journal of Law & Technology*, Vol.29:2, pp.495-526. Available at: https://scholarship.law.umn.edu/faculty_articles/605

⁷³ Shen, F.X. (2016) ‘Neurolegislation: How U.S. Legislators Are Using Brain Science’, *Harvard Journal of Law & Technology*, Vol.29:2, pp.495-526. Available at: https://scholarship.law.umn.edu/faculty_articles/605

⁷⁴ H.R. 1483 – 111th Congress (2009-2010): National Neurotechnology Initiative Act. (2009, March 16). <http://www.congress.gov/>

⁷⁵ S.586 – 111th Congress (2009-2010): National Neurotechnology Initiative Act. (2009, March 12). <http://www.congress.gov/>

⁷⁶ H.R. 1483 – 111th Congress (2009-2010): National Neurotechnology Initiative Act. (2009, March 16) §4a.2.

⁷⁷ Ibid §4b.4

⁷⁸ Ibid §5a.

⁷⁹ HF 424 (Minnesota – 2021 – 2022 Regular Session) §1-2.2.

⁸⁰ Ibid §2.4.

⁸¹ Ibid §2.5 – §4.



powers, as exercised by the Centre for Devices and Radiological Health (CRDH), include banning devices,⁸² ordering device recalls,⁸³ and imposing civil penalties for violations of the FD&C Act (1938).⁸⁴

Significant legal cases

The primary issue in case law involving neurotechnologies is the use and admissibility of neuroscientific evidence in legal proceedings (see Section 3.3 below). Neuroscientific evidence has been introduced in civil law cases such as *Van Middlesworth v. Century Bank and Trust Co*, in which the results of a magnetic resonance imaging (MRI) scan were admitted as evidence of the defendant's mental incompetence.⁸⁵ Reliance upon neuroscientific evidence is more established in criminal law cases,⁸⁶ however, and significant cases in this context include *United States v. Semrau*,⁸⁷ *Florida v. Nelson*,⁸⁸ and *Graham v. Florida*,⁸⁹ pertaining to the admissibility of lie detection evidence, criminal responsibility and sentencing, and brain development in adolescents and the associated treatment of juvenile offenders, respectively.

Current debates and future policy and/or legal developments

As noted above, a key feature of the emerging interdisciplinary field of neuroscience and the law, often referred to by the portmanteau of "neurolaw",⁹⁰ is the growing use of and reliance upon neuroscientific evidence in courtrooms to, inter alia, (dis)prove injury in civil cases and establish mitigating circumstances for defendants in criminal cases.⁹¹ An additional aspect in the growth of neurolaw, as also noted above, is the reference made to neuroscience in a variety of legislative bills, particularly at the state level.⁹² It remains to be seen which of court-made neurolaw and legislature-enacted "Neurolegislation" is more likely to lead to significant legal developments in relation to the regulation of neurotechnologies in the U.S.⁹³

⁸² 21 U.S.C §360f.

⁸³ 21 U.S.C §360h(e).

⁸⁴ 21 U.S.C §333(f)(1)(A).

⁸⁵ *Van Middlesworth v. Century Bank and Trust Co.*, No.215512 (Mich. App., May 5, 2000).

⁸⁶ Farahany, N.A. (2016) 'Neuroscience and behavioural genetics in US criminal law: an empirical analysis', *Journal of Law and the Biosciences*, Vol.2:3, pp.485-509. DOI: <https://doi.org/10.1093/jlb/lsv059>

⁸⁷ *United States v. Semrau*, 693 F.3d 510 (6th Cir. 2012).

⁸⁸ *Florida v. Grady Nelson*, No.FO5-00846 (11th Fla. Cir. Ct., Dec 4, 2010).

⁸⁹ *Graham v. Florida*, 560 U.S. 48 (2010).

⁹⁰ Aggarwal, N.K., and Ford, E. (2013) 'The neuroethics and neurolaw of brain injury', *Behavioural Sciences & The Law*, Vol.31:6, pp.789-802. DOI: <https://doi.org/10.1002/bsl.2086>

⁹¹ See, e.g., Brown E. (2019) *Is "Neurolaw" Coming Soon to a Courtroom Near You?* / Scientific American [Online]. Available at: <https://www.scientificamerican.com/article/is-neurolaw-coming-soon-to-a-courtroom-near-you/>

⁹² Shen, F.X. (2016) 'Neurolegislation: How U.S. Legislators Are Using Brain Science', *Harvard Journal of Law & Technology*, Vol.29:2, pp.495-526. Available at: https://scholarship.law.umn.edu/faculty_articles/605

⁹³ Ibid.



3. Domain-specific legal issues

This section examines the legal implications of neurotechnologies in a U.S. context with respect to the following specific legal domains, namely human rights law, privacy and data protection law, use in legal systems (criminal, civil and evidence law), and liability for harms (tort, contract and criminal).

The following sections analyses some of the ways in which neurotechnologies may be governed by U.S. law and policy within the frameworks of human rights, privacy and data protection, use in legal systems and liability for harms. Each section begins with a brief introduction to the relevant legal issue(s) and associated legal framework(s). Specific legal issues within the identified legal frameworks are then analysed in greater depth, with each discussion including specific references to existing (and proposed) law and an explanation of how the law may regulate and apply to the use of neurotechnologies.

3.1 Human rights law

Advancements in neurotechnology and neuroscience more generally creates new opportunities for the enhancement of certain human rights through beneficial use cases, while also posing challenges to the adequate protection of others through misuse or misapplication. The purpose of this section is to firstly (see 3.1.1) outline the applicable human rights law frameworks under domestic and international law, focusing on three primary sources, namely: the U.S. Constitution, federal legislation and international human rights law. In the second part of this section (Section 3.1.2) the implications of neurotechnologies for the enjoyment of the right to non-discrimination, the right to a fair trial and the privilege against self-incrimination, the right to freedom from torture, the right to freedom of thought, and the right to life will be considered, with a focus on the key issues, gaps and challenges posed by this technology.

3.1.1 The human rights law framework

In accordance with the Supremacy Clause,⁹⁴ one of the primary sources of human rights law is the U.S. Constitution. While the original text contains certain inalienable human rights protections, for instance the right to trial by jury,⁹⁵ the most significant have been enumerated in subsequent constitutional amendments. This includes the following:

- **The Bill of Rights (1791),**⁹⁶ which consists of the first ten amendments to the U.S. Constitution and protects rights including the right to freedom of speech, press and peaceful assembly,⁹⁷ the right to be free from cruel and unusual punishment,⁹⁸ and the right of trial by jury in civil law cases.⁹⁹
- **The Thirteenth Amendment (1865),** which abolishes slavery.¹⁰⁰

⁹⁴ U.S. Const. Art. VI.

⁹⁵ U.S. Const. Art. III §2.

⁹⁶ U.S. Const. Amends. I – X.

⁹⁷ U.S. Const. Amend. I.

⁹⁸ U.S. Const. Amend. VIII.

⁹⁹ U.S. Const. Amend. VII.

¹⁰⁰ U.S. Const. Amend. XIII



- **The Fourteenth Amendment (1868)**, which provides that “All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.”¹⁰¹
- **The Fifteenth Amendment (1870)**, which ensures that voting rights “shall not be denied or abridged by the United States or by any State on account of race, color, or previous condition of servitude”.¹⁰²
- **The Nineteenth Amendment (1920)**, which guarantees that voting rights “shall not be denied or abridged by the United States or by any State on account of sex.”¹⁰³

Whilst not a direct source of human rights, per se, the Ninth Amendment specifies that “[t]he enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage other retained by the people.”¹⁰⁴ This provision has been interpreted, in the obiter dictum of one Supreme Court Justice, as evidencing “a belief of the Constitution’s authors that fundamental rights exist that are not expressly enumerated in the first eight amendments and an intent that the list of rights included there not be deemed exhaustive.”¹⁰⁵ The Ninth Amendment thus expresses the general principle that further human rights may emerge through judicial interpretation of the U.S. Constitution, with the U.S. Supreme Court variously relying upon this provision as well as the Due Process Clauses of the Fifth and Fourteenth Amendments,¹⁰⁶ together with the Equal Protection Clause of the Fourteenth Amendment,¹⁰⁷ as the basis for giving effect to certain unenumerated rights.¹⁰⁸ An example of this is the right to privacy, which is not expressly provided for in the U.S. Constitution, but has been recognised by the Supreme Court as being constitutionally protected in relation to,¹⁰⁹ inter alia, child rearing,¹¹⁰ marriage,¹¹¹ sexual activity,¹¹² and reproductive autonomy.¹¹³

An additional source of human rights law is federal legislation enacted by Congress, including:

- **The Civil Rights Act (1964)**, which prohibits discrimination on the basis of race, colour, religion, sex and national origin and applies to voting, public accommodation, and employment.¹¹⁴

¹⁰¹ U.S. Const. Amend. XIV §1.

¹⁰² U.S. Const. Amend. XV.

¹⁰³ U.S. Const. Amend. XIX.

¹⁰⁴ U.S. Const. Amend. IX.

¹⁰⁵ *Griswold v. Connecticut* 381 U.S. 479 (1965) at 488 (Goldberg, J. concurring).

¹⁰⁶ U.S. Const. Amend. V, XIV.

¹⁰⁷ U.S. Const. Amend. XIV.

¹⁰⁸ Congressional Research Service. (2022) *Privacy Rights Under the Constitution: Procreation, Child Rearing, Contraception, Marriage, and Sexual Activity*. LSB10820. Available at:

<https://crsreports.congress.gov/product/pdf/LSB/LSB10820>

¹⁰⁹ Ibid.

¹¹⁰ See, e.g., *Meyer v. Nebraska*, 262 U.S. 390 (1923).

¹¹¹ See, e.g., *Loving v. Virginia*, 388 U.S. 1 (1967); *Obergefell v. Hodges* 576 U.S. 644 (2015).

¹¹² See, e.g., *Lawrence v. Texas*, 539 U.S. 558 (2003).

¹¹³ See, e.g., *Griswold v. Connecticut*, 381 U.S. 479 (1965); Cf. *Dobbs v. Jackson Women’s Health Organisation*, 597 U.S. (2022).

¹¹⁴ 42 U.S.C §2000d et seq.

- **The Americans with Disabilities Act (ADA) (1990)**, which prohibits employment discrimination, harassment and retaliation against qualified individuals based on disability.¹¹⁵
- **The Genetic Information Nondiscrimination Act (GINA) (2008)**, which prohibits discrimination on the basis of genetic information in relation to health insurance and employment.¹¹⁶

Of the nine core international human rights law treaties, the U.S. has signed, ratified and therefore indicated its consent to be bound as a matter of international law to the following:

- **International Covenant on Civil and Political Rights (ICCPR)**¹¹⁷
- **International Convention on the Elimination of All Forms of Racial Discrimination (CERD)**¹¹⁸
- **Convention against Torture and Other Cruel, Inhuman and Degrading Treatment or Punishment (CAT)**¹¹⁹
- **Optional protocols to the Convention on the Rights of the Child (CRC)**¹²⁰ relating to the involvement of children in armed conflict¹²¹ and the sale of children, child prostitution and child pornography.¹²²

The U.S. has modified its obligations in relation to some of the international human rights treaties to which it is a State Party, however, by treating them as non-self-executing and exercising the reservation, understanding and declaration mechanism (RUDs), which informs the content, effect, interpretation and implementation of treaties so as not to interfere with comparable provisions of the U.S. Constitution.¹²³ In relation to the ICCPR, for instance, the U.S. ratification contained 5 reservations, 5 understandings, 4 declarations and 1 proviso.¹²⁴ The expressed reservations relate, inter alia, to Article 7 ('cruel, inhuman or degrading treatment'), which limits its obligation to prohibit cruel, unusual or inhuman treatment or punishment in accordance with the Fifth, Eighth, and/or Fourteenth Amendments to the U.S. Constitution,¹²⁵ and Article 20 ('incitement to discrimination, hostility or violence'), to the effect that it does not authorize or require the restriction of freedom of speech or freedom of association in a way that would contravene the First Amendment to the U.S. Constitution.¹²⁶

¹¹⁵ 42 U.S.C §12101-12213.

¹¹⁶ 42 U.S.C §2000ff.

¹¹⁷ International Covenant on Civil and Political Rights (entry into force 23 March 1976) G.A. Res 2200A (XXI).

¹¹⁸ International Convention on the Elimination of All Forms of Racial Discrimination (entry into force 4 January 1969) G.A. Res. 2106 (XX).

¹¹⁹ Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (entry into force 26 June 1987) G.A. Res. 39/46.

¹²⁰ Convention on the Rights of the Child (entry into force 2 September 1990) G.A. Res. 44/25.

¹²¹ Optional Protocol to the Convention on the Rights of the Child on the involvement of children in armed conflict (entry into effect 12 February 2002) G.A. Res. A/RES/54/263.

¹²² Optional Protocol to the Convention on the Rights of Child on the sale of children, child prostitution, and child pornography (entry into effect 18 January 2002) G.A. Res. A/RES/54/263.

¹²³ Congressional Research Service. (2022) *Reservations, Understandings, Declarations, and Other Conditions to Treaties*. IF12208. Available at: <https://crsreports.congress.gov/product/pdf/IF/IF12208>

¹²⁴ Senate Comm. On Foreign Relations. (1992) *U.S. Senate Report on Ratification of The International Covenant on Civil and Political Rights*. U.S. Senate Executive Report 102-23 (102d Cong., 2d Sess).

¹²⁵ Ibid.

¹²⁶ Ibid.

Of the remaining core international human rights treaties, the Convention on the Rights of Persons with Disabilities (CRPD)¹²⁷ and the Convention on the Elimination of Discrimination against Women (CEDAW)¹²⁸ have both been signed by the President and submitted to the Senate for advice and consent but are yet to be ratified. The International Covenant on Economic, Social and Cultural Rights (ICESCR)¹²⁹ and the Convention on the Rights of the Child (CRC) have been signed by the President but have not been transferred to the U.S. Senate for ratification.¹³⁰ International human rights treaties to which the US is not a signatory party include the Convention for the Protection of All Persons from Enforced Disappearance (CED)¹³¹ and the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families (ICRMW).¹³²

Finally, the U.S. is a member state of the regional multilateral intergovernmental body for the Americas named the Organisation of American States (OAS),¹³³ through the auspices of which has emerged the Inter-American human rights system, as constituted by the American Declaration of the Rights and Duties of Man,¹³⁴ in conjunction with the legally binding American Convention on Human Rights (ACHR).¹³⁵ The U.S. has signed but not ratified the ACHR, nor therefore accepted the jurisdiction of the judicial organ established by it,¹³⁶ namely the Inter-American Court of Human Rights (IACtHR). As a state party to the OAS Charter,¹³⁷ however, the U.S. is subject to the Inter-American Commission on Human Rights, which separately from but together with the IACtHR is required “to promote the observance and protection of human rights and to serve as a consultative organ of the Organisation in these matters.”¹³⁸

3.1.2 Human rights law implications of neurotechnologies

Neurotechnologies have the potential to impact human rights in various ways, both positively and negatively. In a healthcare context, for instance, neurotechnologies can be used to identify,¹³⁹ diagnose and treat a wide range of psychiatric and neurological disorders,¹⁴⁰ and to restore sensory, cognitive

¹²⁷ Convention on the Rights of Persons with Disabilities (entry into force 3 May 2008) G.A. Res. A/61/611.

¹²⁸ Convention on the Elimination of All Forms of Discrimination against Women (entry into force 3 September 1981) 1249 U.N.T.S. 13.

¹²⁹ International Covenant on Economic, Social and Cultural Rights (entry into force 3 January 1976) G.A. Res 2200A (XXI).

¹³⁰ United Nations General Assembly. (2020) *National report submitted in accordance with paragraph 5 of the annex to Human Rights Council resolution 16/21 A/HRC/WG.6/36/USA/1*, paras 7-9.

¹³¹ International Convention for the Protection of All Persons from Enforced Disappearance (entry into force 23 December 2010) G.A. Res. 47/133.

¹³² Convention for the Protection of the Rights of All Migrant Workers and Members of their Families (entry into force 1 July 2003) G.A. Res. 45/158.

¹³³ Charter of the Organization of American States (entry into force 13 December 1951) OAS, Treaty Series, Nos.1-C and 61.

¹³⁴ American Declaration of the Rights and Duties of Man (OAS) Ninth International Conference of American States, Bogotá, Colombia, 1948.

¹³⁵ American Convention on Human Rights (entry into force 18 July 1978) OAS, Treaty Series, No.36.

¹³⁶ Ibid Art.33.

¹³⁷ Charter of the Organization of American States (entry into force 13 December 1951) OAS, Treaty Series, Nos.1-C and 61.

¹³⁸ Ibid Art.106.

¹³⁹ See, e.g., Pillai, J., and Sperling M.R. (2006) ‘Interictal EEG and the Diagnosis of Epilepsy’, *Epilepsia*, Vol:47, pp.14-22. DOI: <https://doi.org/10.1111/j.1528-1167.2006.00654.x>

¹⁴⁰ See, e.g., Edwards, C.A. (2017) ‘Neurostimulation devices for the treatment of neurological disorders’, *Mayo Clinic Proceedings*, Vol.92:9, pp.1427-1444. DOI: <https://doi.org/10.1016/j.mayocp.2017.05.005>

and motor functions,¹⁴¹ the benefits of which are linked to the right to health. However, such applications could give rise to infringements in relation to the prohibition on torture, for instance, if used for the purposes of medical or scientific experimentation without obtaining the free and informed consent of the participant. This section analyses both domestic and international human rights law in relation to neurotechnologies, focusing on the right to non-discrimination, the right to a fair trial and the privilege against self-incrimination, the right to freedom from torture, the right to freedom of thought, and the right to life. Each subsection starts by outlining the relevant domestic and international law, before moving on to analyse and discuss the key issues, gaps and challenges posed by neurotechnologies. Where reference is made to obligations under international human rights law, it should be borne in mind that these rights may not be judicially enforceable domestically. In relation to the ICCPR, for instance, the U.S. RUDs state that “Articles 1 through 27 of the Covenant are not self-executing”, meaning implementing legislation is required in order to be applied by domestic courts.¹⁴²

The right to a fair trial and the privilege against self-incrimination

Access to justice is a foundational precept of law constituted by several overlapping rights. As guaranteed by the U.S. Constitution, these rights include due process of law,¹⁴³ “the right to a speedy and public trial, by an impartial jury” in all criminal prosecutions,¹⁴⁴ and “the right of trial by jury” in civil law proceedings,¹⁴⁵ as well as restrictions against punitive bail conditions, excessive fines and “cruel and unusual punishments”.¹⁴⁶ Broadly similar rights are guaranteed under international human rights law, including equal access to, protection of and treatment before the law,¹⁴⁷ the right to “a fair and public hearing by a competent, independent and impartial tribunal established by law”,¹⁴⁸ and the right to an “effective remedy”.¹⁴⁹ Also amongst these rights and of particular relevance to neurotechnology is the inclusion among the various “minimum guarantees”¹⁵⁰ under the ICCPR for those charged with a criminal offence of the right “[n]ot to be compelled to testify against himself [or herself] or to confess guilt.”¹⁵¹ It is similarly stipulated in the U.S. Constitution that “[n]o person...shall be compelled in any criminal case to be a witness against himself”,¹⁵² with this privilege against self-incrimination applicable in both federal and state legal proceedings.¹⁵³

In interpreting this provision, the US Supreme Court has observed that the “privilege against self-incrimination”, as “the essential mainstay of our adversary system”, entails that an individual has the “right to remain silent”.¹⁵⁴ This Fifth Amendment protection is not absolute, however, with the Supreme Court having narrowed its scope by identifying three necessary elements of an infringement, namely:

¹⁴¹ See, e.g., Grahn P.J. et al. (2014) ‘Restoration of motor function following spinal cord injury via optimal control of intraspinal microstimulation: toward a next generation closed-loop neural prosthesis’, *Frontiers in Neuroscience*, Vol.8. DOI: <https://doi.org/10.3389/fnins.2014.00296>

¹⁴² U.S. Reservations, Declarations, and Understandings, International Covenant on Civil and Political Rights, 138 Cong. Rec. S4781-01 (1992), §3(1).

¹⁴³ U.S. Const. Amend V, XIV.

¹⁴⁴ U.S. Const. Amend VI.

¹⁴⁵ U.S. Const. Amend VII.

¹⁴⁶ U.S. Const. Amend VIII.

¹⁴⁷ International Covenant on Civil and Political Rights (entry into force 23 March 1976) G.A. Res 2200A (XXI), Art.14(1).

¹⁴⁸ Ibid.

¹⁴⁹ Ibid Art.2(3)(a)-(c).

¹⁵⁰ Ibid Art.14(3)(a)-(g).

¹⁵¹ International Covenant on Civil and Political Rights (entry into force 23 March 1976) G.A. Res 2200A (XXI), Art.14(3)(g).

¹⁵² U.S. Const. Amend. V.

¹⁵³ U.S. Const. Amend. XIV.

¹⁵⁴ *Miranda v. Arizona*, 384 U.S. 460 (1966).

compulsion, testimony, and self-incrimination.¹⁵⁵ Through case law interpreting these different elements, and as codified by the Supreme Court in *Schmerber v. California*,¹⁵⁶ “[t]he distinction which has emerged, often expressed in different ways, is that the privilege is a bar against compelling “communications” or “testimony”, but that compulsion which makes a suspect or accused the source of “real or physical evidence” does not violate it.”¹⁵⁷ In other words, an individual is not protected against being compelled to provide incriminating “real or physical evidence”, but cannot be forced to provide through communication incriminating testimonial evidence.¹⁵⁸

Although intended as “a helpful framework for analysis”, it was also recognised that “[t]here will be many cases in which such a distinction is not readily drawn.”¹⁵⁹ By way of example, the Court in *Schmerber* pointed out that certain physiological tests, “for example, lie detector tests measuring changes in body function during interrogation, may actually be directed to eliciting responses which are essentially testimonial”, and therefore protected by the self-incrimination doctrine.¹⁶⁰ This appears to envisage as the paradigmatic example the contemporary use of the polygraph and is likely to be more even directly applicable to newer and potentially more accurate neurotechnologies, which may to an even greater extent blur the prevailing physical/testimonial distinction.¹⁶¹ Scholars and practitioners alike have already critiqued the practical difficulties associated with this distinction, and further advancements in neurotechnology may render this approach increasingly unworkable.¹⁶² Farahany, for instance, has suggested that there is a broader spectrum of evidence arising in new and emerging neurotechnological applications, including categories such as identifying, automatic, memorialised and uttered evidence, each of which “reveals a growing incoherence in determining Fifth Amendment privilege based on the *form* the contested evidence takes”, specifically by highlighting that “[i]n the era of neuroscience, self-incrimination may now occur silently just as aloud.”¹⁶³

A future-oriented challenge posed by neurotechnology, brought about by increased commercial availability of devices including brain computer interfaces (BCIs), is the possibility that State authorities will be able to sidestep Fifth Amendment protections and gain access to brain and other neural data collected in consumer-devices. It has been suggested, for example, that the voluntary agreement to the storing of data on third-party devices such as health apps may, in accordance with the third-party doctrine, render inapplicable certain Fourth Amendment protections of privacy, with the effect that any such data will be made available for search and access by the State.¹⁶⁴ Albeit indirectly, this may lead to further erosion of protection against self-incrimination.

¹⁵⁵ *Fisher v. United States*, 425 U.S. 391, 408 (1976).

¹⁵⁶ *Schmerber v. California*, 384 U.S. 757 (1966).

¹⁵⁷ *Ibid* at 764.

¹⁵⁸ Ienca, M. and Andorno, R. (2017) ‘Towards new human rights in the age of neuroscience and neurotechnology’, *Life Sciences, Society and Policy*, Vol.13:5. DOI: <https://doi.org/10.1186/s40504-017-0050-1>

¹⁵⁹ *Schmerber v. California* 384 U.S. 757 (1966) at 764.

¹⁶⁰ *Ibid*.

¹⁶¹ Kraft, C.J. and Giordano, J. (2017) ‘Integrating Brain Science and Law: Neuroscientific Evidence and Legal Perspectives on Protecting Individual Liberties’, *Frontiers in Neuroscience*, Vol.11. DOI: <https://doi.org/10.3389/fnins.2017.00621>

¹⁶² For existing critiques of the practical difficulties associated with the physical/testimonial evidence distinction, see, e.g., Allen, R.J. and Kristin Mace, M. (2004) ‘The Self-Incrimination Clause Explained and Its Future Predicted’, *Journal of Criminal Law and Criminology*, Vol.94:2, pp.243-294. Available at: <https://scholarlycommons.law.northwestern.edu/jclc/vol94/iss2/1>

¹⁶³ Farahany, N.A. (2012) ‘Incriminating Thoughts’, *Stanford Law Review*, Vol.64, pp.351-408, p.395. Available at: https://scholarship.law.duke.edu/faculty_scholarship/2651 (emphasis added)

¹⁶⁴ Tournas, L.N. (2021) *If Police Have Devices That Can Read Your Mind, How Does The Fifth Amendment Fit In?* Future Tense [Online]. Available at: <https://slate.com/technology/2021/05/brain-computer-interface-mind-reading-fifth-amendment.html>

Non-discrimination

The principle of non-discrimination, in conjunction with equality before the law and equal protection of the law without discrimination (see above), constitutes a fundamental human rights norm protected by international human rights treaties to which the U.S. is a state party,¹⁶⁵ as well as constitutional,¹⁶⁶ and statutory law.¹⁶⁷ Neurotechnologies may present current and future challenges to the adequate protection of this right. One such future challenge relates to the effects of neurotechnology augmentation or enhancement, a trend as indicated by DARPA's N³ program (see above), with Yuste et al suggesting that "[t]he pressure to adopt enhancing neurotechnologies, such as those that allow people to radically expand their endurance or sensory or mental capacities, is likely to change societal norms, raise issues of equitable access and generate new forms of discrimination."¹⁶⁸ A more contemporary challenge, as potentially exacerbated by the growth in consumer-grade devices, is the risk that the processing of brain and other neural data in neurotechnologies may lead to differential treatment based on "a person's neural signatures (indicating, for example, a dementia predisposition), or mental health, personality traits, cognitive performance, intentions and emotional states."¹⁶⁹ Ienca terms this phenomenon "neurodiscrimination", and advocates "strict and broad prohibitions against neurodiscrimination in the context of health insurance, including employer-based health insurance".¹⁷⁰

Existing statutory disability law in the U.S. offers protection against similar and overlapping forms of discrimination but does not prohibit "neurodiscrimination" specifically. The Americans with Disabilities Act (1990), for instance, prohibits discrimination "on the basis of disability" in a variety of contexts, including employment,¹⁷¹ and defines disability broadly;¹⁷² indicatively including within its definition "a physical or mental impairment that substantially limits one or more major life activities", including neurological and brain functions.¹⁷³ While this may in principle prohibit employers from discriminating against individuals with neurological diseases and disorders, the scope of this protection is restricted to the employment context. Broader protection against discrimination is offered by the Genetic Information Nondiscrimination Act (2008), which prohibits discrimination in relation to both health insurance and employment on the basis of genetic information pertaining to personal genetic tests, the genetic tests of family members and disease or disorder in family members.¹⁷⁴ Whilst restricted to genetic information, this federal law could serve as a model for the establishment of comparable protections against the misuse of brain and other neural data to discriminate in healthcare insurance and employment contexts.¹⁷⁵

¹⁶⁵ International Covenant on Civil and Political Rights (entry into force 23 March 1976) G.A. Res 2200A (XXI), Art.26.

¹⁶⁶ U.S. Const. Amend XV, XIX.

¹⁶⁷ 29 U.S.C. §206(d).

¹⁶⁸ Yuste, R. et al. (2017) 'Four ethical priorities for neurotechnologies and AI', *Nature*, Vol.551, pp.159-163, pp.162. DOI: <https://doi.org/10.1038/551159a>

¹⁶⁹ Ienca, M. (2021) 'Common Human Rights Challenges Raised by Different Applications of Neurotechnologies in Biomedical Fields', *Committee on Bioethics (DH-BIO) of the Council of Europe*, pp.32. Available at: <https://rm.coe.int/report-final-en/1680a429f3>

¹⁷⁰ Ibid.

¹⁷¹ 42 U.S.C §12112(a).

¹⁷² 42 U.S.C §12102(4)(A).

¹⁷³ 42 U.S.C §12102(2)(B).

¹⁷⁴ 42 U.S.C. §2000ff(4)(A)(i)-(iii).

¹⁷⁵ Jwa, A.S. and Poldrack, R.A. (2022) 'Addressing privacy risk in neuroscience data: from data protection to harm prevention', *Journal of Law and the Biosciences*, Vol.9:2, pp.1-25. DOI: <https://doi.org/10.1093/jlb/ljac025>



Freedom of thought

It is stipulated in the ICCPR that “Everyone shall have the right to freedom of thought, conscience and religion.”¹⁷⁶ The equivalent provision of the U.S. Constitution, namely the First Amendment, provides that “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.”¹⁷⁷ Whilst substantively similar, a key difference between these provisions is the express inclusion of the “right to freedom of thought” in the ICCPR and the absence of explicit protections for this right in the U.S. Constitution; a potentially salient difference in the light of the declaration made by the U.S. that the former provision is “not self-executing” and cannot therefore be applied by domestic courts without implementing legislation.¹⁷⁸ In its case law, however, the U.S. Supreme Court has interpreted the First Amendment to include an unenumerated right to freedom of thought, although it has mostly failed to take “a clear position on whether thought must be intertwined with expression in order to be protected.”¹⁷⁹ In *Stanley v. Georgia*,¹⁸⁰ for instance, it was observed in dictum that “the right to control the moral content of a person’s thoughts...is wholly inconsistent with the philosophy of the First Amendment”,¹⁸¹ yet the facts of the case, which involved the defendant being charged with knowingly possessing obscene films, could equally point to protection of the right to freedom of expression.¹⁸²

The right to freedom of thought assumes distinctive importance in the context of neurotechnology, in relation to which both invasive and non-invasive techniques could be used to record brain activity and deduce thoughts for a variety of applications.¹⁸³ For example, “brain-based mind reading” may at present or in the future be applied in the context of forensic psychiatry to assess defendants, prisoners and prospective jurors,¹⁸⁴ while computer games involving brain mapping to spatialise user intentions are emerging as an alternative to gaming involving the use of traditional control methods.¹⁸⁵ Although such and similar use cases (e.g., neuroprosthetic technology)¹⁸⁶ are socially and economically beneficial, there is growing concern that neurotechnology may in the future be used to sanction inferred thoughts,¹⁸⁷ or to otherwise target individuals through “neuromarketing” in order to elicit certain specific consumer behaviours.¹⁸⁸ In such circumstances, the U.S. Supreme Court may be required to

¹⁷⁶ International Covenant on Civil and Political Rights (entry into force 23 March 1976) G.A. Res 2200A (XXI), Art.18.

¹⁷⁷ U.S. Const. Amend. I.

¹⁷⁸ U.S. Reservations, Declarations, and Understandings, International Covenant on Civil and Political Rights, 138 Cong. Rec. S4781-01 (1992), §3(1).

¹⁷⁹ Kolber, A.J. (2016) ‘Two Views of First Amendment Thought Privacy’, *Journal of Constitutional Law*, Vol.18:5, pp.1381-1423. Available at: <https://scholarship.law.upenn.edu/jcl/vol18/iss5/2>

¹⁸⁰ *Stanley v. Georgia*, 394 U.S. 557 (1969).

¹⁸¹ *Ibid* at 565-66.

¹⁸² Kolber, A.J. (2016) ‘Two Views of First Amendment Thought Privacy’, *Journal of Constitutional Law*, Vol.18:5, pp.1381-1423, pp.1394-95. Available at: <https://scholarship.law.upenn.edu/jcl/vol18/iss5/2>

¹⁸³ U.N. Special Rapporteur on freedom of religion or belief. (2021) *Interim report of the Special Rapporteur on freedom of religion or belief*, Ahmed Shaheed. A/76/380, para.76.

¹⁸⁴ Meynen, G. (2017) ‘Brain-based mind reading in forensic psychiatry: exploring possibilities and perils’, *Journal of Law and the Biosciences*, Vol.4:2, pp.311-329. DOI: <https://doi.org/10.1093/jlb/lbx006>

¹⁸⁵ Rosca, S-D. and Leba, M. (2019) ‘Design of a Brain-Controlled Video Game based on a BCI System’, *MATEC Web of Conferences*, Vol.290. DOI: <https://doi.org/10.1051/mateconf/201929001019>

¹⁸⁶ See, e.g., Collinger, J.L. et al. (2013) ‘Neuroprosthetic technology for individuals with spinal cord injury’, *The Journal of Spinal Cord Medicine*, Vol.36:4, pp.258-272. DOI: <https://doi.org/10.1179%2F2045772313Y.0000000128>

¹⁸⁷ U.N. Special Rapporteur on freedom of religion or belief. (2021) *Interim report of the Special Rapporteur on freedom of religion or belief*, Ahmed Shaheed. A/76/380, para.77.

¹⁸⁸ See, e.g., Vences, N.A., Diaz-Campo, J., and Garcia Rosales, D.F. (2020) ‘Neuromarketing as an Emotional Connection Tool Between Organisations and Audiences in Social Networks. A Theoretical Review’, *Frontiers in Psychology*, Vol.11. DOI: <https://doi.org/10.3389/fpsyg.2020.01787>



decide whether the First Amendment protects the privacy of thoughts independently of or only when intertwined with expression, the outcome of which is likely to determine the scope of constitutional protections for the unenumerated right to freedom of thought.¹⁸⁹

Freedom from torture

The prohibition against torture is a *jus cogens* norm of customary international law, reflected in both international treaties to which the U.S. is a state party and municipal law. The ICCPR, for instance, states that “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.”¹⁹⁰ Whilst not specified, it may be inferred from this that subjecting an individual to non-consensual medical or scientific experimentation involving the use of neurotechnologies would in principle constitute a prohibited act of torture, cruel, inhuman or degrading treatment. The CAT reiterates this prohibition on torture (and other forms of cruel, inhuman or degrading treatment or punishment), defined as “any act by which severe pain or suffering, whether physical *or mental*, is intentionally inflicted on a person”, thereby indicating *prima facie* application to acts involving neurotechnology, to be determined on the basis of the purpose for which it was committed.¹⁹¹ From this it can be inferred that, by way of example, the use of neural implants as an instrument of torture to produce various harmful effects, including memory and emotion manipulation and inducement of hallucinations,¹⁹² is likely to be prohibited. Furthermore, in accordance with its obligations under CAT,¹⁹³ the U.S. has codified the criminalisation of torture committed outside the United States by a U.S. national or by an offender who is present in its jurisdiction.¹⁹⁴ This reinforces the unconditional prohibition on torture, in relation to which relevant legal doctrine also includes various state and federal laws criminalising acts of violence against the person (e.g., battery and assault)¹⁹⁵ as well as the unenumerated constitutional protections provided by the Fourth,¹⁹⁶ Fifth,¹⁹⁷ Eighth (which is most directly applicable in referring to “cruel and unusual punishments”),¹⁹⁸ and Fourteenth Amendments.¹⁹⁹

Notwithstanding these various legal protections, the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment has warned that advances in neurotechnology and other emerging technologies may present new difficulties to the enforcement of the prohibition on torture.²⁰⁰ Such novel challenges include the potential for “neurotechnological devices” to be used as “an ‘enabler’ in the perpetration of both physical and psychological forms of torture”,²⁰¹ as well as the possibility that “rapid advances in medical, pharmaceutical and neurotechnological science”, particularly with the emergence of neurotechnology enhancement or augmentation (see above), may cause a

¹⁸⁹ Kolber, A.J. (2016) ‘Two Views of First Amendment Thought Privacy’, *Journal of Constitutional Law*, Vol.18:5, pp.1381-1423. Available at: <https://scholarship.law.upenn.edu/jcl/vol18/iss5/2>

¹⁹⁰ International Covenant on Civil and Political Rights (entry into force 23 March 1976) G.A. Res 2200A (XXI), Art.7.

¹⁹¹ Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (entry into force 26 June 1987) G.A. Res. 39/46, Art.1(1) (emphasis added).

¹⁹² Pérez-Sales, P. (2022) ‘The future is here: Mind control and torture in the digital era’, *Torture Journal*, Vol.32:1-2, pp.280-290. DOI: <https://doi.org/10.7146/torture.v32i1-2.132846>

¹⁹³ Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (entry into force 26 June 1987) G.A. Res. 39/46, Art.4, 5.

¹⁹⁴ 18 U.S.C §2340A.

¹⁹⁵ E.g., 18 U.S.C; Ala. Code 1975 §16-3-35.

¹⁹⁶ U.S Const. Amend IV.

¹⁹⁷ U.S. Const. Amend V.

¹⁹⁸ U.S. Const. Amend VIII.

¹⁹⁹ U.S. Const. Amend. XIV.

²⁰⁰ U.N. Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment. (2020) *Report on psychological torture and ill-treatment*. A/HRC/43/49.

²⁰¹ *Ibid* para.73.



definitional lacuna by allowing “the subjective experience of pain and suffering to be circumvented, suppressed or otherwise manipulated while still achieving the purposes and the profoundly dehumanising, debilitating and incapacitating effects of torture.”²⁰² In order to ensure effective implementation of the prohibition on torture, the Special Rapporteur recommends that interpretation of this and other related obligations under international human rights law “should evolve in line with [the] new challenges and capabilities” that arise in relation to neurotechnology and other emerging technologies.²⁰³

Right to life

Although only implicit in the Bill of Rights amendment to the U.S. Constitution,²⁰⁴ the right to life is expressly guaranteed in the ICCPR, which provides that “Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.”²⁰⁵ However, the emerging potential for neurotechnologies to be used for military applications may present a future challenge to the adequate protection of this right. For example, DARPA’s N³ program aims to develop bidirectional brain-machine interfaces (BMIs) for the purposes of controlling unmanned aerial vehicles (UAV),²⁰⁶ yet such technology could conceivably in the future be deployed in conjunction with Artificial Intelligence (AI) to control weapons systems. One such posited scenario is the use of electroencephalography (EEG) by the operator of an UAV to make missile targeting decisions.²⁰⁷ Such applications may give rise to issues with relevance to both international humanitarian law and international human rights law; the latter insofar as the control of weapons systems via algorithmic processing of brain signals may result in arbitrary deprivation of life.²⁰⁸ In addition to potential military applications, consumer-grade neurotechnological devices could also pose a threat to the right to life. The founder of Oculus, for instance, claims to have designed a virtual reality (VR) headset with built-in explosives designed to detonate and destroy an end-user’s brain simultaneous with the point at which ‘death’ occurs within virtual gameplay.²⁰⁹ The aporetic conflict between such a gaming experience and the legal protection for the right to life, however, means that it is unlikely any such or similar device with the same intended use for gaming purposes could be made commercially available, at least not without explicit recognition that the right to life also includes ‘the right to die’, including through available technological means.²¹⁰

²⁰² Ibid para.32.

²⁰³ Ibid para.76.

²⁰⁴ U.S. Const. Amend. V, XIV.

²⁰⁵ International Covenant on Civil and Political Rights (entry into force 23 March 1976) G.A. Res 2200A (XXI), Art.6.

²⁰⁶ Sarma, G. (no date) *Next-Generational Nonsurgical Neurotechnology* / DARPA [Online]. Available at: <https://www.darpa.mil/program/next-generation-nonsurgical-neurotechnology>

²⁰⁷ Noll, G. (2014) ‘Weaponizing neurotechnology: international humanitarian law and the loss of language’, *London Review of International Law*, Vol.2:2, pp.201-231. DOI: <https://doi.org/10.1093/lril/lru009>

²⁰⁸ Genser, J., Herrmann, S., and Yuste, R. (2022) *International Human Rights Protection Gaps in the Age of Neurotechnology*. *NeuroRights Foundation*, pp.29. Available at: <https://static1.squarespace.com/static/60e5c0c4c4f37276f4d458cf/t/6275130256dd5e2e11d4bd1b/1651839747023/Neurorights+Foundation+PUBLIC+Analysis+5.6.22.pdf>

²⁰⁹ Huet, N. (2022) *Oculus founder claims he made a VR headset that actually kills you if you die in a game* / *euronews.next* [Online]. Available at: <https://www.euronews.com/next/2022/11/09/oculus-founder-claims-he-made-a-vr-headset-that-actually-kills-you-if-you-die-in-a-game>

²¹⁰ See generally, Sunstein, C.R. (1996) ‘Right to Die, The’, *Yale Law Journal*, Vol.106, pp.1123-1163. Available at: https://chicagounbound.uchicago.edu/journal_articles/8539/



3.2 Privacy and data protection law

The interconnected issues of personal data protection and informational privacy have become increasingly important with the rise of new and emerging technologies capable of collecting and processing substantial volumes and various types of data, including information of protected value. In relation to neurotechnology, specifically, the potential for brain and other neural data to reveal sensitive characteristics through processing is significant.²¹¹ Against this background, this section will first explore whether and if so, how the U.S. Constitution protects informational privacy and personal data (Section 3.2.1). It will then go on to provide an overview of the data privacy statutes and regulations at the state and federal level, following which selected examples of the latter will be situated in relation to specific neurotechnology use cases, including healthcare, employment and education (Section 3.2.2).

3.2.1 The right to privacy and data protection

There is no explicit guarantee of the rights to privacy or data protection under the U.S. Constitution. In its case law, however, the U.S. Supreme Court has identified a number of unenumerated constitutional protections for privacy interests rooted in, inter alia, the First Amendment,²¹² the Third Amendment protection of the privacy of the home against compulsory quartering of soldiers,²¹³ and the Fourth Amendment “right of people to be secure in their persons, houses, papers, and effects, [and] against unreasonable searches and seizures”.²¹⁴ In relation to the latter, the U.S. Supreme Court initially took a narrowly textual approach to its interpretation of this provision, finding in *Olmstead v. United States* that governmental wiretapping did not amount to an interference with the Fourth (or Fifth) Amendment since it did not involve a physical or actual trespass.²¹⁵ The judgement is arguably most significant, however, for the dissent of Justice Brandeis who, building upon an argument made extrajudicially advocating the formal recognition and protection of the right to privacy by the courts in order to combat the threats posed by technological innovations,²¹⁶ stated

The makers of our Constitution...conferred, as against the Government, the right to be let alone – the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable interference by the Government upon the privacy of the individual, whatever the means employed, must be deemed a violation of the Fourth Amendment.²¹⁷

Justice Brandeis’ dissent informed the Supreme Court’s subsequent approach in *Katz v. United States*,²¹⁸ in which the Court overruled the precedent from *Olmstead* and “departed from the narrow view on which that decision rested.”²¹⁹ Specifically, the Court reasoned that the application of the Fourth Amendment “cannot turn upon the presence or absence of a physical intrusion” and that “reasonable expectations of privacy may be defeated by electronic as well as physical invasion.”²²⁰ *Katz* thus established the “reasonable expectation of privacy”²²¹ test as the prevailing test for determining

²¹¹ Rainey, S. et al. (2019) ‘Data as a Cross-Cutting Dimension of Ethical Importance in Direct-to-Consumer Neurotechnologies’, *AJOB Neuroscience*, Vol.10:4, pp.180-182. DOI: <https://doi.org/10.1080/21507740.2019.1665134>

²¹² U.S. Const. Amend. I; See, e.g., *NAACP v. Alabama*, 357 U.S. 449 (1958).

²¹³ U.S. Const. Amend. III; See, e.g., *Griswold v. Connecticut*, 381 U.S. 479 (1965).

²¹⁴ U.S. Const. Amend. IV.

²¹⁵ *Olmstead et al. v. United States*, 277 U.S. 438 (1928).

²¹⁶ Warren, S.D. and Brandeis, L.D. (1890) ‘The Right to Privacy’, *Harvard Law Review*, Vol.4:5, pp.193-220. DOI: <https://doi.org/10.2307/1321160>

²¹⁷ *Olmstead et al. v. United States*, 277 U.S. 438 (1928), 479.

²¹⁸ *Katz v. United States*, 389 U.S. 347 (1967).

²¹⁹ *Ibid* at 353.

²²⁰ *Ibid* at 362.

²²¹ *Ibid* at 361.

whether there has been an infringement with Fourth Amendment protections against unreasonable searches and seizures by law enforcement, as well as “the test that substantially all of the federal circuit of appeals use to determine whether a constitutional right to informational privacy attaches to an asserted liberty interest” in relation to the Fourteenth Amendment.²²²

However, it was also observed in the majority opinion of Justice Stewart that

the Fourth Amendment cannot be translated into a general constitutional “right to privacy.” That Amendment protects individual privacy against certain kinds of governmental intrusion, but its protections go further and often have nothing to do with privacy at all. Other provisions of the Constitution protect personal privacy from other forms of governmental invasion. But the protection of a person’s general right to privacy – his right to be let alone by other people – is, like the protection of his property and of his very life, left largely to the law of the individual States.²²³

Whilst in principle this has the effect of narrowing the Fourth Amendment protections for the right to privacy, it has been suggested that this statement should be treated as mere dicta on the basis that the petitioner was not seeking to assert such a right and instead relied on a specific interpretation of the Fourth Amendment to protect against the warrantless recording of private telephone conversations.²²⁴

In addition to the Fourth Amendment, the liberty guaranteed under the Due Process Clause of the Fourteenth Amendment²²⁵ has, as indicated above, also been interpreted as protecting privacy.²²⁶ In *Whalen v. Roe*,²²⁷ for instance, the Supreme Court implicitly recognised a constitutional right to privacy in relation to “two different kinds of interests. One is the individual interest in avoiding disclosure of personal matters, and another is the interest in independence in making certain kinds of important decisions.”²²⁸ This has been cited and re-affirmed in subsequent case law,²²⁹ and appears to be derived from the “right to be let alone” articulated by Justice Brandeis in *Olmstead*,²³⁰ to which the Court in *Whalen* referred to in its opinion.²³¹

The variety of constitutional safeguards for protecting against government interference with privacy interests,²³² notwithstanding, the focus of these protections upon limiting governmental overreach highlights the lack of similar constitutional protections in relation to privacy violations caused by private parties.²³³ Such rights are also unenumerated, meaning in exceptional circumstances the alteration of constitutional precedent could lead to privacy protections being rolled back. In *Dobbs v. Jackson Women’s Health Organisation*,²³⁴ for instance, U.S. the Supreme Court overruled its decisions in the

²²² Pittman, L.J. (2018) ‘The Elusive Constitutional Right to Informational Privacy’, *Nevada Law Journal*, Vol.19:1, pp.135-186, p.147. Available at: <https://scholars.law.unlv.edu/nlj/vol19/iss1/5>

²²³ *Katz v. United States*, 389 U.S. 347 (1967) 350-351.

²²⁴ Pittman, L.J. (2018) ‘The Elusive Constitutional Right to Informational Privacy’, *Nevada Law Journal*, Vol.19:1, pp.135-186, p.148. Available at: <https://scholars.law.unlv.edu/nlj/vol19/iss1/5>

²²⁵ U.S. Const. Amend XIV.

²²⁶ See, e.g., *Lawrence v. Texas*, 539 U.S. 558 (2003) 564-65.

²²⁷ *Whalen v. Roe*, 429 U.S. 589 (1977).

²²⁸ *Ibid* at 599-600.

²²⁹ See, e.g., *Nixon v. Administrator of General Services*, 433 U.S. 425 (1977).

²³⁰ *Olmstead et al. v. United States*, 277 U.S. 438 (1928), 479.

²³¹ *Whalen v. Roe*, 429 U.S. 589 (1977) at 599 n.25.

²³² Swire, P. and Kennedy-Mayo, D. (2017) ‘How Both the EU and the U.S. are “Stricter” Than Each Other for the Privacy of Government Requests for Information’, *Emory Law Journal*, Vol.66:3, pp.617-667. Available at: <https://scholarlycommons.law.emory.edu/elj/vol66/iss3/5>

²³³ Krishnamurthy, V. (2020) ‘A Tale of Two Privacy Laws: The GDPR and the International Right to Privacy’, *American Journal of International Law*, Vol.114, pp.26-30, p.29. DOI: <https://doi.org/10.1017/aju.2019.79>

²³⁴ *Dobbs v. Jackson Women’s Health Organisation*, 597 U.S. (2022).

*Roe*²³⁵ and *Casey*²³⁶ jurisprudence, accordingly finding that the Constitution does not confer a right to obtain an abortion, which had previously been found by the Court to be protected by the “right to privacy that springs from the First, Fourth, Fifth, Ninth and Fourteenth Amendments.”²³⁷ In accordance with the *Whalen* formulation the privacy interests at issue relate equally to the “independence in making certain kinds of important decisions” and the “individual interest in avoiding disclosure of personal matters”,²³⁸ thereby indicating that the constitutional protections for the different aspects of the right to privacy may be subject to further erosion.²³⁹

3.2.2 Data privacy law

In addition to the unenumerated constitutional protections for the right to informational privacy (see above), there exists a substantial and growing body of statutory and regulatory information or data privacy laws at both the federal and state level. In comparison to the predominant approach in European Union (EU) Member States, particular features of U.S. data privacy law include the protection of consumers, rather than fundamental rights-holders, a segmented, sector-specific approach instead of more widely applicable data privacy regulation, and the base presumption “that personal data may be collected, used or disclosed unless a specific legal rule forbids these activities.”²⁴⁰ This section will proceed by first outlining general features and examples of state and then federal data privacy law, before considering in greater detail selected examples of the latter in relation to specific neurotechnology use cases.

State law

According to the National Conference of State Legislatures, in 2022 alone approximately 200 consumer data privacy bills have been filed across 35 states and the District of Columbia.²⁴¹ Of this number, a significant proportion (almost 70 bills across 25 states and the District of Columbia) proposed introducing comprehensive consumer privacy legislation.²⁴² Furthermore, in addition to the forthcoming expansion of the California Consumer Privacy Act of 2018 (CCPA) to include protections for employees,²⁴³ the states of Colorado,²⁴⁴ Connecticut,²⁴⁵ Virginia,²⁴⁶ and Utah²⁴⁷ have each enacted comprehensive consumer privacy laws, all of which will become effective in 2023.²⁴⁸

²³⁵ *Roe v. Wade*, 410 U.S. 113 (1973).

²³⁶ *Planned Parenthood of Southeastern Pa. v Casey*, 505 U.S. 833 (1992).

²³⁷ *Dobbs v. Jackson Women’s Health Organisation*, 597 U.S. (2022).

²³⁸ *Whalen v. Roe*, 429 U.S. 589 (1977) 599-600.

²³⁹ See, e.g., Morse, J. (2022) *Your privacy is at risk now that Roe v. Wade has fallen, experts warn* / Mashable [Online]. Available at: <https://mashable.com/article/supreme-court-roe-wade-digital-privacy>

²⁴⁰ Chander, A., Kaminski, M.E., and McGeeveran, W. (2021) ‘Catalysing Privacy Law’, *Minnesota Law Review*, Vol.15, pp.1733-1802, pp.1747-56. Available at: <https://scholar.law.colorado.edu/faculty-articles/1336>

²⁴¹ National Conference of State Legislatures (2022). *2022 Consumer Privacy Legislation* / [Online]. Available at: <https://www.ncsl.org/research/telecommunications-and-information-technology/2022-consumer-privacy-legislation.aspx>.

²⁴² Ibid.

²⁴³ California Privacy Rights Act of 2020 (Proposition 24).

²⁴⁴ Colorado Privacy Act, 2021 S.B. 190 (Effective 1 July 2023).

²⁴⁵ Connecticut 2022 S.B. 6 (Personal Data Privacy and Online Monitoring) (Effective 1 July 2023).

²⁴⁶ Virginia Consumer Data Protection Act, 2021 H.B. 2307 | 2021 S.B. 1392 (Effective 1 January 2023).

²⁴⁷ Utah Consumer Privacy Act, 2022 S.B. 227 (Effective 31st December 2023).

²⁴⁸ National Conference of State Legislatures (2022). *2022 Consumer Privacy Legislation* / [Online]. Available at: <https://www.ncsl.org/research/telecommunications-and-information-technology/2022-consumer-privacy-legislation.aspx>.

Federal law

Unlike the emerging trend towards state legislatures enacting omnibus data privacy laws,²⁴⁹ there is no single, primary federal law which comprehensively regulates all aspects of the collection, storage and use of data in the public and private sector. Instead, federal data privacy law in the US follows a sector-specific approach focusing on certain types of data and specific regulatory contexts, with the Gramm-Leach-Bliley Act or Financial Services Modernisation Act (1999),²⁵⁰ for instance, restricting the use and disclosure of customers' "non-public personal information" by financial institutions.²⁵¹ Other federal data privacy laws apply to specific sectors including health,²⁵² education,²⁵³ and video rentals,²⁵⁴ with longstanding consumer protection laws offering extra protection against privacy intrusions perpetuated by unfair and deceptive commercial practices.²⁵⁵

The primary federal consumer protection statute, the Federal Trade Commission Act (1914), for example, establishes the U.S. Federal Trade Commission (FTC),²⁵⁶ which is authorised to initiate law enforcement action against individuals and organisations that breach the prohibition on unfair or deceptive acts or practices in or affecting commerce.²⁵⁷ The broad remit of this statutory power extends to bringing legal proceedings against companies that violate consumer data privacy rights, or that fail to maintain adequate security procedures for sensitive consumer information.²⁵⁸ In 2015, for example, the FTC brought enforcement action against and eventually settled with Carrot Neurotechnology, Inc., which it accused of making deceptive health-related claims relating to improvements in vision resulting from the use of a software application marketed by the accused.²⁵⁹ The FTC is also responsible for enforcing the various other federal laws relating to consumer data privacy and security,²⁶⁰ selected examples of which are outlined in relation to specific neurotechnology use cases below.

Healthcare

Neurotechnologies have a range of applications in clinical research, care and management contexts, including stage mapping of neurological diseases, such as Parkinson's.²⁶¹ Whilst beneficial to the overall provision of healthcare, such applications also raise potential data privacy issues relating to the collection, use and disclosure of brain and other neural data. The Health Insurance Portability and Accountability Act (HIPAA) (1996), as implemented by the Privacy Rule published by the Department of

²⁴⁹ Schwartz, P.M. and Nikolaus-Peifer, K. (2017) 'Transatlantic Data Privacy Law', *The Georgetown Law Journal*, Vol.106:1, pp.115-179. Available at: <https://www.law.georgetown.edu/georgetown-law-journal/in-print/volume-106/volume-106-issue-1-november-2017/transatlantic-data-privacy-law/>

²⁵⁰ Financial Services Modernisation Act of 1999, Pub. L. 106-102.

²⁵¹ 15 U.S.C §6801.

²⁵² Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-19.

²⁵³ Family Education Rights and Privacy Act of 1974, Pub. L. 90-247.

²⁵⁴ Video Privacy Protection Act of 1988, Pub. L. 100-618.

²⁵⁵ Krishnamurthy, V. (2020) 'A Tale of Two Privacy Laws: The GDPR and the International Right to Privacy', *American Journal of International Law*, Vol.114, pp.26-30, p.29. DOI: <https://doi.org/10.1017/ajil.2019.79>

²⁵⁶ 15 U.S.C §41-58.

²⁵⁷ 15 U.S.C §45.

²⁵⁸ Federal Trade Commission. *Privacy and Security Enforcement* / [Online]. Available at: <https://www.ftc.gov/news-events/topics/protecting-consumer-privacy-security/privacy-security-enforcement>

²⁵⁹ Federal Trade Commission. (2015) *FTC Charges Marketers of 'Vision Improvement' App With Deceptive Claims* / Press Release [Online]. Available at: <https://www.ftc.gov/news-events/news/press-releases/2015/09/ftc-charges-marketers-vision-improvement-app-deceptive-claims>

²⁶⁰ Federal Trade Commission. (no date) *Privacy and Security Enforcement* / [Online]. Available at: <https://www.ftc.gov/news-events/topics/protecting-consumer-privacy-security/privacy-security-enforcement>

²⁶¹ Mitchell, T. et al. (2021) 'Emerging Neuroimaging Biomarkers Across Disease Stage in Parkinson Disease: A Review', *JAMA Neurology*, Vol.78:10, pp.1262-1272. DOI: <https://doi.org/10.1001/jamaneurol.2021.1312>



Health and Human Services (HHS),²⁶² restricts the use and disclosure,²⁶³ except in specified circumstances, of “protected health information” maintained or transmitted by a “covered entity”, whether in electronic or “any other form or medium”.²⁶⁴ The Privacy Rule protects “individually identifiable health information”, defined as “a subset of health information, including demographic information collected from an individual” that is created or received by a covered entity; relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual or the past, present or future payment for the provision of health care to an individual”; and that identifies the individual or there is “a reasonable basis to believe the information can be used to identify the individual.”²⁶⁵ Therefore, although not expressly included, the use and disclosure of brain and other neural data that constitutes “protected health information” according to this definition would be restricted.

The covered entities to which this regulation applies, however, is limited to health plans, health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a transaction, such as health care claims, payment and benefits.²⁶⁶ As such, whilst the scope of application is slightly extended by the inclusion of “business associates” connected to covered entities,²⁶⁷ there remains a broad range of noncovered entities that are not subject to compliance with these regulations, such as employers and companies that market consumer wellness neurotechnology, including brain computer interfaces (BCIs),²⁶⁸ a type of neurotechnological device enabling direct and occasionally bidirectional communication between the brain and an external computer-based system.²⁶⁹ A related concern is the risk that emerging AI and machine learning techniques,²⁷⁰ such as automated face recognition algorithms,²⁷¹ may be used to reidentify brain and other neural data that has been subject to conventional methods of deidentification, and thereby circumnavigate the absence of restrictions to the use or disclosure of protected health information subject to the HIPAA standard for deidentification.²⁷² The possible privacy risks, notwithstanding, this report did not identify a particular policy or legislative development aimed at addressing this gap in the existing regulation.

Gaming and Entertainment

Although initially developed and still most widely used for clinical medicine and neuroscience research purposes, neurotechnology is also increasingly available to consumers for a wide variety of non-clinical applications, including gaming and other forms of entertainment.²⁷³ Typically retrofitted to existing

²⁶² 45 C.F.R §160.101-105; §164.102 et seq.

²⁶³ 45 C.F.R §164.502(a).

²⁶⁴ 45 C.F.R §160.103.

²⁶⁵ 45 C.F.R §160.103.

²⁶⁶ 45 C.F.R §§160.102-103.

²⁶⁷ 45 C.F.R §§160.102-160.103.

²⁶⁸ Greenberg, J. et al. (2021) ‘Privacy and the Connected Mind. Understanding the Data Flows and Privacy Risks of Brain-Computer Interfaces’, *Future of Privacy Forum*, pp.1-40, pp.12. Available at: <https://fpf.org/wp-content/uploads/2021/11/FPF-BCI-Report-Final.pdf>

²⁶⁹ Saha, S. et al. (2021) ‘Progress in Brain Computer Interface: Challenges and Opportunities’, *Frontiers in Systems Neuroscience*, Vol.15. DOI: <https://doi.org/10.3389/fnsys.2021.578875>

²⁷⁰ Jwa, A.S. and Poldrack, R.A. (2022) ‘Addressing privacy risk in neuroscience data: from data protection to harm prevention’, *Journal of Law and the Biosciences*, Vol.9:2, pp.1-25, p.8. DOI: <https://doi.org/10.1093/jlbb/lzac025>

²⁷¹ Schwartz, C.G. et al. (2021) ‘Changing the face of neuroimaging research: Comparing a new MRI de-facing technique with popular alternatives’, *NeuroImage*, Vol.231, pp.1-12. DOI: <https://doi.org/10.1016/j.neuroimage.2021.117845>

²⁷² 45 C.F.R. §§164.514.

²⁷³ Ienca, M. and Andorno, R. (2017) ‘Towards new human rights in the age of neuroscience and neurotechnology’, *Life Sciences, Society and Policy*, Vol.13:5, p.4 DOI: <https://doi.org/10.1186/s40504-017-0050-1>



devices via head mounted displays (HMDs) or other external device, such applications include non-invasive electroencephalographic (EEG)-based BCIs, which record, collect and interpret the user's electrical impulses and translate such brain and other neural data into outputs.²⁷⁴ The main privacy risks raised by such applications relate to the inferences that can be drawn from the collection of brain and other neural data, which might be of even greater sensitivity than other biological indicators, such as eye tracking.²⁷⁵ In particular, there is the risk that the direct recording of brain and other neural signals may lead to users revealing information involuntarily or without meaningful consent, that could be used by developers or other third parties in unanticipated or potentially harmful ways, such as to track and predict user behaviour.²⁷⁶ The practice of "neuromarketing", describing the process by which consumer behaviours can be analysed, profiled and predicted through neurotechnological applications, is of increasing commercial value for companies specialising in the area, such as MindLab International.²⁷⁷

An additional potential risk is that brain and other neural data could be used to target special categories of person, such as children.²⁷⁸ At the federal level, the main protection against such potential privacy invasions is granted to children via the Children's Online Privacy Protection Act (COPPA) (1998).²⁷⁹ COPPA regulates the collection of information from and about children under 13 years of age on the internet or an online service, specifically by stipulating that the collection, use or disclosure of such information is subject to the operator of a website or online service providing notice of what information is used, how it is used, and the relevant disclosure practices in operation, as well as being required to obtain verifiable parental consent.²⁸⁰ The statute applies to operators who collect or maintain "personal information" from users,²⁸¹ as defined as "individually identifiable information about an individual collected online",²⁸² such as physical or email address,²⁸³ as well as "any other identifier that the Commission determines permits the physical or online contacting of a specific individual; or information concerning the child or the parents of that child that the website collects online from the child and combines with an identifier".²⁸⁴ Whilst not expressly included, the use of a child's brain or other neural data could therefore be covered under the terms of the statute if considered a type of identifier permitting the child to be identified and contacted. Furthermore, as part of its ten-year review brought forward, the FTC has conducted a public consultation on the implementation of COPPA, in which it considered, amongst other things, whether to revise the definition of "personal information" to include "biometric data", such as genetic data, fingerprints and retinal scans.²⁸⁵ Although not explicitly identified, this definition could also conceivably include or be extended to brain and other neural data.

²⁷⁴ Greenberg, J. et al. (2021) 'Privacy and the Connected Mind. Understanding the Data Flows and Privacy Risks of Brain-Computer Interfaces', *Future of Privacy Forum*, pp.1-40, pp.15. Available at: <https://fpf.org/wp-content/uploads/2021/11/FPF-BCI-Report-Final.pdf>

²⁷⁵ Ibid 17.

²⁷⁶ Heller, B. (2021) 'Watching Androids Dream of Electric Sheep: Immersive Technology, Biometric Psychography, and the Law', *Vanderbilt Law Review*, Vol.23:1, pp.1-51. Available at: <https://scholarship.law.vanderbilt.edu/jetlaw/vol23/iss1/1>

²⁷⁷ Ienca, M. (2021) 'Common Human Rights Challenges Raised by Different Applications of Neurotechnologies in Biomedical Fields', *Committee on Bioethics (DH-BIO) of the Council of Europe*, pp.24. Available at: <https://rm.coe.int/report-final-en/1680a429f3>

²⁷⁸ Greenberg, J. et al. (2021) 'Privacy and the Connected Mind. Understanding the Data Flows and Privacy Risks of Brain-Computer Interfaces', *Future of Privacy Forum*, pp.1-40, pp.16. Available at: <https://fpf.org/wp-content/uploads/2021/11/FPF-BCI-Report-Final.pdf>

²⁷⁹ 15 U.S.C §6501-6506.

²⁸⁰ 15 U.S.C §6502(b)(1)(A)(i)-(ii).

²⁸¹ 15 U.S.C §6501 (2)(A).

²⁸² 15 U.S.C. §6501(8).

²⁸³ 15 U.S.C §6501(8)(B)-(C).

²⁸⁴ 15 U.S.C §6501(F)-(g)

²⁸⁵ Federal Trade Commission. (2019) *Request for Public Comment on the Federal Trade Commission's Implementation of the Children's Online Privacy Protection Rule*. 84 FR 35842. Available at:

Based on the type(s) of data being collected, particularly through non-invasive EEG-based BCIs used for gaming, also relevant in this context are the biometric privacy laws enacted at state level, which at the time of writing number at three (Illinois, Texas and Washington).²⁸⁶ Seven other states, including California, Missouri and New York, are at the time of writing considering similar legislative proposals, which are broadly based around the first and most robust of the biometric privacy laws,²⁸⁷ namely the Illinois Biometric Information Privacy Act (BIPA) (2008).²⁸⁸ BIPA establishes various procedures in relation to the retention, collection, disclosure and destruction of “biometric identifiers or biometric information” by private entities,²⁸⁹ while also empowering individuals with a right of action to seek relief for statutory violations.²⁹⁰ It defines “biometric identifiers” and “biometric information” separately, with the former meaning “a retina or iris scan, fingerprint, voiceprint, or scan of hand or face geometry.”²⁹¹ Indicatively, expressly excluded from this narrow definition are magnetic resonance imaging (MRI) scans and other techniques that create “image or film of the human anatomy used to diagnose, prognose or treat an illness or other medical condition or to further validate scientific testing or screening.”²⁹² Other state biometric privacy laws may offer greater interpretative flexibility for the inclusion of brain and other neural data used to or capable of identifying an individual, with the Washington state law, for instance, defining “biometric identifier” more broadly as “data generated by automatic measurements of an individual’s biological characteristics, such as a fingerprint, voiceprint, eye retinas, irises, or other unique biological patterns or characteristics that are used to identify a specific individual.”²⁹³ However, the framing of these laws in terms of biometric data for identification may give rise to regulatory gaps and challenges relating to novel data processing activities, such as the practice of inferring user preferences through a process conceptualised as “biometric psychography”.²⁹⁴

Employment

In an employment context, the use of neurotechnology may in the future permit employers to modify employee abilities and may enable screening of prospective employees for desirable traits.²⁹⁵ Such and similar applications involving brain scanning, biomonitoring, or cognitive modification may give rise to data privacy concerns in relation to the protection of brain and other neural data.²⁹⁶ In the existing patchwork of federal law, however, there exists limited protection for individuals against data privacy infringements arising in an employment context through the misuse of brain and other neural data. The U.S. Privacy Act (1974), as amended,²⁹⁷ protects employees’ personal information by establishing various requirements for federal agencies in maintaining relevant records systems, including a conditional prohibition on disclosure and the right of individual access to and amendment of any such

<https://www.federalregister.gov/documents/2019/07/25/2019-15754/request-for-public-comment-on-the-federal-trade-commissions-implementation-of-the-childrens-online>

²⁸⁶ DiRago, M.S. et al. (2022) *A Fresh “Face” of Privacy: 2022 Biometric Laws* / Troutman Pepper [Online]. Available at: <https://www.troutman.com/insights/a-fresh-face-of-privacy-2022-biometric-laws.html>

²⁸⁷ Ibid.

²⁸⁸ 740 ILCS 14.

²⁸⁹ 740 ILCS 14/15.

²⁹⁰ 740 ILCS 14/20.

²⁹¹ 740 ILCS 14/10.

²⁹² Ibid.

²⁹³ RCW 19.375.010.

²⁹⁴ Heller, B. (2021) ‘Watching Androids Dream of Electric Sheep: Immersive Technology, Biometric Psychography, and the Law’, *Vanderbilt Law Review*, Vol.23:1, pp.1-51. Available at: <https://scholarship.law.vanderbilt.edu/jetlaw/vol23/iss1/1>

²⁹⁵ Hopkins, P.D. and Fiser, H.L. (2017) “This Position Requires Some Alteration of Your Brain”: On the Moral and Legal Issues of Using Neurotechnology to Modify Employees’, *Journal of Business Ethics*, Vol.144, pp.783-797. DOI: <https://doi.org/10.1007/s10551-016-3182-y>

²⁹⁶ Ibid 789.

²⁹⁷ 5 U.S.C §552a.



records.²⁹⁸ However, the scope of this provision is limited in its application to the personal information maintained by federal employees.²⁹⁹

The Electronic Communications Privacy Act (1986),³⁰⁰ meanwhile, offers some protection for employees against monitoring of personal communications, but may allow employer monitoring of communications that take place via company-owned electronic devices.³⁰¹ Finally, the Employee Polygraph Protection Act (1988) prohibits employers from requiring or requesting, directly or indirectly, that any employee or prospective employee take a lie detector test.³⁰² Employers are also prohibited from using the results of such a test and taking discriminatory action against any employee or prospective employee who does not take such a test, or on the basis of the results of such a test.³⁰³ Whilst drafted with application to polygraph tests in mind, the definition of “lie detector” includes “psychological stress evaluator, or any other similar device”,³⁰⁴ thereby indicating that if existing neurotechnologies for lie-detection are to be used by employers,³⁰⁵ then it will follow that the privacy and right to non-discrimination (see Section 3.1) of private sector employees will be covered and protected.

Education

The education system is an emerging use case for neurotechnologies, in particular brain computer interfaces (BCIs).³⁰⁶ In this context, such technology may be used for a variety of purposes, including to diagnose and provide tailored interventions for students with learning disabilities,³⁰⁷ as well as to improve understanding of how the brain works during the learning process,³⁰⁸ the findings from which might be used to enhance the overall effectiveness of educational methods.³⁰⁹ However, such and similar applications involving the collection, processing and sharing of significant volumes of brain and other neural data may present a number of data privacy risks, such as making decisions about students’

²⁹⁸ 5 U.S.C §552a(b)-(d).

²⁹⁹ 5 U.S.C §552b(1).

³⁰⁰ 18 U.S.C. §§2701-2713.

³⁰¹ Greenberg, J. et al. (2021) ‘Privacy and the Connected Mind. Understanding the Data Flows and Privacy Risks of Brain-Computer Interfaces’, *Future of Privacy Forum*, pp.1-40, pp.19. Available at: <https://fpf.org/wp-content/uploads/2021/11/FPF-BCI-Report-Final.pdf>

³⁰² 29 U.S.C. §2002.

³⁰³ 29 U.S.C. §2002.

³⁰⁴ 29 U.S.C §2001.

³⁰⁵ See, e.g., Wolpe, P.R., Foster, K., Langleben, D.D. (2005) ‘Emerging neurotechnologies for lie-detection: promises and perils’, *American Journal of Bioethics*, Vol.5:2, pp.39-49. DOI: <http://dx.doi.org/10.1080/15265160590923367>

³⁰⁶ Wegemer, C. (2019) ‘Brain-computer interfaces and education: the state of technology and imperatives for the future’, *International Journal of Learning Technology*, Vol.14:2, pp.141-161. DOI: <https://dx.doi.org/10.1504/IJLT.2019.101848>

³⁰⁷ See, e.g., Prado, J. (2019) *Can neuroscience help predict learning difficulties in children / International Brain Research Organisation* [Online]. Available at: <https://solportal.ibe-unesco.org/articles/can-neuroscience-help-predict-learning-difficulties-in-children/>; See also, Coben et al. (2015) ‘The Impact of Coherence Neurofeedback on Reading Delays in Learning Disabled Children: A Randomized Controlled Study’, *NeuroRegulation*, 2(4). DOI: 10.15540/nr.2.4.168.

³⁰⁸ See, e.g., McCandliss B. and Toomarian, E. (2020) ‘Putting Neuroscience in the Classroom: How the Brain Changes As We Learn’, *Trend*. Available at: <https://www.pewtrusts.org/en/trend/archive/spring-2020/putting-neuroscience-in-the-classroom-how-the-brain-changes-as-we-learn>.

³⁰⁹ See, e.g., Lodge, J.M. and Harrison, W.H. (2019) ‘The Role of Attention in Learning in the Digital Age’, *Yale Journal of Biology and Medicine*, 92. Available at: <https://pubmed.ncbi.nlm.nih.gov/30923470/>.



cognitive abilities based on inaccurate or unreliable datasets.³¹⁰ Such and similar data privacy risks might also be particularly acute if the data relates to a student who is vulnerable due to age and/or disability.

Amongst the variety of federal privacy laws with application to the educational sector, most relevant is the Family Educational Rights and Privacy Act (FERPA) (1974)³¹¹ and the associated FERPA regulations.³¹² FERPA protects the privacy of students' "education records" by granting parents or eligible students rights of access, review and correction to such records, and prohibiting the release of the "personally identifiable information" contained therein without the written consent of an "eligible student" or that of their parents if the student is under eighteen years of age.³¹³ The statutory definition of "personally identifiable information" includes personal identifiers, "such as the student's social security number, student number or biometric record",³¹⁴ with the latter meaning "a record of one or more measurable biological or behavioural characteristics that can be used for automated recognition of an individual. Examples include fingerprints; retina and iris patterns; voiceprints; DNA sequence; facial characteristics; and handwriting."³¹⁵ Whilst not listed specifically, it is possible that with the growing use of neurotechnology in an educational context, there may be certain circumstances in which students' educational records containing brain and other neural data are protected under the terms of FERPA.³¹⁶

3.3 Use of neurotechnologies in the legal system

Neurotechnologies – and the brain and other neural data they produce – are increasingly relevant in both criminal and civil legal systems. Early forerunners (e.g., polygraph lie detection tests) to modern neurotechnological applications have been used in the courtroom since the early 20th century.³¹⁷ Yet, while not novel, the use of such technology (and discussion of its use) has grown considerably in the past two decades. For instance, the number of judicial opinions referencing neuroscience doubled from 2005 to 2012.³¹⁸

Theoretically, like any type of evidence, neuroscientific evidence could be introduced in court as evidence to prove or disprove a disputed fact. Neuroscientific evidence may be used for a variety of purposes and at various stages in both civil and criminal justice systems, including to assess competency to stand trial,³¹⁹ at the guilt phase to determine criminal culpability, including that of adolescents,³²⁰

³¹⁰ Greenberg, J. et al. (2021) 'Privacy and the Connected Mind. Understanding the Data Flows and Privacy Risks of Brain-Computer Interfaces', *Future of Privacy Forum*, pp.1-40, pp.20. Available at: <https://fpf.org/wp-content/uploads/2021/11/FPF-BCI-Report-Final.pdf>

³¹¹ 20 U.S.C §1232g.

³¹² 34 CFR §99.

³¹³ 20 U.S.C. §1232g(a)(2)-(b).

³¹⁴ 34 CFR §99.3.

³¹⁵ 34 CFR §99.3 (emphasis in original).

³¹⁶ Greenberg, J. et al. (2021) 'Privacy and the Connected Mind. Understanding the Data Flows and Privacy Risks of Brain-Computer Interfaces', *Future of Privacy Forum*, pp.1-40, p.20. Available at: <https://fpf.org/wp-content/uploads/2021/11/FPF-BCI-Report-Final.pdf>

³¹⁷ See, e.g., *LeFevre v. State*, 242 Wis. 416, 7 N.W.2d 288 (1943).

³¹⁸ Farahany, N.A. 'Neuroscience and behavioural genetics in US criminal law: an empirical analysis', *Journal of Law and the Biosciences*, Vol.2:3, pp.485-509. DOI: <https://doi.org/10.1093/jlb/lsv059>

³¹⁹ See, e.g., Perlin, M.L. and Lynch, A.J. (2018) "'My Brain is So Wired": Neuroimaging's role in competency cases involving persons with mental disabilities', *Boston University Public Interest Law Journal*, Vol.27:1, pp.73-98. Available at: https://digitalcommons.nyls.edu/fac_articles_chapters/1093/

³²⁰ See, e.g., Steinberg, L. (2013) 'The influence of neuroscience on US Supreme Court decisions about adolescents' criminal culpability', *Nature Review Neuroscience*, Vol.14, pp.513-518. DOI: <https://doi.org/10.1038/nrn3509>



and at the sentencing phase in mitigation,³²¹ particularly in death penalty trials.³²² Other potential current and future applications of neurotechnologies in the legal system include assessing jury (or judicial) bias,³²³ eliciting memories,³²⁴ and predicting recidivism, namely the risk of re-offending.³²⁵

This section will proceed by first outlining the different sources of criminal law (Section 3.3.1), tort law, and civil law (Section 3.3.2), as well as the associated evidential and procedural law (Section 3.3.3), at the federal and state level. Following this, the use of neurotechnologies for assessing the impartiality of the jury and the competence of defendants will be explored, wherein it will be shown that there are significant challenges to the accepted and widespread use of neurotechnology for such purposes (Section 3.3.4).

3.3.1 Criminal law

The criminal law is a system of rules governing how the government can punish individuals who commit crimes (an act or omission defined by law). Criminal procedure law is the set of rules stipulating how the criminal proceeding take place. The U.S. Constitution establishes the basic rights of criminal defendants, notably due process rights.³²⁶

In the United States, some crimes are defined in federal law and handled in federal courts. The definitions of these crimes, available defences and rules for proceedings are codified in Title 18 of the U.S. Code. The provisions on definitions and defences are informally known as the federal penal or criminal code. The provisions on procedure, i.e., the Federal Rules of Criminal Procedure, govern every step of the proceeding from issuing a warrant through a trial to post-conviction procedures.

Crimes defined under state law are handled in state courts and governed by state law. Each state has its own criminal and criminal procedure code, and there is “enormous diversity” amongst them.³²⁷ In an attempt to harmonize the different criminal justice systems, the American Law Institute published the Model Penal Code (MPC), which includes standardised definitions of criminal offenses. While not itself legally binding, many states have adopted portions of the MPC as part of state law, leading some legal scholars to characterise the MPC as “the closest thing to being an American criminal code.”³²⁸ Each state also has its own criminal procedure code, but many choose to replicate the Federal Rules of Criminal Procedure in state law.

³²¹ See, e.g., Du, Y. (2020) ‘The Application of Neuroscience Evidence on Court Sentencing Decisions: Suggesting a Guideline for Neuro-Evidence’, *Seattle Journal for Social Justice*, Vol.18:2, pp.493-524. Available at: <https://digitalcommons.law.seattleu.edu/sjsj/vol18/iss2/19>

³²² Denno, D.W. (2015) ‘The Myth of the Double-Edged Sword: An Empirical Study of Neuroscience Evidence in Criminal Cases’, *Boston College Law Review*, Vol.56:2, pp.493-551. Available at: https://ir.lawnet.fordham.edu/faculty_scholarship/548

³²³ See generally, Jolly, R.L. (2019) ‘The New Impartial Jury Mandate’, *Michigan Law Review*, Vol.117:4, pp.713-760. DOI: <https://doi.org/10.36644/mlr.117.4.new>

³²⁴ Roelfsema, P.R., Denys, D. and Klink, P.C. (2018) ‘Mind Reading and Writing: The Future of Neurotechnology’, *Trends in Cognitive Sciences*, Vol.22:7, pp.598-610. DOI: <https://doi.org/10.1016/j.tics.2018.04.001>

³²⁵ See, e.g., Lamparello, A. (2011) ‘Using Cognitive Neuroscience to Predict Future Dangerousness’, *Columbia Human Rights Law Review*, Vol.41:2, pp.481-539. Available at: <https://ssrn.com/abstract=1742940>

³²⁶ U.S. Const. Amend. V, XIV.

³²⁷ Robinson, P.H. (2007) ‘The American Model Penal Code A Brief Overview’, *New Criminal Law Review*, Vol.10:3, pp.319-341. Available at: https://scholarship.law.upenn.edu/faculty_scholarship/131

³²⁸ Ibid.



3.3.2 Tort law, civil law and civil procedure law

The U.S. Constitution establishes basic due process rights for civil cases.³²⁹ Civil law cases take place in civil courts, which are distinct from criminal courts and have their own set of rules and regulations, including rules on procedure. The substance of civil procedure laws significantly differs from the equivalent criminal procedure rules and applies throughout the legal process, from initial complaint to potential awarding of damages. Civil proceedings in federal courts are subject to the Federal Rules of Civil Procedure. Rules of civil procedure in state courts vary, but some states follow the Federal Rules of Civil Procedure.

3.3.3 Evidence and procedural law

Rules of evidence determine how items and information can be admitted to a court in the form of evidence. State laws relating to rules of evidence vary, but many states have adopted a version of the Uniform Rules of Evidence, which are closely aligned with the Federal Rules of Evidence (FRE) used by federal courts in both criminal and civil cases. Evidential law at the federal level is heavily informed by the trilogy of landmark U.S. Supreme Court cases handed down in the 1990s,³³⁰ the particular relevance of which is in the establishment of a general framework by which courts may determine the admissibility of expert testimony, including that which relates to neuroscientific evidence.³³¹ Indeed, it has been noted that neuroscientific evidence may not only appear in the form of “graphic images produced through methods such as fMRI, electroencephalography (EEG), quantitative electroencephalography (qEEG), and others”, but may also consist of “expert testimony about the brain, from researchers and clinicians”.³³² In the first of these cases, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,³³³ the U.S. Supreme Court determined that the previously established *Frye* test of “general acceptance”³³⁴ for the admission of expert testimony had been superseded by but still inform the application of the Federal Rules of Evidence, particularly Rule 402 on “relevant evidence”³³⁵ and the more specific Rule 702 on expert testimony.³³⁶ Further, when considering the admissibility of expert scientific testimony in accordance with Rule 702, federal trial judges “must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”³³⁷ Finally, in exercising the “gatekeeping” function associated with admitting or excluding expert testimony, federal judges are directed to conduct a “flexible” inquiry to determine “whether a theory or technique is scientific knowledge that will assist the trier of fact” based on various factors, including whether the theory or technique can or has been

³²⁹ U.S. Const. Amend. VII.

³³⁰ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993); *General Electric Co. v. Joiner*, 552 U.S. 136 (1997); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999).

³³¹ Kraft, C.J. and Giordano, J. (2017) ‘Integrating Brain Science and Law: Neuroscientific Evidence and Legal Perspectives on Protecting Individual Liberties’, *Frontiers in Neuroscience*, Vol.11. DOI: <https://doi.org/10.3389/fnins.2017.00621>

³³² Jones, O.D. and Shen, F.X. (2012) ‘Law and Neuroscience in the United States’, in Spranger, T.D. (ed) *International Neurolaw: A Comparative Analysis* (Berlin, Springer). DOI: <https://doi.org/10.1007/978-3-642-21541-4>

³³³ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

³³⁴ *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) cited in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) at 585.

³³⁵ “The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.”

³³⁶ 28 U.S.C. 702: “A witness who is qualified as an expert by knowledge, skill, experience, training or education may testify in the form of an opinion or otherwise if: (a) the expert’s scientific, technical, or other specialised knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.”

³³⁷ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), 589.



tested, whether it “has been subject to peer review and publication”, its “known or potential rate of error”, “the existence and maintenance of standards controlling the technique’s operation”, and whether it has garnered “[w]idespread acceptance” within the relevant scientific community.”³³⁸

In the follow-up case of *Kumho Tire Co. v. Carmichael*,³³⁹ the Supreme Court further established that the *Daubert* “gatekeeping obligation” is applicable to “all expert testimony”, but clarified that in exercising this function a trial judge “may”, consistent with the flexible nature of the inquiry, consider a range of factors since the *Daubert* “list of factors was meant to be helpful, not definitive. Indeed, those factors do not all necessarily apply even in every instance in which the reliability of scientific testimony is challenged.”³⁴⁰ Whilst not conclusive, an indication of how U.S. federal courts might apply the *Daubert* standard to neuroscientific evidence can be derived from the approach taken in *United States v. Semrau*.³⁴¹ Here, in the first case of its kind, the court considered the admissibility of fMRI lie-detection tests under FRE 702 in conjunction with the *Daubert* standard, as well as FRE Rule 402, and found that the technique was not generally accepted by the scientific community and therefore that the district court “did not abuse its discretion in excluding the fMRI evidence” relied upon by the defendant.³⁴²

Whilst illustrative, this may not necessarily be instructive as to the future admissibility of fMRI and other neuroscientific evidence in U.S. courts, particularly as the evidence was proffered at the liability/guilt stage, where the more stringent FRE and *Daubert* standard apply.³⁴³ Indeed, in comparison, the sentencing phase may be more conducive to the admissibility of neuroscientific evidence,³⁴⁴ since it is governed by a lower threshold of the court being able to consider “relevant information without regard to its admissibility under the rules of evidence applicable at trial, provided that the information has sufficient indicia of reliability to support its probable accuracy.”³⁴⁵ That the sentencing phase may be a more suited and accepted point at which to admit neuroscientific evidence is illustrated by the case of *Florida v. Grady Nelson*, in which the admission of qEEG brain mapping evidence at the sentencing phase as mitigation contributed to the verdict of life imprisonment instead of the state capital punishment.³⁴⁶

3.3.4 Issues relating to the use of neurotechnologies in the legal system

Impartiality of the jury

Jury trials are a constitutionally enshrined right in the United States for criminal and some civil defendants.³⁴⁷ The rules for jury trials are primarily set out in the Federal Rules of Criminal Procedure, Federal Rules of Civil Procedure, and case law. A jury is a group of people (usually 6-12) selected to hear evidence and issue a verdict in a case.³⁴⁸ A fundamental element of due process is that the jury must be impartial, which means the “jurors must lack specific bias against the parties.”³⁴⁹ The U.S. Supreme Court defines biases as any outside influence, such as conflicts of interests and previously held beliefs, that

³³⁸ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), 594-597.

³³⁹ *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999).

³⁴⁰ *Ibid* at 150-151 (emphasis added).

³⁴¹ *United States v. Semrau*, 693 F.3d 510 (6th Cir.) (2012).

³⁴² *Ibid* at 17.

³⁴³ Jones, O.D. and Shen, F.X. (2012) ‘Law and Neuroscience in the United States’, in Spranger, T.D. (ed) *International Neurolaw: A Comparative Analysis* (Berlin, Springer). DOI: <https://doi.org/10.1007/978-3-642-21541-4>

³⁴⁴ *Ibid*.

³⁴⁵ Federal Sentencing Guidelines, §6A1.3.

³⁴⁶ *Florida v. Grady Nelson*, No.FO5-00846 (11th Fla. Cir. Ct., 4 Dec 2010).

³⁴⁷ U.S. Const. Amend. VI, VII.

³⁴⁸ Fed. R. Crim. P. 23; Fed. R. Civ. P. 38-39.

³⁴⁹ Jolly, R.L. (2019) ‘The New Impartial Jury Mandate’, *Michigan Law Review* 117(4), p714. DOI: <https://doi.org/10.36644/mlr.117.4.new>



cannot be traced directly to the “evidence and arguments in open court.”³⁵⁰ The process of selecting jurors, which includes questions about potential bias, is called *voir dire*.³⁵¹ During *voir dire*, prospective jurors are asked about their ability to judge a case fairly, including whether they believe they have a relevant bias and the extent to which the bias will impact their decisions in the case.³⁵² This method of self-reporting was considered by the Supreme Court as the best and “only sure method of fathoming”³⁵³ whether a potential juror “has an unbiased mind.”³⁵⁴ Based on the answers provided during *voir dire* and observations of the jurors’ behaviour, the parties can make a request to the court that the prospective juror is disqualified for actual or impartial bias.³⁵⁵

Neurotechnologies could be used to help courts assess juror bias. Current ways of assessing bias – self-assessment and behavioural observation – are unreliable and “cannot detect bias with any precision at the individual level.”³⁵⁶ Therefore, some neuroscientists believe that brain imaging might better uncover “whether jurors are lying, even to themselves, about the influences that affect the way they think and the decisions they make,”³⁵⁷ an approach one legal scholar has termed “neuro-voir dire.”³⁵⁸ Some studies suggest it is possible³⁵⁹ and more reliable³⁶⁰ to identify bias through brain imaging techniques like fMRI. At present, there are no rules explicitly prohibiting the use of neurotechnologies for this purpose, though there are no examples of this happening in courtrooms yet.

Critiques of this proposal point to several concerns. Some concerns, like current high costs and logistical challenges, may be alleviated in the future as neurotechnologies become less expensive and easier to use – though they are serious considerations at present.³⁶¹ Like the use of neurotechnologies in general, concerns about accuracy are also pressing, but these may also be addressed as the technology develops. More fundamental are concerns about juror privacy. Jurors have a right to privacy and a “right against being forced to disclose certain personal information.”³⁶² Normally, a juror can refuse to answer a question in *voir dire* if it is not relevant,³⁶³ but there is a risk that “neuro-voir dire deprives her of that choice.”³⁶⁴ Furthermore, brain imaging related to potential bias, especially, “could reveal sensitive personal information... that a person would not wish to share or may not even yet know to be true.”³⁶⁵

³⁵⁰ *Skilling v. United States*, 130 S. Ct. 2896, 2913 (2010) (quoting *Patterson v. Colorado*, 205 U.S. 454, 462 (1907)).

³⁵¹ NB: French for “to speak the truth.”

³⁵² Fed. R. Crim. P. 24; Fed. R. Civ. P. 47.

³⁵³ *Aldridge v. United States*, 283 U.S. 308, 313-14 n.3 (1931) (quoting *State v. McAfee*, 64 N.C. 339, 340 (1870)).

³⁵⁴ *Smith v. Phillips*, 455 U.S. 209, 217 n.7 (1982) (quoting *Dennis v. United States*, 339 U.S. 162, 171 (1950)).

³⁵⁵ Fed. R. Crim. P. 24; Fed. R. Civ. P. 47.

³⁵⁶ Fox, D. (2014) ‘Neuro-Voir Dire and the Architecture of Bias’, *Hastings Law Journal*, Vol. 65:4, pp.1012-13. Available at: https://repository.uchastings.edu/hastings_law_journal/vol65/iss4/2

³⁵⁷ Ibid 1014.

³⁵⁸ Greely, H.T. (2009) ‘Law and the Revolution in Neuroscience: An Early Look at the Field’, *Akron Law Review* 42(3), p697.

³⁵⁹ See, e.g., Gilbert, S.J. Swencionis, J.K. and Amodio, D.M. (2012) ‘Evaluative vs. trait representation in intergroup social judgments: Distinct roles of anterior temporal lobe and prefrontal cortex’, *Neuropsychologia* 50.

³⁶⁰ See, e.g., Korn, H.A, Johnson, M.A. and Chun, M.M. (2012) ‘Neurolaw: Differential brain activities for Black and White faces predicts damage awards in hypothetical employment discrimination case’, *Social Neuroscience* 7(4).

³⁶¹ Fox, D. (2014) ‘Neuro-Voir Dire and the Architecture of Bias’, *Hastings Law Journal*, Vol.65(4), p1017. Available at: https://repository.uchastings.edu/hastings_law_journal/vol65/iss4/2

³⁶² Ibid 1018.

³⁶³ *Brandborg v. Lucas*, 891 F. Supp. 352, 360 (E.D. Tex. 1995).

³⁶⁴ Fox, D. (2014) ‘Neuro-Voir Dire and the Architecture of Bias’, *Hastings Law Journal*, Vol.65(4), p1019. Available at: https://repository.uchastings.edu/hastings_law_journal/vol65/iss4/2

³⁶⁵ Ibid 1018.

Competency

In U.S. law, there are many types of specific competencies that have precise legal definitions, including competency to stand trial, testify, plead guilty, be sentenced and be executed. For the purpose of this analysis, the focus is on competency to stand for trial (CST or trial competency), which is the most frequent 'disability law' issue in criminal law.³⁶⁶

Trial competency refers specifically to the mental capacity or ability of the defendant to participate in legal proceedings. In the U.S., it is a constitutional due process requirement that the accused (known as the defendant) must be competent to stand for trial.³⁶⁷ The requirement for competency supports the legal values of dignity in the legal process, accuracy of the adjudication, and autonomy of the defendant to make decisions about the legal case.³⁶⁸ The rules for competency are primarily set out in the federal penal code, Federal Rules of Criminal Procedure, and case law. An incompetent defendant is someone with a mental illness that makes them unable "to understand the nature and consequences of the proceedings [and] assist in [the] defense" during the time of the trial.³⁶⁹ Competency can be assessed at any time pre-trial or during the legal proceedings. The government, the defense, or the court itself can request the assessment, but it must be ordered by the court.³⁷⁰ An expert witness (e.g., psychiatrist or psychologist) conducts the CST evaluation, which includes information on whether the defendant has a mental illness, a description of the signs and symptoms of the illness, and an assessment (based on the clinician's judgment) of any impairments to the mental capacities needed to participate in legal proceedings.³⁷¹ The CST evaluation is then presented to the judge for a legal decision on competency. The standard is preponderance of the evidence,³⁷² which means the judge must be convinced there is a greater than 50 percent chance that the defendant is incompetent.³⁷³ If the defendant is found incompetent, the proceedings are halted.³⁷⁴

Neurotechnologies can be used to help assess competency. While the Federal Rules on Criminal Procedure and Federal Rules on Evidence do not explicitly discuss neurotechnologies and competency assessments, judges have interpreted the rules to allow neuroscientific evidence in court for this purpose. In *United States v. Kasim* (2008),³⁷⁵ for instance, the admission of neuroimaging evidence contributed to a finding of incompetence. As part of the competency assessment, the defendant underwent a functional neuroimaging scan called SPECT (single photon emissions computerized tomography). This test measures metabolic activities and cerebral processes, including blood flow. The SPECT results indicated reduced blood flow to the defendants' front temporal lobes, which "control the cognitive, memory and speech functions." Based on the SPECT results, a medical expert (neurologist

³⁶⁶ Perlin, M.L. and Lynch, A.J. (2018) "'My Brain Is So Wired': Neuroimaging's Role in Competency Cases Involving Persons with Mental Disabilities', *Public Interest Law Journal*, 27, p75. Available at: https://digitalcommons.nyls.edu/fac_articles_chapters/1093/

³⁶⁷ "No person shall...be deprived of life, liberty, or property, without due process of law." U.S. Const. Amend. V. "The Conviction of a legally incompetent defendant violates due process." *Pate v. Robinson*, 383 U.S. 375, 378 (1966) (citing *Bishop v. United States*, 350 U.S. 961 (1956)).

³⁶⁸ Bonnie, R.J. (1990) 'The Competence of Criminal Defendants with Mental Retardation to Participate in Their Own Defense', *Journal of Criminal Law and Criminology*, 81(3).

³⁶⁹ 18 U.S.C. § 4241(a) (1948). The federal court standard was established in case law: "whether he has sufficient present ability to consult with his lawyer with reasonable degree of rational understanding – and whether he has a rational as well as factual understanding of the proceedings against him." *Dusky v. United States*, 362 U.S. 402 (1960).

³⁷⁰ 18 U.S.C. § 4241(a) (1948); Fed. R. Crim. P. 12.2(c).

³⁷¹ Wall, B. and Lee, R. (2020) 'Assessing Competency to Stand Trial', *Psychiatric Times*, 37(10).

³⁷² *Cooper v. Oklahoma*, 116 S.Ct. 1373 (1996).

³⁷³ NB: This is a lower threshold than *beyond a reasonable doubt or clear and convincing evidence*. See generally, https://www.law.cornell.edu/wex/preponderance_of_the_evidence

³⁷⁴ Proceedings may commence again if "the mental condition is so improved." 18 U.S.C. § 4241(d) (1948).

³⁷⁵ *United States v. Kasim*, No. 2:07 CR 56 (N.D. Ind. Nov. 3, 2008).



and neuropsychiatrist) diagnosed the defendant with dementia, a neurological condition which affects memory, judgment, and ability to concentrate. The court found that the SPECT evidence was admissible and credible, and that the preponderance of the evidence standard was satisfied to find the defendant incompetent for trial.³⁷⁶

However, the use and acceptance of neuroscientific evidence to assess competency as in *Kasim* is not typical. While the number of competency cases involving neuroscientific evidence is increasing, they still represent a “relatively small number” of competency cases overall.³⁷⁷ This is partly because courts have been and continue to show reluctance towards the admission of neuroscientific evidence. In a high-profile case in the late 1990s, for instance, a court rejected neuroscience evidence from a PET (positron emissions tomography) because it was “dubious, based on speculative scientific theories lacking full development, research and support.”³⁷⁸ This case illustrates multiple concerns with the use of neuroscientific evidence to prove incompetence.³⁷⁹ One concern is the accuracy and reliability of the technology. Many of the current neurotechnologies present an oversimplification of complex brain functions because there is “no one-to-one mapping of a particular function to a particular brain region,”³⁸⁰ meaning there isn’t one section of the brain that uniquely corresponds to competency. Additionally, mental illnesses that may inhibit competency do not have a ‘loci’ that can be “quantified, scanned or measured” in the same way as traumatic brain injuries, meaning that brain scans may not be useful for some defendants (and potentially harmful to an incompetency argument if a lack of abnormality is interpreted to mean a lack of mental illness).³⁸¹

Furthermore, neuroimaging scans, which only show areas of abnormality, are more limited than traditional neuropsychological exams “designed to measure aspects of mental function and to provide information about an individual’s ability to process, understand, and react appropriately.”³⁸² For all of these reasons, the expert witness must carefully present a clinical assessment of the neuroscientific evidence in a way that is relevant and clear to the court, bridging the “analytical gap” between the neurodata and the question of competence.³⁸³ This relates to a second major concern: the expert witness must have good knowledge of the legal standards and legal counsel must understand the neurotechnologies well-enough to ensure the specific evidence supports the facts and legal argument.

A third concern is more theoretical, namely: whether neuroscientific evidence supports the legal value and right of human dignity. If presented appropriately, voluntarily, and in a nuanced way, neuroscientific evidence can support human dignity and enhance an argument for incompetency. Part of human dignity is giving an individual a voice “to speak for himself or articulate something that he believes to be important.” The opportunity to present neuroscientific evidence might be seen as a way to bolster personal testimony of mental illness or help explain certain actions, particularly if the evidence in

³⁷⁶ “The objective SPECT scan support these symptoms and represent objective evidence of a medical disability.” *United States v. Kasim*, No. 2:07 CR 56, ¶ 38 (N.D. Ind. Nov. 3, 2008).

³⁷⁷ Gaudet, L.M. and Marchant, G.E. (2016) ‘Under the Radar: Neuroimaging Evidence in the Criminal Courtroom’, *Drake Law Review*, 64, pp. 647-48. Available at: <https://ssrn.com/abstract=2838996>; Perlin, M.L. and Lynch, A.J. (2018) “My Brain Is So Wired”: Neuroimaging’s Role in Competency Cases Involving Persons with Mental Disabilities’, *Public Interest Law Journal*, 27, p75. Available at:

https://digitalcommons.nyls.edu/fac_articles_chapters/1093/

³⁷⁸ *United States v. Gigante*, 982 F. Supp. 140, 147 (E.D.N.Y. 1997).

³⁷⁹ For discussion, see Gaudet, L.M. and Marchant, G.E. (2016) ‘Under the Radar: Neuroimaging Evidence in the Criminal Courtroom’, *Drake Law Review*, 64, pp. 687-88. Available at: <https://ssrn.com/abstract=2838996>

³⁸⁰ Perlin, M.L. and Lynch, A.J. (2018) “My Brain Is So Wired”: Neuroimaging’s Role in Competency Cases Involving Persons with Mental Disabilities’, *Public Interest Law Journal*, 27, pp80-81. Available at: https://digitalcommons.nyls.edu/fac_articles_chapters/1093/

³⁸¹ *Ibid* 81-82.

³⁸² *Ibid* 81.

³⁸³ *Ibid* 80.

integrated in a way that it highlights the defendant as a person, rather than a caricature of a “mentally ill person.”³⁸⁴ However, it could equally undermine human dignity by forcing or allowing the neuroscientific evidence alone to speak in place of the defendant. Despite all the current concerns, courts will likely be confronted with more neuroscience evidence as “future defendants will seek to introduce neuroimaging evidence as early in a trial as possible, which would be the competency phase.”³⁸⁵ This increase will be made possible as technologies further develop, lawyers become more familiar and knowledgeable with the potential benefits, and the costs associated with the use of such technologies decrease.

3.4 Liability for harms

3.4.1 Liability for harms under tort law

At the federal level, there is no general statute on tort law as a whole. Addressing a specific aspect of tort law, the Federal Tort Claims Act (FTCA) (1946), for instance, enables private persons who have suffered a tortious infringement caused by an agent of the federal government to receive compensation.³⁸⁶ Specifically, it provides that “[t]he United States shall be liable...in the same manner and to the same extent as a private individual under like circumstances, but shall not be liable for interest prior to judgement or for punitive damages.”³⁸⁷ The majority of tort law, however, is state based. The essential components of tort liability are broadly similar – a tortious infringement with or without fault, damage suffered, chain of causation, relevant defences, and the awarding of damages – but there is much variation at the micro level of specific tort laws which differ in various aspects, including whether and in what circumstances liability is strict, the extent to which contributory negligence is relevant, and whether and the extent to which punitive damages may be granted.³⁸⁸

This variety, notwithstanding, some basic uniformity is derived from the primary source of U.S. tort law being the common law, with judges often having regard to relevant judgements handed down in other states and federal courts, as well as consulting the non-binding but strongly persuasive uniform tort rules set out in the Restatement of Torts published by the American Law Institute (ALI).³⁸⁹ Amongst its treatises, perhaps most relevant to the liabilities arising in relation to neurotechnologies is the Restatement (Third) of Torts: Products Liability (1998), which outlines the general rules of tort liability applicable to commercial sellers or distributors for harm caused by defective products.³⁹⁰ Also potentially relevant to neurotechnologies, particularly those devices used to enable XR applications that blur the public/private distinction, is the privacy tort of intrusion upon seclusion, for which the Restatement (Second) of Torts provides that “One who intentionally intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns, is subject to liability to the other for invasion of his privacy, if the intrusion would be highly offensive to a reasonable person.”³⁹¹

³⁸⁴ Ibid 91.

³⁸⁵ Gaudet, L.M. and Marchant, G.E. (2016) ‘Under the Radar: Neuroimaging Evidence in the Criminal Courtroom’, *Drake Law Review*, 64, p. 651. Available at: <https://ssrn.com/abstract=2838996>

³⁸⁶ Federal Tort Claims Act, of 1946, Pub. L. 79-601.

³⁸⁷ U.S.C §2674.

³⁸⁸ Magnus, U. (2010) ‘Why is US Tort Law so Different?’, *Journal of European Tort Law*, Vol.1:1, pp.102-124, p.103. DOI: <https://doi.org/10.1515/jetl.2010.102>

³⁸⁹ Ibid p.103-104; See, e.g., Restatement (Second) of Torts (1965); Restatement (Third) of Torts: Products Liability (1998); Restatement (Third) of Torts: Apportionment of Liability (2000); Restatement (Third) of Torts: Liability for Physical and Emotional Harm (2010).

³⁹⁰ Restatement (Third) of Torts §1.

³⁹¹ Restatement (Second) of Torts §652B.

3.4.2 Liability for harms under contract law

Similar to tort law, most contract law in the U.S. is located at the state level, with each state having its own rules regulating contracts involving the sale of goods. The fundamental aspects of contract law are outlined in the Restatement (Second) of the Law of Contracts published by the ALI, which defines a contract as “a promise or a set of promises for the breach of which the law gives a remedy, or the performance of which the law in some way recognises as a duty.”³⁹² Furthermore, whilst not federal law, the Uniform Commercial Code (UCC) provides a comprehensive framework governing all commercial transactions in the US, including contractual arrangements relating to the sale of goods,³⁹³ which has been adopted uniformly across all states.³⁹⁴ This provides that the general “obligation of the seller is to transfer and deliver” the goods, while the general obligation “of the buyer is to accept and pay in accordance with the contract.”³⁹⁵ There is a suite of possible remedies available to both buyer and/or seller, depending on which party is found to be in breach of contract.³⁹⁶

3.4.3 Liability for harms under criminal law

At the national level, Congress has codified federal criminal law in Title 18 of the U.S. Code.³⁹⁷ There is scope for variation between the federal and state level since each state has a criminal code which determines the offences subject to criminalisation in that jurisdiction. There is no specific criminal liability for manufacturers of defective products, although a defendant could be found criminally liable under state law if found to have the requisite level of criminal intent for a similar offence.³⁹⁸ The overall trend towards the increased integration of neurotechnologies into daily life, as indicated by the growing availability of consumer-grade devices and applications, gives rise to various considerations in relation to the application of the criminal law, including whether and if so how neurotechnological interventions may affect existing understanding of essential ethical-legal concepts, such as criminal responsibility.³⁹⁹

³⁹² Restatement (Second) of Contracts §1.

³⁹³ U.C.C. §2.

³⁹⁴ National Conference of Commissioners on United State Laws. *Uniform Commercial Code* / Uniform Law Commission [Online]. Available at: <https://www.uniformlaws.org/acts/ucc>

³⁹⁵ U.C.C. §2-301.

³⁹⁶ U.C.C. §2-701-725.

³⁹⁷ 18 U.S.C.

³⁹⁸ Cofer, W.L. and Donahue, A.J. (2018) *Product Liability in the USA* / Shook Hardy & Bacon LLP [Online]. Available at: <https://www.lexology.com/library/detail.aspx?q=3714f105-6d2e-4e33-be4f-17289ae7e547>

³⁹⁹ See generally, Thompson, K. (2019) ‘Committing Crimes with BCIs: How Brain-Computer Interface Users can Satisfy Actus Reus and be Criminally Responsible’, *Neuroethics*, Vol.14, pp.311-322. DOI: <https://doi.org/10.1007/s12152-019-09416-5>; Müller, O. and Rotter, S. (2017) ‘Neurotechnology: Current Developments and Ethical Issues’, *Frontiers in Systems Neuroscience*, Vol.11. DOI: <https://doi.org/10.3389%2Ffnsys.2017.00093>

4. Overview of gaps, challenges and future trends

This section highlights the main gaps and challenges identified in the previous sections and advances some recommendations for the amendment or enhancement of existing legal frameworks.

- The U.S. human rights law framework outlined in Section 3.1.1 protects various rights which may be both positively and/or negatively impacted by neurotechnologies. However, as explored in Section 3.1.2, a number of key challenges remain, including the blurring of the real/testimonial evidence distinction pursuant to the Fifth Amendment privilege against self-incrimination, the adequate protection of individuals against discriminatory treatment on the basis of their brain and other neural data, and the lack of clarity around the independence or interdependence of expression in the application of First Amendment protection to the right to freedom of thought.
- As discussed in relation to Section 3.1.2, the U.S. Congress has addressed some of the risks posed by genomic technologies to the adequate protection of genetic data through the enactment of the Genetic Information Non-discrimination Act (GINA) (2008).⁴⁰⁰ Within the legal academic literature two possible regulatory solutions to better protect individuals' rights to privacy and non-discrimination have been proposed, namely: the extension of the remit of GINA to include brain and other neural data, or the enactment by Congress of an equivalent federal regulatory framework addressing the various harmful risks associated with the misuse of such data.⁴⁰¹
- As identified in Section 3.2.1, notwithstanding the absence of explicit textual guarantees, there are various potential sources of protection for the unenumerated constitutional right to privacy. However, the continuance of these constitutional safeguards, as well as their direct applicability to the various privacy risks associated with neurotechnologies, may be subject to limitations.
- The patchwork of sector-specific federal data privacy laws outlined in Section 3.2.2 may protect against interference with brain and other neural data in certain specific contexts and in certain circumstances relating to the collection, use or processing of such data. Considering current and future neurotechnology use cases, federal data privacy laws with application to the healthcare, education, and entertainment sectors are all likely to be applicable.
- However, the premise of most federal (and state) data privacy laws is that any such data-related activity is in principle permitted unless expressly restricted, and as such the coverage of protection is narrowly demarcated. Following the nascent trend towards state legislatures enacting omnibus data privacy laws, a proposal for the enactment of comprehensive federal data privacy legislation may serve the dual purpose of offering more direct, robust and comprehensive protection of individuals' data privacy, while also reducing the burden of regulatory compliance for the private sector by pre-empting relevant state law and establishing uniformity in the application of federal standards across all states.

⁴⁰⁰ 42 U.S.C §1320d-9.

⁴⁰¹ Jwa, A.S. and Poldrack, R.A. (2022) 'Addressing privacy risk in neuroscience data: from data protection to harm prevention', *Journal of Law and the Biosciences*, Vol.9:2, pp.1-25. DOI: <https://doi.org/10.1093/jlb/lbac025>



- As described in Section 3.3, ongoing and significant improvements in the accuracy and reliability of neurotechnologies are increasing attempts to seek admission of neuroscientific evidence in legal proceedings, particularly criminal law proceedings. Factors that may affect more widespread use and acceptance of neuroscientific evidence in legal proceedings include the rules on admissibility of evidence (see Section 3.3.3), costs and other practical constraints (see generally Section 3.3.4), the legal system (i.e., whether civil or criminal), the stage at which the evidence is proffered (e.g., guilt/liability stage and/or sentencing), and the purpose behind its admission (e.g., in mitigation).
- The existing legal framework in relation to liability for harms is outlined in Section 3.4. For those neurotechnological devices used to enable XR applications that blur the public/private distinction, a tort of particular relevance is the privacy tort of intrusion upon seclusion, for which the Restatement (Second) of Torts provides that “One who intentionally intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns, is subject to liability to the other for invasion of his privacy, if the intrusion would be highly offensive to a reasonable person.”⁴⁰² As regards liability for criminal harms, the overall trend towards the increased integration of neurotechnologies into daily life, as indicated by the growing availability of consumer-grade devices and applications, gives rise to various considerations in relation to the application of criminal law doctrine, including whether and if so how neurotechnological interventions may affect existing understanding of essential ethical-legal concepts, such as criminal responsibility.⁴⁰³

⁴⁰² Restatement (Second) of Torts §652B.

⁴⁰³ See generally, Thompson, K. (2019) ‘Committing Crimes with BCIs: How Brain-Computer Interface Users can Satisfy Actus Reus and be Criminally Responsible’, *Neuroethics*, Vol.14, pp.311-322. DOI: <https://doi.org/10.1007/s12152-019-09416-5> ; Müller, O. and Rotter, S. (2017) ‘Neurotechnology: Current Developments and Ethical Issues’, *Frontiers in Systems Neuroscience*, Vol.11. DOI: <https://doi.org/10.3389%2Ffnsys.2017.00093>

5. Conclusion

The U.S. national legal case study has set out some of the key legal issues and policy developments relating to the governance and regulation of neurotechnologies in the USA. As highlighted in Section 2, the centrepiece of U.S. policy in relation to neurotechnologies is the BRAIN initiative, the immediate priorities for which included to research and development (R&D) of innovative neurotechnologies to better understand the human brain and treat its disorders.⁴⁰⁴ Now in its second phase, the BRAIN initiative is seeking to achieve its long-term goals, which in terms of technology have shifted towards the application of these innovative tools for a wide range of clinical applications.⁴⁰⁵ Whilst the significant body of research generated is likely to inform future R&D, it remains to be seen whether this initiative will be renewed or whether a similar initiative will be devised in the event of its anticipated end in 2026. Importantly, these significant policy developments have not been paralleled by any dedicated legal regulation. Indeed, at the time of writing, this national legal case study did not identify any federal or state legislation (or ongoing proposals for such legislation) with direct and comprehensive application to neurotechnologies. Different existing laws in the domain-specific areas identified above are likely to apply to particular human rights, information privacy, criminal, civil, evidential and contractual law issues, but there remains the inherent risk that the pace of neurotechnological developments, particularly those enabling unforeseen and/or unregulated commercial and dual-use applications, outstrip existing legal protections. As outlined in Section 3.2.2., consumer neurotechnology is already available in the form of wearable EEG for gaming and entertainment purposes,⁴⁰⁶ while recent developments driven by the private sector (see Sections 1.2 and 2) indicates the future availability of more invasive BCIs that may be used for both clinical and, eventually, consumer purposes. Particular issues identified in this national legal case study that may affect future legal regulation of neurotechnologies and therefore warrant further research include the appropriate protection of brain and other neural data in both human rights and information privacy law, the extent to which a comprehensive information privacy legal framework at the federal level is both viable and normatively desirable, and the role and effect of neuroscientific evidence in both criminal and civil legal proceedings.

⁴⁰⁴ Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Working Group Report to the Advisory Committee to the Director, NIH. (2014) *Brain 2025 – A Scientific Vision*, p.6. Available at: https://braininitiative.nih.gov/sites/default/files/pdfs/brain2025_508c.pdf

⁴⁰⁵ Ibid 107.

⁴⁰⁶ Shen, F.X. (2016) 'Law and Neuroscience 2.0', *Arizona State Law Journal*, Vol.48, pp.1043-1086. Available at: https://scholarship.law.umn.edu/faculty_articles/604.



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