TECHETHOS

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FUTURE O TECHNOLOGY O ETHICS

Annex 9.5 National Legal Case Study: Neurotechnologies in Ireland

D4.2 Comparative analysis of national legal case studies

December 2022

Draft version submitted to the European Commission for review





TechEthos receives funding from the EU H2020 research and innovation programme under Grant Agreement No 101006249. This deliverable and its contents reflect only the authors' view. The Research Executive Agency and the European Commission are not responsible for any use that may be made of the information contained herein.

D4.2 National legal case studies: Annex 9.5 – Neurotechnologies in Ireland				
Work Package		WP4 Policy, legal and regulatory analysis		
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Date published		22/12/2022		
Version number	1.0		Status	Final

Version control			
Version	Date	Description	
0.1	25/07/2022	Outline	
0.2	05/09/2022	First draft	
0.3	04/11/2022	Final draft for QA	
1.0	22/12/2022	Final version for inclusion in D4.2	

Keywords

Neurotechnologies; neuroscience; Ireland; Irish Constitution; human rights law; privacy and data protection law; criminal law; civil law; contract law; tort law; evidence law.



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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 to four 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
Bunreacht na hÉireann	Constitution of Ireland
Dáil Éireann	Lower house of the Irish Parliament
Neurotechnologies	Devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons
Oireachtas	Irish Parliament
Seanad Éireann	Upper house of the Irish Parliament
Taoiseach	Irish Prime Minister

Table 2: List of Abbreviations

Term	Explanation
BCI	Brain computer interfaces
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
CFREU	Charter of Fundamental Rights of the European Union
CJEU	Court of Justice of the European Union
CRC	International Covenant on Civil and Political Rights
CRC	Convention on the Rights of the Child



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Annex 9.5 National Legal Case Study: Neurotechnologies in Ireland

CRPD	Convention on the Rights of Persons with Disabilities
DBS	Deep Brain Stimulation
DNA	Deoxyribonucleic acid
DoA	Description of Action
DPC	Irish Data Protection Commission
ECHR	European Convention on Human Rights
ECoG	Electrocorticography
ECtHR	European Court of Human Rights
EEG	Electroencephalogram
elSB	Electronic Irish statute book
EU	European Union
fMRI	Functional Magnetic Resonance Imaging
GDPR	General Data Protection Regulation
HPRA	Health Products Regulatory Authority
HRCDC	Health Research Consent Declaration Committee
HRR	Health Research Regulations
ICERD	International Convention on the Elimination of All Forms of Racial Discrimination
ICESCR	International Covenant on Economic, Social and Cultural Rights
ISIS	Irish Sentencing Information System
IVDD	la Vitra Disapartic Davisas
	III-VILIO DIAGNOSLIC DEVICES
MDR	Medical Devices Regulation (EU)
MDR MEG	Medical Devices Regulation (EU) Magnetoencephalography
MDR MEG NAI	Medical Devices Regulation (EU) Magnetoencephalography Neurological Alliance of Ireland
MDR MEG NAI NCA	Medical Devices Regulation (EU) Magnetoencephalography Neurological Alliance of Ireland National Competent Authority
MDR MEG NAI NCA PC	Medical Devices Regulation (EU) Magnetoencephalography Neurological Alliance of Ireland National Competent Authority Project Coordinator
MDR MEG NAI NCA PC PIAB	Medical Devices Regulation (EU) Magnetoencephalography Neurological Alliance of Ireland National Competent Authority Project Coordinator Personal Injury Assessment Board
MDR MEG NAI NCA PC PIAB TAS	Medical Devices Regulation (EU) Magnetoencephalography Neurological Alliance of Ireland National Competent Authority Project Coordinator Personal Injury Assessment Board Treatment Abroad Scheme



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Abstract

The objective of this study is to review the current state of the law on and legal responses to neurotechnologies in Ireland, as evidenced in policy, legislation (including, where applicable, the existence of proposals to create new law or adapt existing law in response to those neurotechnological developments), case law and regulation. 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 legal proceedings, and liability for harms under tort, contract and criminal law. This study sets out the extent to which these legal domains already regulate neurotechnologies, before highlighting the ongoing gaps and challenges in the existing legal frameworks.

A summary overview of the main findings and legal issues surrounding neurotechnologies in Ireland is provided in Section 4.1.2 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 Irish policymakers and regulators, of the main regulatory gaps and challenges applicable to neurotechnologies in Ireland.

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D4.2

1. Introduction

Neurotechnologies present many significant legal issues that impact socioeconomic equality and fundamental rights in Ireland. This study provides an overview of those legal issues and challenges.

This study analyses relevant laws and policies from the Irish legal system in relation to neurotechnologies. There is no comprehensive or dedicated legislation in Ireland governing this technology family, although many elements of existing laws and policies in Ireland 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.¹

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.² For more information about the TechEthos technology families and their innovation ecosystems, visit: <u>https://www.techethos.eu/resources/</u>.

1.1 Purpose of the Irish legal case study

The objective of this study is to review the current state of the law on and legal responses to neurotechnologies in Ireland, as evidenced in policy, legislation, case law and regulation. We prepared this study through desk research, using legal research and academic databases such as the electronic Irish Statute Book (eISB).

Whilst there are no specific laws and policies on neurotechnologies in Ireland, many existing laws and policies (including human rights law, privacy and data protection law, use in criminal, civil and evidence law) are relevant and are 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).

This study is part of a series of national legal case studies prepared in the TechEthos project covering three technology families: climate engineering, extended digital reality, and neurotechnologies. A complementary report covers the international and European Union law dimensions of the three technology families. The following table provides an overview of the nine national legal case studies conducted as part of the *Comparative analysis of national legal case studies* (D4.2 of the TechEthos project):

<u>content/uploads/2022/05/TechEthos factsheet Neurotechnologies website.pdf;</u> TechEthos (2022) *Technology Factsheet: Digital Extended Reality / TechEthos*, [Online]. Available at: https://www.techethos.eu/wp-content/uploads/2022/05/TechEthos factsheet Digital-Extended-





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

² TechEthos (2022) *Technology Factsheet: Climate Engineering / TechEthos*, [Online]. Available at: <u>https://www.techethos.eu/wp-content/uploads/2022/05/TechEthos_factsheet_Climate-</u>

Engineering website.pdf; TechEthos (2022) *Technology Factsheet: Neurotechnologies / TechEthos*, [Online]. Available at: <u>https://www.techethos.eu/wp-</u>

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 study

Section II explores the existing and proposed laws and policies that specifically address neurotechnologies. **Section III** explores the legal implications of neurotechnologies in relation to specific legal domains, including human rights law, privacy and data protection, use in criminal and civil legal proceedings, and liability for harms. **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.

1.3 Scope and limitations

This national legal case study of Ireland was prepared as part of the TechEthos project's work package 4 on policy, legal and regulatory analysis. Therefore, the scope is demarcated by the project task's workplan. The legal issues related to neurotechnologies are too vast to be covered comprehensively in a report of this size. Therefore, this national legal case study seeks to provide a high-level overview of the legal implications of neurotechnologies in Ireland, focusing on a pre-defined range of topics and legal frameworks with significant human rights and socio-economic impacts that are of high policy relevance. This defined scope allows for the comparative analysis of legal implications with the other TechEthos national legal case studies on neurotechnologies, namely Germany and the U.S.

1.4 Overview of the Irish legal system

Ireland is a unitary, parliamentary republic. Its legislature, the Oireachtas, is comprised of the *Dáil Éireann* (lower house) and the *Seanad* (upper house). The head of State is the Irish President, whilst the head of government is the *Taoiseach* (Prime Minister). Like most anglophone jurisdictions, Ireland is part of the common law family of legal systems, meaning its body of laws gradually evolved through judicial decisions. Much of Irish legal origins can be traced back to the common law of England.³ However, particularly since the Irish partition from the United Kingdom in 1921, Irish law has increasingly evolved into its own legal tradition.⁴ Sources of Irish law include case law, as well as legislation enacted by the *Oireachtas*, the Irish Constitution as enacted in 1937, and European Union law.⁵ International law, such as international treaties to which Ireland is party, may be incorporated into domestic law through Acts of the *Oireachtas*.⁶

⁶ Constitution of Ireland (Bunreacht na hÉireann) (enacted by the People 1st July 1937, in operation as from 29th December 1937), Article 29 (6); Byrne, R. (1996) *The Irish legal system*. Dublin: Butterworths, p. 8.



³ Byrne, R. (1996) *The Irish legal system*. Dublin: Butterworths, p. 4.

⁴*History of the Law in Ireland* / An tSeirbhís Chúirteanna Courts Service [Online]. Available at: <u>https://www.courts.ie/history-law-ireland</u>.

⁵ Byrne, R. (1996) *The Irish legal system*. Dublin: Butterworths, p. 5-7.

The Irish legal system is comprised of various laws and statutes which govern several principles. The most fundamental law in Ireland is the Irish Constitution or *Bunreacht na hÉireann* which informs the validity of all other laws in Ireland. Other laws which are worth examining to inform the use of neurotechnologies include: criminal laws, evidence laws, and criminal procedure laws. Also relevant to this national legal case study is the Data Protection Act 2018 as examined in relation to issues surrounding privacy and data protection. Additional rules which may govern the working of the courts include Rules of the Superior Courts. Although these are not official pieces of regulation, they are informed by legislation and the Constitution.

The Irish Constitution:

The Irish Constitution (*Bunreacht na hÉireann*) sets out the fundamental principles which inform all parts of the Irish government including the legislative, executive and the judiciary. The importance of the Irish Constitution is found in its power to outline the way in which laws are written and executed. The Constitution also lays out fundamental rights, including personal rights and family rights, which are found in Articles 40 to 44. Furthermore, it advises the judiciary power in Ireland on how to act. For example, Articles 34 to 37 of the Irish Constitution outlines the basic laws of the Courts in Ireland including the powers and limitations of each Court that exists in Ireland.⁷ Articles 38 and 39 of the Constitution define the basic principles of trials of various offences. Notably, Article 38.1 finds that no person may be tried in a court of law without the observance of their due process rights.⁸ All laws enacted by the Oireachtas have to be compatible with the Irish Constitution.⁹

International and European Union law:

Ireland is party to a number of international treaties. The Irish Constitution recognises "principles of international law as its rule of conduct in relations with other States".¹⁰ As a dualist legal system, international law becomes part of Irish domestic law through express incorporation by or under an Act of the Oireachtas.¹¹ This dualist aspect is expressed and enshrined in the Constitution, which states that "[n]o international agreement shall be part of the domestic law of the State save as may be determined by the Oireachtas."¹² Some of the main United Nations (UN) treaties to which Ireland is a signatory, and which are relevant to this national legal case study, include the International Covenant on Civil and Political Rights (ICCPR), the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), the International Covenant on Economic, Social and Cultural Rights (ICESCR), the Convention on the Rights of the Child (CRC), and the Convention on the Rights of Persons with Disabilities (CRPD).¹³

¹² Bunreacht na hÉireann, Article 29(6).

¹³ International Covenant on Civil and Political Rights (entered into force 23 March 1976), G.A. Res 2200A (XXI); Convention on the Elimination of All Forms of Discrimination against Women (entered into force 3 September 1981), 1249 U.N.T.S. 13; International Convention on the Elimination of All Forms of Racial Discrimination (entry into force 4 January 1969) G.A. Res. 2106 (XX) (ICERD); 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 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.



⁷ Bunreacht na hÉireann, Article 34-37.

⁸ Ibid Article 38 (1).

⁹ Sheridan, P. (2021) *Civil Law in Ireland / Lawyers in Ireland* [Online]. Available at: <u>https://www.lawyersireland.eu/civil-law-in-</u>

ireland#:~:text=The%20Irish%20legal%20system%20has,breaches%20of%20provisions%20of%20contract <u>s</u>.

¹⁰ Bunreacht na hÉireann, Article 29 (3).

¹¹ Ibid Article 29 (6); *Treaties* / Department of Foreign Affairs, [Online]. Available at: <u>https://www.dfa.ie/our-role-policies/international-priorities/international-law/treaties/</u>.

Furthermore, Ireland is a Member State of the Council of Europe and incorporated the European Convention on Human Rights into Irish domestic law through an Act of the Oireachtas in 2003.¹⁴

Ireland is an EU Member State since 1973, and is subject to European Union laws, including Regulations, Directives, and Decisions.¹⁵

Irish court system

The Irish court system is split between two types of disputes: civil law proceedings and criminal law proceedings.¹⁶ Ireland has five distinct types of court, operating in a hierarchy. With a few exceptions, the district court is generally speaking the country's court of first instance, followed by the Circuit Court, High Court, Court of Appeal and Supreme Court.¹⁷ Ireland operates a jury system, and the right to a jury trial is recognised as a constitutional right for indictable criminal offences.¹⁸

1.5 Current state of neurotechnologies in Ireland

There are limited neurotechnology-specific policy and legal developments in Ireland. Neuroscience in itself is still a relatively young field.¹⁹ Some neurotechnologies, such as deep brain stimulation, are recognised procedures for treating neurological disorders, such as dystonia.²⁰ However, due to cost and lack of economies of scale, patients in Ireland are typically referred to hospitals elsewhere in the EU under the Treatment Abroad Scheme (TAS), or to hospitals the UK, in order to receive treatment.²¹

²⁰ Ibid.

²¹ Ibid; Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community (OJ L 149, 5.7.1971, p. 2); Regulation (EEC) No 574/72 of the Council of 21 March 1972 fixing the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community, (OJ L 74, 27.2.1972, p. 1); Health Information and Quality Authority (2012) *Health technology assessment of a national deep brain stimulation service in Ireland*. Health Information and Quality Authority, [Online]. Available at: https://www.nai.ie/assets/45/114E52E4-0202-6A35-112870131738C8D7 document/HTA-Deep-Brain-Stimulation-Service.pdf.



 ¹⁴ European Convention on Human Rights Act 2003 (Number 20 of 2003), Act of the Oireachtas (Ireland).
 ¹⁵ Ireland / European Union, [Online]. Available at: <u>https://european-union.europa.eu/principles-countries-</u>

history/country-profiles/ireland en.

¹⁶ What the Courts do / An tSeirbhís Chúirteanna Court Service, [Online]. Available at: https://www.courts.ie/what-courts-do.

¹⁷ Ibid.

¹⁸ Bunreacht na hÉireann, Article 38 (5).

¹⁹ Irish Brain Council / Neuroscience Ireland, [Online]. Available at:

https://neuroscienceireland.com/neuroscience-advocacy/.

2. Neurotech-specific legal developments

This section provides an overview of the legal and policy developments pertaining to neurotechnologies in Ireland. 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.

Irish policy on neurotech

The Irish Department of Health is the governmental institution which seeks to improve the health and wellbeing of all people in Ireland.²² Headed by the Minister of Health, the Department of Health is responsible for setting the government's strategic health objectives. The Statement of Strategy 2021-2023 is the department's corporate strategy over a three-year period.²³ Whilst technological innovation and digitisation is seen as a key enabler, the policy document makes no reference to neurotechnologies. The Irish Health Services Executive is the publicly funded body responsible for the provision of health services. The National Strategy & Policy for the Provision of Neuro-Rehabilitation Services in Ireland does not explicitly refer to neurotechnological developments, such as advances in neuroimaging, as part of its overall vision.²⁴

Since 2013, the Irish Brain Council has provided a platform for policy development and advocacy in relation to brain research.²⁵ It is an umbrella organisation of groups and professional societies with an interest in brain research. The Irish Brain Council is committed to 'promoting neuroscience advocacy in Ireland through public outreach, legislative engagement, strategic partnership and individual member engagement.'²⁶ In its inaugural position paper of March 2017, the Irish Brain Council recognises the need for developing networks in order to create economies of scale in accessing emerging technologies, and sees access to emerging technologies as a means to becoming leader in brain health and research.²⁷ In this position paper, the Irish Brain Council also calls for legislative change and policy development to support brain health and research in Ireland.²⁸ Ireland's health information landscape is fragmented,

²⁸ Ibid 15.



²² About the Department of Health / gov.ie, [Online]. Available at: <u>https://www.gov.ie/en/organisation-information/7d70f7-about-the-department-of-health/</u>.

²³ Department of Health (2021) *Department of Health: Statement of Strategy 2021-2023*. [Online]. Available at: <u>https://www.gov.ie/en/organisation-information/0fd9c-department-of-health-statement-of-strategy-2021-</u>

^{2023/#:~:}text=supporting%20people%20to%20lead%20healthy,health%20and%20social%20care%20servi ce, p. 6.

²⁴ Health Services Executive (2019) *National Strategy & Policy for the Provision of Neuro-Rehabilitation Services in Ireland: from Theory to Action.* [Online]. Available at:

https://www.hse.ie/eng/services/list/4/disability/neurorehabilitation/national-strategy-policy-for-the-provision-of-neuro-rehabilitation-services-in-ireland.pdf.

²⁵ NAI, Irish Brain Council and Novartis (2015) *Meeting Report: Brain Research in Ireland – Delivering on the Potential*. Nai, Irish Brain Council and Novartis, [Online]. Available at:

https://irishbraincouncil.files.wordpress.com/2015/05/brain research in ireland report.pdf

 ²⁶ Advocacy / The Irish Brain Council, [Online]. Available at: <u>https://irishbraincouncil.com/advocacy/</u>.
 ²⁷ Clarke, S., et al. (2017) Building a Supportive Framework for Brain Research in Ireland: Inaugural Position

Paper – The Irish Brain Council. Irish Brain Council, [Online]. Available at:

https://neuroscienceireland.com/wp-content/uploads/2017/03/ibc-position-paper-march-2017.pdf, p. 12-13.

and strong health information policies and legislation are required to support the introduction of new systems or technologies, such as electronic health records.²⁹

In addition to the Irish Brain Council, there are a number of not-for-profit organisations that seek to advance neuroscience and brain research in Ireland. Neuroscience Ireland, for instance, is Ireland's National Neuroscience Society. Established in 2005, this charitable organisation advocates for greater public and political awareness to advance neuroscience in Ireland.³⁰ The Neurological Alliance of Ireland (NAI) represents over thirty organisations advocating for the rights of people with a neurological condition in Ireland.³¹

Irish law on neurotech

There are no Irish laws that explicitly mention the regulation of neurotechnologies. Medical devices in general are regulated by the Health Products Regulatory Authority (HPRA) as the Competent Authority (CA) in Ireland.³² Medical devices legislation, which in Ireland is predominantly derived from the EU, distinguishes between three types of devices: general medical devices, active implantable medical devices, and *in-vitro* medical devices. Regulation 2017/45 on Medical Devices (MDR) and Regulation 2017/746 on *In-Vitro* Diagnostic Devices (IVDR) were adopted to replace earlier Directives and significantly strengthen the regulation of medical devices across the EU.³³ As Regulations, these EU laws are directly applicable in all EU Member States and do not need to be transposed into national law.³⁴

The MDR is the main piece of EU legislation applicable to the use of neurotechnologies and the introduction of such technologies on the Irish market. The MDR and its implications for the use of neurotechnologies in Ireland is considered in more detail in Section 3.4 below.

Proposals for dedicated law

There are no known active proposals for dedicated legislation on neurotechnologies in Ireland.

Responsibility for enforcement

The Department of Health is the Irish governmental department responsible for the development of the country's health policy and strategic objectives. The Health Services Executive is the national healthcare service and is publicly funded.³⁵ The Health Products Regulatory Authority (HPRA) is the Irish

³⁵ HSE Organisational Structure / HSE, [Online]. Available at: <u>https://www.hse.ie/eng/about/who/</u>.



²⁹ Rogers, M. et al. (2019) 'Building a supportive framework for brain research in Ireland: Inaugural position paper of the Irish Brain Council' *European Journal of Neuroscience*, 49, 1362-1370, [Online]. Available at: <u>https://doi.org/10.1111/ejn.14351</u> pp.1367-1368.

³⁰ About us / Neuroscience Ireland, [Online]. Available at: <u>https://neuroscienceireland.com/about/</u>.

 ³¹ About us / Neurological Alliance of Ireland, [Online]. Available at: <u>https://www.nai.ie/go/about_us</u>.
 ³² Regulatory Information / HPRA [Online]. Available at: <u>http://www.hpra.ie/homepage/medical-</u>

devices/regulatory-information.

³³ Regulation (EU) 2017/45 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directive 90/385/EEC and 93/42/EEC, (OJ L 117, p. 1); Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, (OJ L 117, p. 176); *Regulatory Information* / HPRA [Online]. Available at: <u>http://www.hpra.ie/homepage/medical-devices/regulatoryinformation</u>.

³⁴ *Regulatory Information /* HPRA [Online]. Available at: <u>http://www.hpra.ie/homepage/medical-</u> <u>devices/regulatory-information</u>; Consolidated version of the Treaty on the Functioning of the European Union (2012) OJ C326/47, article 288.

regulator for medicines and medical devices.³⁶ It is the National Competent Authority (NCA) within the meaning of the MDR and regulates health products including devices to ensure they comply with relevant standards and legislation.³⁷

Significant legal cases

The most significant case law relates to the admissibility of neuroscientific evidence in legal proceedings for the purposes of *inter alia* establishing a relevant defence, such as insanity,³⁸ in criminal law cases, as well as quantifying injuries for the purposes of awarding damages in civil law cases (see further Section 3.3 below).³⁹

Current debates and future policy and/or legal developments

Whilst there are limited debates in Ireland on neurotechnologies specifically, various brain institutions are calling for more policy and legislative development in relation to brain research and health information sharing. The Irish Brain Council, in its 2017 inaugural paper, is calling for legislative change and policy development to support brain health and research in Ireland.⁴⁰ The Health Information and Quality Authority is also calling to reform Ireland's national health information system.⁴¹ The current lack of legislation hinders the coordination of information sharing between various health institutions.⁴²

http://www.hpra.ie/homepage/about-us/how-we-regulate; *Medical Devices* / European Medicines Agency, [Online]. Available at: https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices; Regulation (EU) 2017/45 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directive 90/385/EEC and 93/42/EEC, (OJ L 117, p. 1).

³⁸ DPP v Ramzan [2018] IESCDET 34, [2018] 2JIC 0512.

⁴² Ibid 6.



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³⁶ Keena C. (2018) *Implant Files: Medical devices may have caused more than 1,000 health incidents last year /* The Irish Times, [Online]. Available at: <u>https://www.irishtimes.com/news/ireland/irish-news/implant-files-</u> <u>medical-devices-may-have-caused-more-than-1-000-health-incidents-last-year-1.3708071</u>.

³⁷ What We Regulate and How We Regulate / HPRA, [Online]. Available at:

³⁹ Oliver Bennett v John Codd and Wallace Taverns Ltd [2020] IEHC 554, [2020] 11 JIC 0301.

⁴⁰ Clarke, S., et al. (2017) *Building a Supportive Framework for Brain Research in Ireland: Inaugural Position Paper – The Irish Brain Council*. Irish Brain Council, [Online]. Available at:

https://neuroscienceireland.com/wp-content/uploads/2017/03/ibc-position-paper-march-2017.pdf, p. 15. ⁴¹ Health Information and Quality Authority (2019) *The Need to Reform Ireland's National Health Information System: to support the delivery of health and social care* services. Health Information and Quality Authority, Dublin, [Online]. Available at: https://www.hiqa.ie/sites/default/files/2021-10/The-need-for-reform-of-the-health-information-system.pdf.

3. Domain-specific legal issues

This section examines the legal implications of neurotechnologies in an Irish context with respect to specific legal domains with a high socio-economic impact. The legal domains covered include 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 discuss some of the ways that neurotechnologies are or may be governed by Irish law and policy within the frameworks of human rights (Section 3.1), privacy and data protection (Section 3.2), use in legal systems (Section 3.3), and liability for harms (Section 3.4). Each section begins with a brief introduction to the relevant legal issues and a summary of the Irish legal framework. Specific legal issues within the identified egal frameworks are then presented in more detail, with each discussion including specific references to existing (and proposed) law(s) and an explanation of how the law(s) may apply to neurotechnologies in Ireland. Overall, whilst there is no dedicated Irish law regulating the use of neurotechnologies, many aspects are subject to the identified domains of the Irish legal system.

3.1 Human rights law

The purpose of this section is to firstly (Section 3.1.1) outline the applicable human rights law frameworks under domestic and international law, focusing on four major sources, namely: the Irish Constitution, statutory law enacted by the *Oireachtas*, international human rights law and regional human rights law, including relevant EU law. In the second part of this section (Section 3.1.2), and before considering how the various sources of the right to privacy might protect against the misuse of brain and other neural data generated through the use of neurotechnologies (see Section 3.2.1), the prospective use of neurotechnologies for the purposes of rehabilitating criminal offenders will be situated against the protection afforded by the unenumerated constitutional right to bodily integrity.

3.1.1 Sources of Irish human rights law

The human rights law framework in Ireland includes a variety of national and international legal sources. The primary source of human rights law in Ireland is the Irish Constitution, one of the stated purposes of which is "that the dignity and freedom of the individual may be assured".⁴³ Whilst several unenumerated constitutional rights have been recognised by the courts, including the right to bodily integrity (see Section 3.1.2), the right to privacy (see Section 3.2.1) and the right to be free from torture not to be subject to inhuman or degrading treatment or punishment,⁴⁴ the majority of fundamental rights are explicitly contained in the text of the Irish Constitution. Here, protected rights are grouped into personal rights,⁴⁵ family rights,⁴⁶ education rights,⁴⁷ children's' rights,⁴⁸ private property rights,⁴⁹ and religious rights.⁵⁰ In the context of neurotechnologies, the most applicable includes the following:

⁵⁰ Ibid Article 44.



⁴³ Bunreacht na hÉireann, preamble.

⁴⁴ See, e.g., *The State (C.) v. Frawley* [1976] IR365.

⁴⁵ Bunreacht na hÉireann, Article 40.

⁴⁶ Ibid Article 41.

⁴⁷ Ibid Article 42.

⁴⁸ Ibid Article 42A.

⁴⁹ Ibid Article 43.

- Right to life;⁵¹
- o Right to a fair trial;⁵²
- Right to equality before the law;⁵³
- Freedom of expression;⁵⁴
- The rights of the family,⁵⁵ including the rights of children;⁵⁶
- Freedom of conscience.⁵⁷

An additional source of human rights law in Ireland is statutory law enacted by the Oireachtas, including:

- **The European Convention on Human Rights Act (2003)**, which gives "further effect" to the eponymous European Convention on Human Rights (ECHR), the cornerstone of the Council of Europe human rights law framework.⁵⁸ Domestic courts in Ireland are required to interpret and apply Irish law compatibly with the ECHR, while "every organ of the State" is similarly required to perform its functions "in a manner compatible with the State's obligations under the Convention provisions."⁵⁹
- **The Irish Human Rights and Equality Commission Act (2014**), which creates the Irish Human Rights and Equality Commission (*Coimisiún na hÉireann um Chearta an Duine agus Comhionannas*)⁶⁰ and establishes a positive duty on public bodies to "eliminate discrimination", "promote equality of opportunity", and "protect the human rights of its members".⁶¹

As an EU Member State, the **Charter of Fundamental Rights of the European Union** (CFREU)⁶² is applicable to the Irish government when implementing EU law. This means that the transposition of an EU directive or the passing of legislation to align with an EU regulation must be in accordance with the various rights contained therein, including the right to health,⁶³ the right to education,⁶⁴ and the right to rest.⁶⁵

- ⁵³ Ibid Article 40.1.
- ⁵⁴ Ibid Article 40.6.1.
- ⁵⁵ Ibid Article 41.
- ⁵⁶ Ibid Article 42A.
- ⁵⁷ Ibid Article 44.2.1.
- ⁵⁸ European Convention on Human Rights Act 2003, preamble.
- ⁵⁹ Ibid s.2(1)-3(1).
- ⁶⁰ Irish Human Rights and Equality Commission Act 2014, s.9.
- ⁶¹ Ibid, s.42(1)(a)-(c).

⁶⁵ Ibid, Article 31(2).



⁵¹ Ibid Article 40.3.

⁵² Ibid Article 38.1.

⁶² Charter of Fundamental Rights of the European Union (CFREU) (entry into force 18 December 2009) 2000/C 364/01.

⁶³ Ibid, Article 35.

⁶⁴ Ibid, Article 14.

In addition to constitutional, statutory and regional human rights law, Ireland is a state party to a number of United Nations (UN) international human rights law treaties, including the following:

- o International Covenant on Economic, Social and Cultural Rights (ICESCR);66
- o International Covenant on Civil and Political Rights (ICCPR);⁶⁷
- Convention on the Elimination of All Forms of Discrimination against Women (CEDAW);⁶⁸
- o International Convention on the Elimination of All Forms of Racial Discrimination (ICERD);⁶⁹
- Convention on the Rights of the Child (CRC);⁷⁰
- Convention on the Rights of Persons with Disabilities (CRPD).⁷¹

3.1.2 Human rights law implications

Neurotechnologies have the potential to impact human rights in many ways, both positively and negatively. In relation to some rights in particular contexts, neurotechnologies have the potential to enhance the enjoyment of rights, such as when neurotechnologies provide innovative treatment options that positively impact the right to health. In other situations, however, the use of neurotechnologies may interfere with protected human rights, for instance if use in the courtroom violates the prohibition on self-incrimination as guaranteed under international human rights law. Building upon the analysis in TechEthos Deliverable 4.1 of the various human rights protected under international and EU law that neurotechnologies may enhance and/or interfere with,⁷² this section explores the right to bodily integrity in relation to the prospective use of neurotechnologies in the criminal justice system for the purposes of staging medical interventions designed to rehabilitate offenders.

Right to bodily integrity

A key conceptual component of putative "neurorights" is the right to mental integrity, the progenitor for which is rooted in the more widely recognised and protected right to bodily integrity.⁷³ Indeed, although not explicitly contained within the Irish Constitution, the right to bodily integrity has been recognised by the courts as an unenumerated constitutional right guaranteeing protection against the physical intrusion on a person's body, as well as freedom from torture and inhumane treatment.⁷⁴ Thus

⁷⁴ Doyle, O. (2008) *Constitutional Law: Text, Cases and Materials*. Dublin: Clarus Press. p.124.



⁶⁶ 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.

 ⁶⁷ International Covenant on Civil and Political Rights (entry into force 23 March 1976) G.A. Res 2200A (XXI).
 ⁶⁸ Convention on the Elimination of All Forms of Discrimination against Women (entered into force 3 September 1981), 1249 U.N.T.S. 13.

⁶⁹ International Convention on the Elimination of All Forms of Racial Discrimination (entry into force 4 January 1969) G.A. Res. 2106 (XX).

⁷⁰ Convention on the Rights of the Child (entered into force 2 September 1990) GA Res. 44/25, 1577 U.N.T.S. 3

⁷¹Convention on the Rights of Persons with Disabilities (entered into force 3 May 2008), GA Res. A/61/106. ⁷² Santiago, N. et al. (2022) *TechEthos D4.1: Analysis of International and EU law and policy*. TechEthos Project Deliverable. Available at: https://www.techethos.eu/

⁷³ Ienca, M. (2021) Common Human Rights Challenges Raised by Different Applications of Neurotechnologies in Biomedical Fields. Council of Europe. Available at: <u>https://rm.coe.int/report-final-en/1680a429f3</u>

framed as a negative right,⁷⁵ the constitutional basis for this right is Article 40.3.1, which provides that "The State guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate the personal rights of the citizen."⁷⁶ In the most widely cited judicial pronouncement on the right to bodily integrity, it is understood

to mean that no mutilation of the body or any of its members may be carried out on any citizen under authority of the law except for the good of the whole body and that no process which is or may, as a matter of probability, be dangerous or harmful to the life or health of the citizens or any of them may be imposed (in the sense of being made compulsory) by an Act of the Oireachtas.⁷⁷

Further case law has since considered the parameters of the protection against intrusions into physical integrity, with the Irish Court of Appeal extending this right and recognising that "[b]odily integrity includes psychological integrity."⁷⁸ Protection for the latter right may be seen as closely connected to or a direct analogue for the so-called neuroright to mental integrity, which is conceptualised as protecting against harms arising from neurotechnology-related forced intrusion into and/or alteration of an individual's neural processes.⁷⁹ In addition to protection as a matter of constitutional law, Ireland is a Member State of the European Union (EU), whose Charter of Fundamental of Rights (CFREU) provides that "everyone has the right to respect for his or her physical and mental integrity",⁸⁰ as well as being a state party to international human rights laws treaties establishing protection for bodily and/or mental integrity.⁸¹ As ratified by Ireland in 2018, the Convention on the Rights of Persons with Disabilities (CRPD), for instance, states that "[e]very person with disabilities has a right to respect for his or her physical and mental integrity on an equal basis with others."⁸²

The issue of bodily integrity and the associated aspect of psychological integrity may be examined against prospective uses of neurotechnology in rehabilitative treatment of criminal offenders. Although the use of medical interventions for criminal rehabilitation has been limited to date,⁸³ emerging technologies involving direct brain interventions such as deep-brain stimulation (DBS) or neurotherapy may become more prevalent in the future.⁸⁴ The critical ethical-legal questions surrounding the use of such technologies relates to consent and the right to bodily and mental integrity. Several scholars have pointed to the potential ethical issues of using neurotechnologies for the purposes of treating offenders, for instance, noting that the right of voluntary consent should be given by the offender to interfere with their brain.⁸⁵ Other scholars, such as Douglas, have considered that committing a crime

⁷⁸ McDonnell v The Governor of Wheatfield Prison [2015] IECA 216 , [2015] 2 ILRM 361, [58].

⁸⁵ See, e.g., Craig, J.N. (2016) 'Incarceration, Direct Brain Intervention, and the Right to Mental Integrity- a Reply to Thomas Douglas' *Neuroethics*, 9 (1); Gkotsi, G.M., Benaroyo, L. (2012) 'Neuroscience and the



⁷⁵ A negative right may be defined as the right not to be subjected to actions (usually abusive) by another person or group. Where the person is subjected to, for instance, an abusive act by another person or institution, it may be said their negative right (such as the one for bodily integrity) is being breached.
⁷⁶ Bunreacht na hÉireann, Article 40.3.1.

⁷⁷ Ryan v. Attorney General [1962] No.913 P; Ryan v Attorney General [1965] IR 294.

⁷⁹ 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: <u>https://doi.org/10.1186/s40504-017-0050-</u>

⁸⁰ Charter of Fundamental Rights of the European Union 2012/C 326/02, Article 3.

⁸¹ See, e.g., International Covenant on Civil and Political Rights (entry into force 23 March 1976) G.A. Res 2200A (XXI).

⁸² Convention on the Rights of Persons with Disabilities (entered into force 3 May 2008), GA Res. A/61/106, Article 17.

⁸³ Douglas, T. (2014) 'Criminal Rehabilitation Through Medical Intervention: Moral Liability and the Right to Bodily Integrity', *The Journal of Ethics*, Vol. 18(1), pp.101-122. DOI: <u>https://doi.org/10.1007/s10892-014-</u> <u>9161-6</u>

⁸⁴ Gkotsi, G.M., Benaroyo, L. (2012) 'Neuroscience and the Treatment of Mentally Ill Criminal Offenders: Some Ethical Issues' *Journal of Ethics in Mental Health*, 6 (Supplement).

may render individuals morally liable for accepting certain types of medical treatment, prospectively including neuroscientific interventions.⁸⁶ However, this view may be considered particularly problematic in the context of invasive neurotechnological procedures, such as DBS.⁸⁷

The Irish criminal justice system has adopted several ways in which treatment is proposed for those who have come into contact with the criminal justice system. Once of such ways is through Drug Treatment Courts. Drug Treatment Courts in Ireland provide a programme for treatment and rehabilitation of individuals who have pleaded guilty or have been found guilty of violent crimes in the District Court.⁸⁸ Individuals are referred to the programme by the District Court Judge, but participation is voluntary.⁸⁹ Similarly, where individuals with mental disorders present to the District Court, the Bail Act 1997 finds the Court may consider appropriate conditions for granting bail.⁹⁰ These may include attending psychiatric centres. However, the District Court does not have a statutory power to impose custody to psychiatric centres or other treatment facilities. They may comment on the need for treatment, or inquire that *An Garda Siochana* (see Section 3.3 below) uses their power to place them under custody,⁹¹ but consent to and participation in treatment is done on a voluntary basis.⁹² Based on current trends, it seems any novel rehabilitative treatment proposals, including neuroscientific techniques, would solely be considered on a voluntary basis.

3.2 Privacy and data protection law

Neurotechnologies collect and process brain and other neural data that can be used to gain insights into brain activity, mental states and emotions, primarily for the purposes of medical treatment and research, but also increasingly for consumer-directed purposes. The collection and processing of such data, however, raises significant concerns related to privacy and data protection law. In Ireland, there are multiple sources of privacy and data protection law, including the Constitution, statute and the common law, as well as the State's obligations under international law and, in particular, EU law. Of particular importance is the General Data Protection Regulation (GDPR), which establishes a comprehensive framework for privacy and data protection that is directly applicable in all EU Member States.⁹³ Ireland has given "further effect"⁹⁴ to this provision through its enactment of the Data Protection Act 2018 and, moreover, assumed an active role in shaping how this regulation applies in practice.

 ⁹³ Consolidated version of the Treaty on the Functioning of the European Union C-326/49, Article 288.
 ⁹⁴ Data Protection Act 2018, preamble.



Treatment of Mentally Ill Criminal Offenders: Some Ethical Issues' *Journal of Ethics in Mental Health*, 6 (Supplement); Kirchmair, L. (2019) 'Objections to Coercive Neurocorrectives for Criminal Offenders- Why Offenders' Human Rights Should Fundamentally Come First' *Criminal Justice Ethics*, 38 (1). ⁸⁶ Douglas, T. (2014) 'Criminal Rehabilitation Through Medical Intervention: Moral Liability and the Right to Bodily Integrity' *The Journal of Ethics*, Vol. 18(1), pp.101-122. DOI: <u>https://doi.org/10.1007/s10892-014-</u>

<u>9161-6</u>

⁸⁷ Deep-brain stimulation involves the use of surgically implanted devices to deliver electrical stimulation to targeted areas deep in the brain. It may be used for treatment of movement disorders and is being proposed for use on other neurological disorders although this is still debated in the scientific industry (Gkotsi, G.M., Benaroyo, L. (2012) 'Neuroscience and the Treatment of Mentally Ill Criminal Offenders: Some Ethical Issues' Journal of Ethics in Mental Health, 6 (Supplement).)

⁸⁸ The Courts Service of Ireland. (2022) *What Happens in The Drug Treatment Court /* [Online]. Available at: <u>https://www.courts.ie/what-happens-drug-treatment-court-0</u>.

⁸⁹ Loughran, H., Hohman, M., Carolan, F., Bloomfield, D. (2015) 'Practice Note: The Irish Drug Treatment Court' *Alcoholism Treatment Quarterly*, 33 (1).

⁹⁰ Bail Act 1997, s. 6 (1) (b).

⁹¹ This may be carried out under section 12 of the Mental Health Act 2001.

⁹² Whelan, D. (2007) 'Fitness for Trial in The District Court: The Legal Perspective', *Judicial Studies Institute Journal*, 2 (1).

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The hosting of the European headquarters of multiple Big Tech multinational corporations, including Google, Meta and LinkedIn, has enabled the Irish Data Protection Commission (DPC), the domestic "supervisory authority" constituted in accordance with the GDPR,⁹⁵ to monitor the data processing activities of these companies for compliance with the GDPR, both in Europe and extraterritorially.⁹⁶ The latter is underscored by the judgements of *Schrems I*,⁹⁷ and *Schrems II*,⁹⁸ following an action brought before the Irish High Court against Facebook Ireland, from which a request for a preliminary ruling⁹⁹ resulted in the Court of Justice of the European Union (CJEU) invalidating two separate adequacy determinations by the European Commission,¹⁰⁰ leading to first the Safe Harbour and latterly the Privacy Shield data transfer and sharing agreements between the U.S. and the EU being struck down. Although an agreement in principle for a new Trans-Atlantic Data Privacy framework between the EU and the US has since been reached,¹⁰¹ this highlights a general point relating to the scope of this inquiry, namely: it should be borne in mind that whilst the focus of this section is upon specific aspects of privacy and data protection law in Ireland, the wider legal implications of and issues associated with the GDPR for the regulation of neurotechnologies in the EU, as analysed in TechEthos Deliverable 4.1,¹⁰² are also relevant.

3.2.1 **Privacy**

The various applications of neurotechnologies, both within and outside clinical and research contexts, present a wide range of challenges related to the right to privacy, including discriminatory use and unwanted disclosure of potentially highly sensitive information, as well as intrusion into the inner sanctum of the brain.¹⁰³ The right to privacy in Ireland is protected by various legal frameworks, including the Constitution, statutes and statutory instruments, as well as the State's obligations under international law and EU law.

The right to privacy is not expressly provided for nor guaranteed by the Constitution of Ireland but is considered to be an unenumerated right implicitly embedded within it.¹⁰⁴ Through case law it has been recognised that although not "an unqualified right", nor "specifically guaranteed by the Constitution, the right to privacy is one of the fundamental personal rights of the citizen which flow from the Christian and democratic nature of the state."¹⁰⁵ This right was first recognised by a 4:1 majority of the Supreme Court in the context of marital relations, with Walsh J holding that "Article 41 of the Constitution

Data Privacy Framework / European Commission [Online]. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip 22 2087

 ¹⁰⁴ Kelleher, D. (2015) *Privacy and Data Protection Law in Ireland* (2nd Edition. Bloomsbury) pp.7.
 ¹⁰⁵ Kennedy v Ireland [1987] I.R. 587 at 591.



 ⁹⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119. Article 51.
 ⁹⁶ McLaughlin, S. (2018) 'Ireland: A Brief Overview of the Implementation of the GDPR', *European Data Protection Law Review*, vol.4:2, pp.227-234, pp.234. DOI: 10.21552/edpl/2018/212.

⁹⁷ Judgement of the Court (Grand Chamber) of 6 October 2015 Case C-362/14 *Maximillian Schrems v Data Protection Commissioner*.

⁹⁸ Judgement of the Court (Grand Chamber) of 16 July 2020 Case C-311/18 *Data Protection Commissioner v Facebook Ireland Limited and Maximillian Schrems*.

 ⁹⁹ Consolidated version of the Treaty on the Functioning of the European Union C-326/49, Art.267.
 ¹⁰⁰ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.45.
 ¹⁰¹ European Commission. (2022) European Commission and United States Joint Statement on Trans-Atlantic

¹⁰² Santiago, N. et al. (2022) *TechEthos D4.1: Analysis of International and EU law and policy*. TechEthos Project Deliverable. Available at: <u>https://www.techethos.eu/</u>

¹⁰³ 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/lsac025

guarantees the husband and wife against...invasion of their privacy by the State."¹⁰⁶ Following this, the High Court held that the "personal rights of the citizen"¹⁰⁷ include an unenumerated general right to privacy which protects against the "deliberate, conscious and unjustified interference" with the telephone conversations of private parties by State agents.¹⁰⁸

It has been observed that there are "many different facets of the right to privacy", with particular aspects of the right having application to various other constitutional rights, including the right to voting under Article 16, the rights of certain litigants under Article 34, the right to freedom from arrest and detention under Article 40.4, the right to inviolability of the dwelling under Article 40.5, the rights to freedom of opinion, assembly and association under Article 40.6.1, the rights of the family under Article 41 (including with regard to education under Article 42), the right of private property under Article 43 and the right to freedom of conscience and free practice of religion under Article 44,¹⁰⁹ as well as the right to personal autonomy implicit in Articles 40.3.1 and 40.3.2 and the commitment to respect for human dignity and freedom of the individual in the preamble.¹¹⁰

Aspects of the right to privacy are also protected by statutes and statutory instruments.¹¹¹ For example, the Privacy and Electronic Communications Regulations 2011, as amended in 2019,¹¹² refer to "the right to privacy" of users and subscribers in the context of itemised billing for electronic communications services.¹¹³ Additionally, the European Convention on Human Rights Act (2003) requires that when "interpreting and applying any statutory provision or rule of law, a court shall, in so far as is possible, subject to the rules of law relating to such interpretation and application, do so in a manner compatible with the State's obligations under the Convention provisions."¹¹⁴ It also requires that every organ of the State performs "its functions in a manner compatible with the State's obligations under the Convention on Human Rights (ECHR), including the right of everyone "to respect for his private and family life, his home and his correspondence."¹¹⁶

Regarding its obligations under international law, Ireland ratified the International Covenant on Civil and Political Rights (ICCPR) in December 1989, Article 17 of which provides that "[n]o one shall be subjected to arbitrary or unlawful interference with his privacy, family, home, or correspondence, nor to unlawful attacks on his honour and reputation." Further, as indicated above, Ireland has signed and ratified the ECHR and is therefore obligated to respect the right to private and family life under Article 8. Lastly, following its accession to membership of the EU (formerly the European Economic Community) in January 1973, Ireland is bound by the Charter of Fundamental Rights of the European Union (CFREU) when implementing EU law,¹¹⁷ Article 7 of which provides that "[e]veryone has the right to respect for his or her private and family life, home and communications."

A key consideration emerging from the foregoing is whether the right to privacy, as effected by international and domestic law, including constitutional law, protects against interference with brain and other neural data generated through the use of neurotechnologies. In the case law identified above

¹¹⁴ European Convention on Human Rights Act 2003, s.2(1).

¹¹⁷ Charter of Fundamental Rights of the European Union 2012/C 326/02, Article 51(1).



¹⁰⁶ McGee v Attorney General [1974] IR 284 at 313.

¹⁰⁷ Bunreacht na hÉireann, Article 40.3.1.

¹⁰⁸ Kennedy v Ireland [1987] I.R. 587 at 592.

¹⁰⁹ Norris v The Attorney General [1984] I.R. 36 at 100-101.

¹¹⁰ Schrems v Data Protection Commissioner [2014] IEHC 310 at 53.

¹¹¹ Kelleher, D. (2015) *Privacy and Data Protection Law in Ireland* (2nd Edition. Bloomsbury) pp.27.

¹¹² European Communities (Electronic Communications Networks and Services) (Privacy and Electronic Communications) (Amendment) Regulations 2019.

¹¹³ European Communities (Electronic Communications Networks and Services) (Privacy and Electronic Communications) Regulations 2011, Reg.7(2).

¹¹⁵ Ibid s.3(1).

¹¹⁶ European Convention on Human Rights (ECHR) (as amended by Protocols 11, 14 and 15) (entry into force 3 September 1953) E.T.S. 5, 4.XI.1950, Article 8.

it has been recognised that the Constitution provides for a general right to privacy, which establishes that the privacy interests of private citizens are protected against intrusion by the State and State agents. However, the specific circumstances in which the right to privacy was recognised as being engaged related to the sexual relationship of private citizens and the unlawful interference with private citizens' communications, neither of which have straightforward application to the privacy challenges associated with neurotechnologies.

The right to privacy under the ECHR, however, is potentially more applicable. In this context, brain and other neural data might be considered analogous to genetic and biometric data, including cellular samples, DNA profiles and dactyloscopic data, the collection and/or retention of which has been determined by the European Court of Human Rights (ECtHR) in various cases before it to constitute a prima facie interference with the right to respect for private life.¹¹⁸ Also relevant here is the interpretation of the right to privacy under Article 8 to protect information relating to an individual's health, including mental health.¹¹⁹ Should the ECtHR recognise through a declaration, decision, advisory opinion or judgement that these or another basis for privacy protection are applicable to brain and other neural data, such protections may also be made available as a matter of domestic law, with Irish courts bound by the European Convention on Human Rights Act to "take due account of the principles laid down by those declarations, decisions, advisory opinions, opinions and judgements."¹²⁰

3.2.2 Data protection

The wide range of primarily clinical applications of neurotechnologies raises a variety of potential challenges in relation to Irish data protection law, chief among which is the legal status of, and protection afforded to, brain and other neural data. Ireland has signed and ratified a number of international data protection law treaties, including those relating to the automatic processing of personal data,¹²¹national compliance bodies and transborder data flows.¹²² In addition to its obligations under international law, Ireland has also enacted various data protection statutes and statutory instruments. The E-Privacy Regulations,¹²³ for instance, establish specific rules applicable "to the processing of personal data in connection with the provision of publicly available electronic communication services",¹²⁴ including that "the listening, tapping, storage or other kinds of interception or surveillance of communications and the related traffic data by persons other than users, without the consent of the users concerned, is prohibited."¹²⁵ The primary statutory source of data protection law in Ireland, however, is the Data Protection Acts 1988 to 2018, implementing the Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data,¹²⁶

¹²⁶ CETS 108.



 ¹¹⁸ See, e.g., *Case of S. and Marper v. The United Kingdom* (Application nos.30562/04 and 30566/04) (4
 December 2008); *Case of Gaughran v. The United Kingdom* (Application no.45245/15) (13 February 2020).
 ¹¹⁹ See, e.g., *Case of Surikov v. Ukraine* (Application no.42788/06) (26 January 2017); *Case of Mockute v. Lithuania* (Application no.66490/09) (27 February 2018).

¹²⁰ European Convention on Human Rights Act 2003, s.4

¹²¹ Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108) (entry into force 10 October 1985).

¹²² Additional Protocol to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, regarding supervisory authorities and transborder data flows (ETS No. 181) (entry into force 1 July 2004).

¹²³ European Communities (Electronic Communications Networks and Services) (Privacy And Electronic Communications) Regulations 2011.

¹²⁴ Ibid Reg.3(1).

¹²⁵ Ibid Reg.5(1).

the European Union (EU) Data Protection Directive 95/46/EC,¹²⁷ and Regulation 2016/679,¹²⁸ respectively.

The latter General Data Protection Regulation (GDPR) seeks to enhance individuals' rights to privacy and data protection by establishing a comprehensive framework for the governance of data processing that is directly applicable in all EU Member States, including Ireland.¹²⁹ The Data Protection Act 2018 gives "further effect" to this provision,¹³⁰ for instance by creating a supervisory authority pursuant to Article 51 GDPR,¹³¹ while also promoting closer alignment with EU data protection law by repealing, subject to certain exceptions,¹³² the majority of the provisions contained in the Data Protection Act 2018 and the GDPR apply "to the processing of personal data wholly or partly by automated means and to the processing other than by automated means of personal data which form part of a filing system or are intended to form part of a filing system."¹³⁴ When "processing" personal data, for instance by collecting, recording or disseminating such information,¹³⁵ data controllers and processers are required to comply with various principles,¹³⁶ including that personal data is processed lawfully, fairly and "for one or more specified, explicit and legitimate purposes".¹³⁷

The concept of "personal data" is not separately defined in the Data Protection Act 2018 and thus, in accordance with s.2(2),¹³⁸ the term has the same expansive meaning as provided for in the GDPR, namely "any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person".¹³⁹ Although not defined specifically, reference to mental identity may indicate that brain and other neural data are likely to be treated as personal data, particularly as it has been noted that such data is uniquely related to an individual when collected and processed through neurotechnologies such as electroencephalography (EEG) and functional magnetic resonance imaging

¹³² Ibid s.8(1)(a)-(b); s.8(2)-(3).

¹³⁹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.4(1).



¹²⁷ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data OJ L 281.

¹²⁸ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119.

¹²⁹ Ibid Art.3; Consolidated version of the Treaty on the Functioning of the European Union C-326/49, Article 288.

¹³⁰ Data Protection Act 2018, preamble.

¹³¹ Ibid s.11.

¹³³ Ibid s.7.

¹³⁴ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.2(1).
¹³⁵ Ibid Art.4(2).

¹³⁶ Data Protection Act 2018, s.71(1); Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.5.

¹³⁷ Data Protection Act 2018, s.71(1)(a)-(b).

¹³⁸ "Subject to *subsection (1)*, a word or expression used in this Act, other than in *Part 5*, that is also used in the Data Protection Regulation has, unless the context otherwise requires, the same meaning in this Act as it has in that Regulation."

(fMRI).¹⁴⁰ There are also various neurotechnological applications the effective use of which may require the processing of personal data so defined. For instance, it has been suggested that the optimum functioning and operability of various brain computer interfaces (BCIs), as used for a variety of clinical and consumer-related purposes, depends on the calibration of, and is therefore constitutive of a potentially identifying link between, the brain signal recordings obtained by the device and its user.¹⁴¹

Alongside the requirements relating to the processing of personal data, both the GDPR and the Data Protection Act 2018 regulate the processing of special categories of personal data, the definition for and types of data included within which are substantially similar.¹⁴² In accordance with Article 9(4) GDPR, pursuant to which it is provided that "Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data, or data concerning health", ¹⁴³ s.41 and s.46-54 of the Data Protection Act 2018 specifies a range of circumstances in which the processing of special category personal data is permitted, ¹⁴⁴ including for purposes of employment and social welfare law, ¹⁴⁵ legal advice and legal proceedings, ¹⁴⁶ and insurance and pension purposes.¹⁴⁷ The processing of special category personal data outside of these specified circumstances is subject to compliance with Article 9 GDPR, ¹⁴⁸ which identifies a number of exceptions to the prohibition on the processing of such data, ¹⁴⁹ including that the "data subject has given explicit consent".¹⁵⁰ In the context of neurotechnologies, the attainment of explicit and informed consent may be difficult to achieve, particularly in circumstances where the consequences are not fully known or are still being understood.

Of the various circumstances in which the processing of special category personal data is permitted, most relevant to neurotechnologies such as neuroimaging, neuromodulation and neurostimulation, the primary application of which is in a clinical context for a range of diagnosis, treatment,¹⁵¹ and research purposes,¹⁵² is s.53 of the Data Protection Act 2018. This provision permits as lawful the processing of special categories of personal data "where it is necessary for public interest reasons in the area of public health", such as "protecting against serious cross-border threats to health and ensuring high standards of quality and safety of health care and of medicinal products and medical devices."¹⁵³ There are a range of medical neurotechnology applications, including invasive neurosurgical procedures such as Deep

¹⁵³ Data Protection Act 2018, s.53(a)-(b).



D4.2

¹⁴⁰ Ienca, M., and Malgieri, G. (2022) 'Mental data protection and the GDPR', *Journal of Law and the Biosciences*, vol.9:1, pp.1-19. DOI: <u>https://doi.org/10.1093/jlb/lsac006</u>

¹⁴¹ Rainey, S., et al. (2020) 'Is the European Data Protection Regulation sufficient to deal with emerging data concerns relating to neurotechnology?', *Journal of Law and the Biosciences*, vol.7:1, pp.10. DOI: https://doi.org/10.1093/jlb/lsaa051

¹⁴² Data Protection Act 2018, s.2(1); Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.9(1).

¹⁴³ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.9(4).
¹⁴⁴ Data Protection Act 2018, s.41, 45-54.

¹⁴⁵ Ibid s.46.

¹⁴⁶ Ibid s.47.

¹⁴⁷ Ibid s.50.

¹⁴⁸ Ibid s.45(b).

¹⁴⁹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.9(2)(a)-(j). ¹⁵⁰ Ibid Art.9(2)(a).

¹⁵¹ See, e.g., Ning, S. et al. (2022) 'Neurotechnological Approaches to the Diagnosis and Treatment of Alzheimer's Disease', *Frontiers in Neuroscience*, 16 (854992). DOI:10.3389/fnins.2022.854992.

¹⁵² See, e.g., Vázquez-Guardado, A., Yang, Y., Bandodkar, A.J., et al. (2020) 'Recent advances in

neurotechnologies with broad potential for neuroscience research', *Nature Neuroscience*, vol.23, pp.1522-1536. DOI: <u>https://doi.org/10.1038/s41593-020-00739-8</u>

Brain Stimulation (DBS) and neuroimaging techniques such as fMRI, EEG and the more invasive electrocorticography (ECoG), through which the processing of special category personal data in the form of data concerning health may accordingly be lawful, subject to the implementation of "suitable and specific measures to safeguard the fundamental rights and freedoms of data subjects".¹⁵⁴ More challenging is the example of newly emerging consumer neurotechnologies, for which it has been suggested the enhanced level of protection prospectively afforded to brain and other neural data classified as "data concerning health" may not be applicable as a result of the data being collected and processed for non-clinical health-related applications and therefore falling outside the scope of medical device regulatory regimes.¹⁵⁵ The exception to this is if such devices are used in the context of health-related research, in relation to which the broad remit of Section 3 of the Health Research Regulations (HRRs) will likely apply (see Section 3.2.3 below).¹⁵⁶

Finally, both the GDPR and the Data Protection Act 2018 introduce various rights of the data subject, including a right of access,¹⁵⁷ a right not to be subject to a decision based solely on automated processing, including profiling,¹⁵⁸ and a right to erasure.¹⁵⁹ The particular characteristics of brain and other neural data, however, may pose significant challenges to ensure effective realisation of these rights.¹⁶⁰ For example, the right to erasure, also known as the "right to be forgotten",¹⁶¹ enables data subjects to request the deletion of their personal data by data controllers, yet there are various potential challenges to the realisation of this right in practice, including the potential re-identifiability of brain data and other neural data, the retention of "unconscious" brain and other neural data of which the data subject is unaware, and the risk of negatively impacting the accuracy of predictive models.¹⁶²

3.2.3 Health research

As noted above, notwithstanding the overall increase in consumer-facing applications, the primary use case of neurotechnologies is in a clinical context for a variety of treatment and research purposes, including exploring functions of the brain, deciphering neural code, and gaining an improved

¹⁵⁸ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.22; Data Protection Act 2018, s.89.

¹⁵⁹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.17; Data Protection Act 2018, s.92.

¹⁶¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.17.
 ¹⁶² Ienca, M. et al. (2022) 'Towards a Governance Framework for Brain Data', *Neuroethics*, vol.15. DOI: https://doi.org/10.1007/s12152-022-09498-8



¹⁵⁴ Ibid s.53.

¹⁵⁵ Ienca, M., et al. (2022) 'Towards a Governance Framework for Brain Data', *Neuroethics*, vol.15. DOI: <u>https://doi.org/10.1007/s12152-022-09498-8</u>; Rainey, S., et al. (2020) 'Is the European Data Protection Regulation sufficient to deal with emerging data concerns relating to neurotechnology?', *Journal of Law and the Biosciences*, vol.7:1, pp.14. DOI: https://doi.org/10.1093/jlb/lsaa051

¹⁵⁶ Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018.

¹⁵⁷ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Art.15; Data Protection Act 2018, s.91.

¹⁶⁰ Ienca, M. et al. (2022) 'Towards a Governance Framework for Brain Data', *Neuroethics*, vol.15. DOI: https://doi.org/10.1007/s12152-022-09498-8

understanding of neurological diseases and disorders.¹⁶³ Such neuroscientific research can also be used to uncover cognitive mechanisms which may help to evidence and explain different behavioural findings.¹⁶⁴ In recognition of the importance of research and innovation,¹⁶⁵ the GDPR provides that where data "processing is necessary" for inter alia scientific research, including health research, such data processing is exempt from the prohibition on the processing of special categories of personal data,¹⁶⁶ a category which includes "data concerning health".¹⁶⁷ To avail of this exception, however, such research must also be "in accordance with Article 89(1)",¹⁶⁸ through which the EU identifies some of the general features of the framework of "appropriate safeguards" to be established by the Member States, such as to "ensure that technical and organizational measures are in place in particular in order to ensure respect for the principle of data minimisation",¹⁶⁹ but in general leaves the specific content of its implementation to the discretion of the Member States.

In Ireland, the Health Research Regulations (HRR),¹⁷⁰ as effectuated under Article 36(2) of the Data Protection Act 2018,¹⁷¹ institute a framework of "appropriate safeguards" pursuant to Article 89(1) GDPR, accordingly requiring that the processing of personal data for the purposes of health research is compliant with a range of "suitable and specific measures"¹⁷² relating to governance,¹⁷³ processes and procedures.¹⁷⁴ The broad definition of "health research" as "research for the purpose of human health", including "research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury" and "research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals",¹⁷⁵ indicates that health research involving the use of neurotechnologies will be subject to compliance with these requirements.

The various "suitable and specific" measures are designed to "safeguard the fundamental rights and freedoms of the data subject",¹⁷⁶ and firstly require that personal data is processed "as is necessary to achieve the object of the health research" and not "in such a way that damage or distress is, or is likely to be, caused to the data subject".¹⁷⁷ Data controllers are then further required to establish appropriate governance structures, including by attaining ethical approval from a research ethics committee,¹⁷⁸ following on from which "processes and procedures relating to the management and conduct of health research" must be put in place,¹⁷⁹ such as "controls to limit access to the personal data undergoing

https://doi.org/10.1111%2Fj.1467-8721.2008.00563.x

¹⁷⁹ Ibid Reg.3(1)(c).



¹⁶³ Stieglitz, T. (2021) 'Why Neurotechnologies? About the Purposes, Opportunities and Limitations of Neurotechnologies in Clinical Applications', *Neuroethics*, vol.14, pp.5-16, pp.5. DOI: <u>https://doi.org/10.1007/s12152-019-09406-7</u>.

¹⁶⁴ Diamond, A. and Amso, D. (2008) 'Contribution of Neuroscience to Our Understanding of Cognitive Development', *Current Directions in Psychological Science*, vol.17:2, pp.136-141. DOI:

¹⁶⁵ Kirwan, M. et al. (2021) 'What GDPR and the Health Research Regulations (HRRs) mean for Ireland: "explicit consent" – a legal analysis', *Irish Journal of Medical Science*, vol.190, pp.515-521, pp.516. DOI: <u>https://doi.org/10.1007/s11845-020-02331-2</u>

¹⁶⁶ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, Article 9(2)(j). ¹⁶⁷ Ibid Article 9(1).

¹⁶⁸ Ibid Article 9(2)(j).

¹⁶⁹ Ibid Article 89(1).

¹⁷⁰ Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018.

¹⁷¹ Ibid preamble.

¹⁷² Ibid Reg.3(1).

¹⁷³ Ibid Reg.3(1)(b).

¹⁷⁴ Ibid Reg.3(1)(c).

¹⁷⁵ Ibid Reg.3(2)(a)(i)-(v).

¹⁷⁶ Ibid Reg.3(1).

¹⁷⁷ Ibid Reg.3(1)(a).

¹⁷⁸ Ibid Reg.3(1)(b)(i).

processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data".¹⁸⁰ The final two requirements under Reg.3(1) are for data controllers to make "arrangements to ensure that personal data are processed in a transparent manner",¹⁸¹ as well as to ensure the "explicit consent" of the data subject has been obtained "prior to the commencement of the health research".¹⁸²

The requirement to obtain "explicit consent" relates to the processing of the data subject's "personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof,"¹⁸³ and is considered to be one of the most significant procedural challenges for healthcare researchers.¹⁸⁴ However, whilst in principle mandatory, the HRRs enable health researchers to apply for a consent declaration from the Health Research Consent Declaration Committee (HRCDC),¹⁸⁵ as constituted by the HRRs,¹⁸⁶ the granting of which means that the public interest in granting the declaration outweighs the competing interest in obtaining explicit consent from the data subject.¹⁸⁷ Prior to making such an application, however, the data controller must have first carried out a data protection impact assessment and obtained "ethical approval of the health research from a research ethics committee."¹⁸⁸ There are also various procedural requirements with which data controllers are required to comply, including that the application is made in writing and evidences, inter alia, "that the controller has a valid and lawful basis for the processing of the personal data, and that the controller meets one of the conditions in Article 9(2)" GDPR.¹⁸⁹ A declaration of exemption can only then be granted by the HRCDC where these procedural requirements have been fully complied with and it "is satisfied that the public interest in carrying out the research significantly outweighs the public interest in requiring the explicit consent of the data subject".¹⁹⁰

These requirements relating to a declaration of exemption, particularly the threshold for the public interest in carrying out the research to *significantly outweigh* the public interest in attaining explicit consent, goes beyond what is required by the GDPR and it has been suggested that this may limit the scope for the awarding of a declaration of exemption.¹⁹¹The requirement for "explicit consent" is similarly not stipulated in Article 89(1) GDPR, and scholars have suggested that this may effectively negate the research exemption as provided for in Article 9(2)(j).¹⁹² For healthcare researchers, therefore, this may in practice impose a significant technical and bureaucratic burden, one effect of which may be an overall "chilling effect"¹⁹³ on the conducting of health research in Ireland, with possible implications for neuroscientific research involving the use of neurotechnologies. For healthcare research participants, however, this acts as a safeguard against non-consensual interference and ensures effective protection of personal data, which may be of particular importance in the context of neurotechnological healthcare research given the sensitivity and intimacy of the type of personal data being processed.

¹⁹¹ Donnelly, M. and McDonagh, M. (2019) 'Health Research, Consent and the GDPR Exemption', *European Journal of Health Law*, vol.26, pp.97-119. DOI: <u>https://doi.org/10.1163/15718093-12262427</u>

¹⁹² Kirwan, M. et al. (2021) 'What GDPR and the Health Research Regulations (HRRs) mean for Ireland: "explicit consent" – a legal analysis', *Irish Journal of Medical Science*, vol.190, pp.515-521, pp.516. DOI: https://doi.org/10.1007/s11845-020-02331-2

¹⁹³ Donnelly M and McDonagh M. (2019) 'Health Research, Consent and the GDPR Exemption', *European Journal of Health Law*, vol.26, pp.97-119, pp.118. DOI: <u>https://doi.org/10.1163/15718093-12262427</u>



¹⁸⁰ Ibid Reg.3(1)(c)(iv).

¹⁸¹ Ibid Reg.3(1)(d).

¹⁸² Ibid Reg.3(1)(e).

¹⁸³ Ibid Reg.3(1)(e).

¹⁸⁴ Clarke, N. et al. (2019) 'GDPR: an impediment to research?', *Irish Journal of Medical Science*, vol.188, pp.1129-1135. DOI: <u>https://doi.org/10.1007/s11845-019-01980-2</u>

¹⁸⁵ Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, Reg.5(1).

¹⁸⁶ Ibid Reg.7; Schedule.

¹⁸⁷ Ibid Reg.5(2).

¹⁸⁸ Ibid Reg.5(3)(a)-(b).

¹⁸⁹ Ibid Reg.5(4)(a)-(e).

¹⁹⁰ Ibid Reg.5(5).

3.3 Use in the Irish legal system

An emerging application of neurotechnologies is in the context of both criminal and civil legal proceedings. In criminal cases, for instance, techniques such as neuroimaging may be used to establish the competency of individuals to stand trial.¹⁹⁴ Brain scans may also form a part of evidence admitted by neuroscience experts to be used to determine the applicability of defences such as insanity and diminished responsibility.¹⁹⁵ Addressing witness and defendant testimonies can also potentially be furnished by neuroscanning techniques. This is relevant in memory elicitations and determining guilt of an individual. Furthermore, some studies have shown brain scans may detect deception.¹⁹⁶

As will be discussed in Section 3.3.1 below, additional proposed uses of neurotechnologies include jury selection, assessing judicial bias in sentencing, and examining the age of criminal responsibility. Following the discussion of the use of neurotechnologies in the criminal justice system, the role of neurotechnologies in civil law proceedings will then be considered (Section 3.3.2). Here, the most prevalent application of neuroimaging may be in tort law cases, in particular personal injury cases where it is alleged by a plaintiff that brain injuries have been sustained. An MRI scan, for instance, creates images of soft tissue injuries that could be used to quantify personal injuries and inform the appropriate remedy in tort law cases.¹⁹⁷

3.3.1 Use in the criminal justice system

Irish criminal law is comprised of several sources including the Constitution, statutes and common law. Relevant legislation includes the Criminal Law (Insanity) Act 2006. Much of the Irish criminal law is derived from English case law, and subsequently Irish case law. This case law is used to inform current legislation and is still a useful tool of interpretation of terms defined within statutes. In its interpretation, case law often has the means to develop the law as it exists and acknowledges where new case law may be introduced. This is particularly important in considering the issue of neurotechnologies. This is as this area of technology is ever evolving, and its incorporation within case law may push for new legislation in the area.

Competency to stand trial

Neurotechnologies may be used to help the court assess a person's competency to stand trial. When considering competency to stand trial in Ireland, the law refers to the "fitness" of a person to be tried in court.¹⁹⁸ The law considers an individual unfit for trial where they are unable to understand nature of proceedings due to a mental disorder.¹⁹⁹ A mental disorder is characterized as mental illness, mental disability, dementia, or any disease of the mind but does not include intoxication.²⁰⁰ Moreover, the law defines who determines fitness. In summary offences, the fitness will be determined by the judge only in the District Court. For indictable offences, fitness will be determined at the court of trial in which the

²⁰⁰ Ibid s 1.



¹⁹⁴ Kolla, N. J., Brodie, J.D. (2012) 'Application of Neuroimaging in Relationship to Competence to Stand Trial and Insanity' in Simpson, J.R. ed. (2012) *Neuroimaging in Forensic Psychiatry: From the Clinic to the Courtroom*. Chichester, West Sussex: Wiley-Blackwell, pp. 159.

¹⁹⁵ Aono, D., Yaffe, G., Kober, H. (2019) 'Neuroscientific Evidence in the Courtroom: A Review', *Cognitive Research: Principles and Implications*, 4 (40), 2-20.

¹⁹⁶ Reese, B. (2009) 'Using fMRI as a Lie Detector- Are We Lying to Ourselves?', *Journal of Science and Technology*, 19 (1), 206-230; See also, Rusconi, E. and Mitchener-Nissen, T. (2003) 'Prospects of Functional Magnetic Resonance Imaging as Lie Detector', *Frontiers in Human Neuroscience*, 7 (594), 1-12., Pulice, E.B. (2010) 'The Right to Silence at Risk: Neuroscience-Based Lie Detection in The United Kingdom, India, and the United States', *The George Washington International Law Review*, 42 (4), 865-896.

¹⁹⁷ See generally, Alces, P.A. (2018) *The Moral Conflict of Law and Neuroscience*. Chicago: The University of Chicago Press, pp. 183.

¹⁹⁸ Criminal Law (Insanity) Act 2006, s 4.

¹⁹⁹ Ibid s 4 (2).

defendant would be tried.²⁰¹ Where the Courts determine an individual is not fit for trial, proceedings will be adjourned²⁰² and the Court may recommend further care in designated centres, especially with the evidence of an approved medical officer.²⁰³ Although it is desired that medical evidence is compiled by the Court for determining fitness, the law does not require it.²⁰⁴

In some cases, brain scanning techniques have been applied to establish competency of individuals. For example, in *O'C (J) v DPP*,²⁰⁵ an order of prohibition of further prosecution was sought due to the applicant's diagnosis of Alzheimer's disease. The application included evidence from a Consultant Psychiatrist and CT scans which showed atrophic changes in the applicant's brain, i.e., brain shrinkage which were evidence of the Alzheimer's disease. In another case, *Geraldine Nolan v Joseph Carrick and Others*²⁰⁶ the court considered medical evidence relating the defendant's mental capacity because they argued they were not competent to stand trial. The mental capacity evidence included severe pain caused from depression and other health issues, mild cognitive impairment, and an evolving pattern of dementia. This evidence included a report from a Consultant Neuropsychiatrist which included evidence of cognitive examinations and MRI scans which depicted ischemic changes in the brain. The Court accepted all psychiatric and psychological evidence presented, however it concluded that it was not satisfied that the defendant lacked capacity. Although there are not many cases presently which consider the use of neurotechnologies in determining fitness for trial, the above cases show the Irish legal system may be headed in this direction.

However, as the law does not presently require medical evidence to be presented before the court, this raises significant doubts about which kind of evidence may be permissible. The Interdepartmental Group,²⁰⁷ which consists of representatives from various governmental departments, has examined issues relating to people with mental illnesses that come into contact with the Irish criminal justice system. Their First Interim Report recommended an amendment to section 4 of the Criminal Law (Insanity) Act which would require medical evidence, such as a report, to be considered before determining fitness to stand trial. This is a welcomed recommendation as it may serve the purpose of outlining exactly what kind of medical evidence is appropriate in such cases. Provisions regarding the requirement of medical evidence could potentially limit or expand admission of neuroscientific evidence which in some cases proposes the ability to determine competency.

Age of Criminal Responsibility

Recent developments in neuroscience and neurotechnologies are changing the way in which we may consider the age of criminal responsibility. In Ireland, the age of criminal responsibility is governed in the Children Act 2001. The legislation lays out that it is presumed no child under the age of twelve years can commit an offence.²⁰⁸ Furthermore, there is a rebuttable presumption that a child who is not less than twelve but under the age of fourteen is incapable of committing an offence because the child did not have the capacity to know that the act or omission concerned is wrong. There is, however, an exception for children ages ten and eleven who are charged with very serious offences such as unlawful killing, rape offences or aggravated sexual assault.²⁰⁹ Any charges brought to children under the age of

²⁰⁸ Children Act 2001, s 52.

²⁰⁹ Criminal Justice Act 2006, s 129.



²⁰¹ Ibid s 4 (3) (a); s. 4 (4) (a).

²⁰² Ibid s 3 (b).

²⁰³ An approved medical officer is defined as a consultant psychiatrist (as found within the meaning in the Mental Health Act 2001), Criminal Law (Insanity) Act 2006, s 1.

²⁰⁴ Whelan, D. (2007) 'Fitness for Trial in The District Court: The Legal Perspective', *Judicial Studies Institute Journal*, 2 (1).

²⁰⁵ O'C (J) v DPP [2002] IEHC 151, [2002] 10 JIC 0804.

²⁰⁶ Geraldine Nolan v Joseph Carrick and Others [2013] IEHC 523, [2013] 10 JIC 2505.

²⁰⁷ Government of Ireland. (2016) *First Interim Report of the Interdepartmental Group to Examine Issues Relating to People with Mental Illness Who Come in Contact with the Criminal Justice System*. Dublin: Government of Ireland, pp. 21-22.

fourteen are only brought with the consent of the Director of Public Prosecutions.²¹⁰ Minor charges against children are dealt with by the Children Court, and all major charges may be dealt with by the Central Criminal Court.²¹¹

The age of criminal responsibility has been disputed for several years. In 2006 the Report on the Youth Justice Review prepared by the Department of Justice, Equality and Law Reform has found Ireland has the lowest age of criminal responsibility in comparison to the rest of Europe.²¹² This was recently reaffirmed by the European Committee of Social Rights which found the age of criminal responsibility in Ireland not to be in conformity with the European Social Charter.²¹³ Currently, the Department of Justice is reviewing the Children Act 2001, including a consideration for the age of criminal responsibility.²¹⁴ It is, however, still unclear whether the age of criminal responsibility will be changed in Ireland. Further concern about the age of criminal responsibility in Ireland has been raised with the recent case of the Anna Kriégel murder trial. Two boys, aged thirteen at the time, were charged with committing a murder against a fourteen-year-old girl.²¹⁵ The question remains how this case may affect the Irish youth justice, considering the James Bulger trial in England was considered as a turning point in youth justice in the UK,²¹⁶ adopting a more punitive turn.

The development of neuroscience and psychology now allows scientists to make use of brain scanning technologies to examine brain structure and place its findings against developmental theory.²¹⁷ This may allow scientists to better understand at which stage a child may develop parts of the brain responsible for empathy, consequential thinking which in turn may be used to inform the age of criminal responsibility.²¹⁸ Although this does not mean that a brain scan may essentially tell us whether a child is of the age of criminal responsibility, it is useful for creating an informed and comprehensive approach to determining criminal responsibility. Although it is currently unclear whether the age of criminal responsibility will be raised in the context of the Children Act 2001, taking into consideration current neuroscientific and psychological research in the area is useful for determining the minimum age for serious offences. It is likely that neuroscientific findings on brain development may be more widely applied in the future, as they become more robust and accurate.

Jury trial

Neurotechnological techniques such as brain scanning have the potential to assess eligibility of jurors and challenge jurors by identifying underlying biases. The Juries Act 1976 outlines the rules about the eligibility for jury service in Ireland. The law finds that person's incapable of standing on a jury include persons without a sufficient capacity to read, deafness or other permanent infirmity.²¹⁹ It also includes

²¹⁹ Juries Act 1976, part I.



²¹⁰ The Courts Service of Ireland. (2022) *Children Court*. / [Online]. Available at: <u>https://www.courts.ie/children-court</u>

²¹¹ Ibid.

²¹² Department of Justice, Equality and Law Reform. (2006) *Report on the Youth Justice Review*. Dublin: The Stationery Office.

²¹³ European Social Charter. (2020) *European Committee of Social Rights: Conclusions 2019 Ireland.* Strasbourg: Council of Europe.

²¹⁴ Irish Legal News (2020), 'Ireland Urged to Raise Age of Criminal Responsibility', *Irish Legal News*, 25 March.

²¹⁵ Gallagher, C. (2019) 'Ana Kriégel Murder Trial: The Complete Story', *The Irish Times*, 18 June.

 ²¹⁶ Stewart, A. (2019) 'Ana Kriegel Murder: What Next for Irish Youth Justice', *BBC News*, 6 November.
 ²¹⁷ Delmage, E. (2013) 'The Minimum Age of Criminal Responsibility: A Medico-Legal Perspective', Youth Justice, 13 (2).

²¹⁸ For a discussion on this topic see: Jha, A. (2011) 'Age of Criminal Responsibility is Too Low, Say Brain Scientists', *The Guardian*, 13 December.

persons who suffer from mental illnesses or mental disabilities on an account of residing at a hospital (or a similar institution) or regularly attend treatment by medical practitioners.²²⁰

In the Irish jury system, each side of the case may challenge seven potential jurors without giving any reason and can challenge any number of jurors if they are able to "show cause". This is called peremptory challenge. Scholars have noted that the peremptory challenge practice reflects a subjective assessment of the likely attitude of the juror to the challenger's case, based on matters of sex, age, appearance, address, or employment.²²¹ Challenges for cause shown is rarely used in Ireland. Where it does happen, however, the trial judge may decide whether they think the challenge should be upheld. Walsh commented the "challenge without cause" may satisfy the factors under which an individual is rendered ineligible to serve, but beyond this point there is less certainty.²²² It is presumed that the parties challenge the jurors on the basis of cogent reasons- which they would also put through to challenge a juror and discharge the obligations of jury service fairly and impartiality.

The impact of the peremptory challenge may be such that brain scanning technologies may not be soon introduced for jury selection. However, the Irish law does leave this possibility where the "challenges for cause" are being used. The introduction of neuroscientific technology in jury selection could be used to challenge a juror based on their bias which would create a more impartial jury.²²³ Thus, a brain scan could potentially find biased jurors which could be used by the legal counsel as a challenge. In such a case, the trial judge would determine whether this is to be upheld. As Irish judges have traditionally been reluctant to admit scientific evidence within the courtroom setting,²²⁴ the question is left open for future development.

Judge bias

As mentioned above, neurotechnologies have developed assessments by which a person's underlying bias may be identified. This may be particularly useful to address judge bias. The Irish sentencing system is guided by the Irish constitutional jurisprudence which has given judges broad discretion in relation to sentencing.²²⁵ Depending on the offence committed, minimum or maximum sentences may be applied.²²⁶ For those offences which do not assesses sentencing, the Judicial Council publishes sentencing guidelines for superior courts.²²⁷ The guidelines propose examination of personal circumstances which apply as mitigating factors prior sentencing. They may include drug addiction, age, or character.²²⁸ Judges can gather sentencing information through different sources such as The Irish Sentencing Information System (ISIS). The ISIS collected data between 2007 and 2009 and in 2013²²⁹ which provided information on various offences and sentences imposed. The ISIS system has been criticised, however, as the limited sample collected may not accurately reflect sentencing trends.

²²² Ibid.

²²⁵ Dempsey, L. (2016) 'The Greater of Two Evils- Examining Sentencing Variations in the Irish Courts: A Critical and Methodological Appraisal', *University College Dublin Law Review*, 16 (1).

²²⁶ Citizen Information. (2020) *Types of Sentences*.

²²⁹ Guilfoyle, E., Marder, I. (2021) 'Using Data to Design and Monitor Sentencing Guidelines: The Case of Ireland', *Common Law World Review*, 50 (2-3).



²²⁰ Ibid.

²²¹ Walsh, D. (2016) *Criminal Procedure*. 2nd edn. Dublin: Round Hall. Ch 20.

²²³ Suskin, Z.D. (2021) 'Lady Justice may be Blind, but is She Racist? Examining Brains, Biases, and Behaviours Using Neuro-Voir Dire', *Cambridge Quarterly of Healthcare Ethics*, 30 (4).

²²⁴ Fennell, C. (2020) *The Law of Evidence in Ireland*. 4th edn. London: Bloomsbury Publishing. Ch 7.

²²⁷ For example: The Judicial Council. (2022) *Sentencing Guidelines and Information Committee- Sentencing Judgements Guidance for the General Public*. Dublin: The Judicial Council.

²²⁸ Citizen Information. (2022) *Sentencing at Criminal Trials in Ireland*.

Apart from general guidelines, the sentencing system in Ireland has been highly individualised and unstructured.²³⁰ Because of this, scholars have noted a presence of disparities in the Irish sentencing system based on characteristics such gender, class, race, or nationality.²³¹ The Judicial Council Act 2019 aims to address this by introducing formal sentencing guidelines.²³² To this effect, The Judicial Council's sentencing committee has recently published a public information guide on reasons for sentencing.²³³ The guide aimed to set out sentencing guidelines for a range of offences, however the guide did not adequately address the apparent bias.

Neurotechnologies, such as brain scans, may help us to identify judge bias. Although current research has not identified the possibility of detecting bias with just brain scans, a combination of psychological tests and brain scans have been used to determine implicit biases in individuals²³⁴ (see above in jury trial). Technology in this area is not yet developed to the stage where it may accurately identify bias, particularly is such application was for judges of various courts but may identify a turn towards adoption of a more inclusive legal system. The benefit of identifying bias in judges may potentially help to resolve the widespread issue of sentencing disparities in Ireland.

Another such move is seen with the move towards adoption of artificial intelligence in the Irish legal system. The Department of Enterprise, Trade and Employment has in 2021 published the national strategy for the use of artificial intelligence in Ireland.²³⁵ The Strategy outlines the possibility of the use of artificial intelligence to support sentencing through the use of Automated decision-support tools. Kennedy²³⁶ found a new system is currently being developed by the Judicial Council which aims to replace the Irish Sentencing Information System. Although it is not clear whether the new system will use artificial intelligence, such an adoption may be possible. The adoption of artificial intelligence in the Irish legal system may not comprehensively address issues of judge bias as one of the crucial limitations of such technologies was the possibility of reinforcing existing biases.²³⁷ Comparing the current trends in adopting artificial intelligence is useful against any future applications of neurotechnologies such as brain scans for the purposes of addressing judge bias.

Eliciting Memories

The two main ways in which eliciting memories may be useful to a court is for the purpose of determining guilt in the defendant and eliciting a witness testimony. Neurotechnological advancements may aid memory elicitation through brain scanning techniques. In considering elicitation of memories for witness testimony we find that witnesses can be called to court to testify and provide oral evidence in relation to facts or the character of the accused. The witness testimony procedure in Ireland is the following: The witness must first be sworn in to ensure the truthfulness of their testimony. The testimony is then given through the process of examination by counsel for the party they were called

²³¹ For example, see: Bacik, I. (1999) 'The Courts: Consistent Sentencing?' An Irish Quarterly Review, 88 (1); Brandon, A.M., O'Connell, M. (2017) 'Same Crime: Different Punishment? Investigating Sentencing Disparities Between Irish and Non-Irish Nationals in the Irish Criminal Justice' *The British Journal of Criminology*, 58 (5).

²³⁷ Ibid 30.



²³⁰ Dempsey, L. (2016) 'The Greater of Two Evils- Examining Sentencing Variations in the Irish Courts: A Critical and Methodological Appraisal', *University College Dublin Law Review*, 16 (1).

²³² Judicial Council Act 2019.

²³³ Carolan, M. (2022) 'Guide for Public on Reasons for Sentences Published by Body for State's Judges', *The Irish Times*, 23 January.

²³⁴ Greely, H.T. (2013). 'Mind Reading, Neuroscience, and the Law' in Morse, S.J. Roskies, A.L. (eds). A Primer on Criminal Law and Neuroscience: A Contribution of the Law and Neuroscience Project, Supported by the MacArthur Foundation. New York: Oxford University Press, pp. 133.

²³⁵ Department of Enterprise, Trade and Employment. (2021) *AI-Here for Good: A National Artificial Intelligence Strategy for Ireland*. Dublin: Government of Ireland, pp. 44.

²³⁶ Kennedy, R. (2021) *Algorithms, Big Data and Artificial Intelligence in the Irish Legal Services Market*. Dublin: Houses of the Oireachtas.

for. The examination-in-chief is the person qualified by either counsel to elicit information from the witness and to verify whether the testimony is valid.²³⁸ This is referred to as cross-examination. The application of rules relating to cross-examination is particularly stringent in criminal cases where the fairness of the processes is particularly examined. This is well examined in historic sexual abuse cases where the courts have examined the to balance treatment of historic sexual abuse allegations within the confines of trial.²³⁹

When considering the application of neuroscientific technologies for memory elicitation in such regard, we must pay close attention to the interplay between fairness of trial and credibility issues. Research has shown the possibility of the use of neuroimaging techniques such as fMRIs or PET scans for identifying emotional activation in the brain. The benefit of such technology may be in the finding and resolving of criminal cases, as the court then achieves fairness for the victim. Though, such technology must be entirely precise. Where they may not be precise, they may lead to false convictions and miscarriages of justice. Another point to consider may be the emotional impact on victims where such memory eliciting technology is used.

The Irish courts have generally been reluctant in considering experts in memory elicitation (for example see discussion on admissibility of evidence below). For instance, considering hypnotist evidence for the purpose of memory elicitation was rejected by the courts in *C* (*N*) *v DPP*.²⁴⁰ They found the "expertise" under which the memory was recovered had no effective test or control, the effect of which rendered the admission of such evidence "fraught with the risk of unfairness".²⁴¹ The Law Reform Commission has noted the Irish courts require a high proof of reliability from any novel form of expertise, although they note no formal reliability test is articulated. Thus, the application of novel neuroscientific elicitation techniques may be challenging unless high proof of reliability is provided.

Determining Guilt

As discussed above, certain memory elicitation techniques may be used to determine the guilt of individuals. Neurotechnologies may, in this regard, help detect dishonesty. When considering determination of guilt in Ireland, it is important to consider the issue of self-incrimination and the right of silence. To determine guilt of an individual, the Irish Constitution provides rules on the trial of offences which finds that any person tried criminal charge shall be tried with consideration of due course of law.²⁴² The plea of guilt will be determined by a jury finding beyond reasonable doubt. The constitution also grants the right to silence.²⁴³ The right to silence and the privilege against self-incrimination work concurrently. The right against self-incrimination protects the accused from being required to answer questions by which they would incriminate themselves.²⁴⁴ The two are related to the presumption of innocence afforded to every individual. Therefore, the accused should not be forced to speak to assist the prosecution. The right to silence is not absolute, as certain inferences may be drawn from silence. This is confirmed in case law, where courts find the restriction to the right may be subjected to the test of proportionality.²⁴⁵ The right to silence may be limited where the objective of the inquiry outweighs it.

When a person is first arrested, a member of *An Garda Siochana* has an obligation to inform the arrested individual about the general right to remain silent during questioning²⁴⁶ and the right to legal advice

²⁴⁶ Citizen Information. (2020) *Right to Silence in Criminal Cases*.



²³⁸ Fennell, C. (2020) *The Law of Evidence in Ireland*. 4th edn. London: Bloomsbury Publishing. Ch 4.

²³⁹ *DPP v C* (C) [2012] IECCA 86, [2012] 12 JIC 0601.

²⁴⁰*C* (*N*) *v DPP* [2001] IESC 54, [2001] 7 JIC 0502.

²⁴¹ Ibid.

²⁴² Bunreacht na hÉireann, Article 38.1.

²⁴³ Confirmed in *Heaney v Ireland* [1996] WJSC-SC 3768, [1996] 1 IR 580.

²⁴⁴ Doyle, O. (2008) *Constitutional Law: Text, Cases and Materials*. Dublin: Clarus Press. Pg 33.

²⁴⁵ DPP v Stephen Burke [2019] IECA 239, [2020] 2 IR 527.

prior to the questioning. The right to a legal counsel in the pre-trial process has been confirmed in case law.²⁴⁷ In relation to collection of forensic evidence in the pre-trial process, the Supreme Court finds the results of forensic testing are objective and they do not depend on the will of the subject.²⁴⁸ Thus, the Court was not satisfied that otherwise lawful collection of forensic sampling taken prior to legal advisor arriving renders subsequent trial where reliance is placed on test results, unfair.

Recent research is attempting to develop neuroscience-based lie detection tests. One of such tests may be using fMRIs to detect deception or lying by individuals²⁴⁹ in, for example, the cross-examination process or by law enforcement during inquiry. This is done through experimentation where individuals are asked to answer questions, some truthfully and to lie in others. The fMRI would assist in identifying the brain regions which are associated in lying. Such lie detection would measure involuntary responses of the brain.²⁵⁰ The question of the right to silence and right against self-incrimination may be raised against this technology. Although this technology is not currently used in Ireland, it is worth questioning how its use may limit the right to silence where the objective of the inquest may be reached by a neuroscientific test. Especially, where such technology would reach the objective. Furthermore, considering that the Irish courts have found certain forensic testing which do not depend on the will of the subject are valid in the pre-trial process, the same may potentially be applied to results of fMRI testing.

Criminal Law Defences (Insanity and Diminished Responsibility)

The Irish criminal law recognises two defences which may stop criminal punishment against an individual as they lack the mental element of the crime, or the *mens rea*. These two are the insanity defence and the diminished responsibility defence. Neurotechnologies may be relevant in this area of criminal law to help courts establish the criminal defence.

The contemporary defence of insanity in Ireland is derived from the *M'Naghten* case.²⁵¹ The case outlined the core of the insanity defence and has been used by Irish Courts until it was codified in 2006. The law today finds that where a person is tried for an offence, the court/jury may consider evidence relating to the accused's mental condition given by a consultant psychiatrist.²⁵² Where such evidence shows that the accused was suffering from a mental disorder and that such mental disorder made the accused not responsible for the act alleged (through not knowing the nature/quality of the act, what they were doing was wrong and where they were unable to refrain to commit the act) the court may find the special verdict- "not guilty by reason of insanity". Case law has considered whether physical conditions such as arteriosclerosis²⁵³ or epilepsy²⁵⁴ may qualify as mental disorders where there may impair the defendant's ability to reason.²⁵⁵ Thus, the law is found to be concerned with the "mind" in its ordinary sense of meaning (including mental faculties of reason, memory and understanding) and not the brain or whether the condition is curable, permanent, or transitory.²⁵⁶

²⁵⁴ *R v Sullivan* [1984] AC 156.

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²⁴⁷ DPP v Gormley and White [2014] IESC 17, [2014] 2 IR 591.

²⁴⁸ Ibid.

²⁴⁹ Rusconi, E., Mitchener-Nissen, T. (2013) 'Prospects of Functional Magnetic Resonance Imaging as Lie Detector' *Frontiers in Human Neuroscience*, 7 (1).

 ²⁵⁰ Pulice, E.B. (2010) 'The Right to Silence at Risk: Neuroscience-Based Lie Detection in The United Kingdom, India, and the United States' *The George Washington International Law Review*, 42 (4).
 ²⁵¹ R v M'Naghten [1843] 8 E.R. 718, [1843] 10 Cl. & F. 200.

²⁵² Criminal Law (Insanity) Act 2006, s 5.

²⁵³ Arteriosclerosis is a heart condition which restricts blood flow to organs and tissues in the body. In *R v Kemp* [1957] 1 QB 399.

 ²⁵⁵ Hanly, C. (2015) An Introduction to Irish Criminal Law. 3rd edn. Dublin: Gill Education. pp.167.
 ²⁵⁶ R v Kemp [1957] 1 QB 399.

The defence of diminished responsibility in Ireland is influenced by English law. In England, the defence was first introduced as a partial defence where an individual who is charged with murder suffers from a mental disorder that impairs their responsibility for their acts.²⁵⁷ The Irish law now recognises the defence of diminished responsibility.²⁵⁸ The law that where a person is tried for murder and where there is evidence that their mental disorder was such as to diminish their responsibility, but not enough to justify not finding them not guilty by reason of insanity, the court/jury may find the person guilty of manslaughter on the grounds of diminished responsibility.

When considering the term mental disorder, it is important to consider the details of its context. The law outlines a definition for the term (find above: under competency to stand trial). The Mental Health Act 2001 provides for a more in-depth definition of the term mental disorder, meaning: "mental illness, severe dementia, or significant disability where because of the illness, disability of dementia, there is a serious likelihood of the person concerned causing immediate and serious harm to himself or herself or to other persons".²⁵⁹ Furthermore, the section goes on to outline the meaning of each of the terms "mental illness", "severe dementia" and "significant intellectual disability".²⁶⁰

Although not used at present, brain scanning techniques may be used for identifying mental illnesses or mental disorders for the purposes of establishing a criminal defence. Recent research supports the use of structural brain imaging techniques for supporting diagnosis of a variety of mental disorders including Alzheimer disease, bipolar disorder, or schizophrenia.²⁶¹ Thus, the application of such medical evidence when establishing a criminal defence may be useful, however, it should not be the only marker for such a conclusion. Establishing a mental disorder for the purpose of confirming a defence of insanity or diminished responsibility should be a robust process. It is not clear how Irish law may develop to base the establishment of such defence on the basis of neuroimaging techniques alone, as evidence relating to a mental disorder must be given by a consultant psychiatrist.

3.3.2 Use in civil law

Civil law is the body of law that deals with non-criminal disputes, such as accidents, or breaches of contract. Irish civil law comprises a body of legislation, such as the Civil Liability and Courts Act 2004, and common law concepts, such as negligence (see Section 3.4.1 on liability for harms due to negligence). Civil law disputes may be resolved by a mediator, or before an Irish court of law.²⁶² Neurotechnologies have potential to be used in the resolution of civil law disputes, either through mediation or through the Irish court system. Particularly in relation to personal injuries claims, neurotechnologies offer enhanced ways of assessing the severity of brain injury following an accident for instance. This section explores how neurotechnologies may be used in such cases in more detail.



²⁵⁷ Hanly, C. (2015) *An Introduction to Irish Criminal Law.* 3rd edn. Dublin: Gill Education. Pg 167.

²⁵⁸ Criminal Law (Insanity) Act 2006, s 6.

²⁵⁹ Mental Health Act 2001, s 3.

²⁶⁰ Ibid s 3 (2).

²⁶¹Falkai, P., Schmitt, A., Andreasen, N. (2018) 'Forty Years of Structural Brain Imaging in Mental Disorders: Is it Clinically Useful or Not?' *Dialogues in Clinical Neuroscience*, 20 (3).

²⁶² Sheridan, P. (2021) *Civil Law in Ireland / Lawyers Ireland*, [Online]. Available at: https://www.lawyersireland.eu/civil-law-in-

Quantifying Personal Injuries

Quantifying a person's injury or suffering may be examined in the scope of civil and criminal proceedings in Irish law. Where brain injuries are sustained, neurotechnological brain scanning techniques may be used to determine an injury and the extent of injury for the purposes of compensation in civil law cases.

Within the context of criminal cases, brain scanning is relevant to claims brought to the Criminal Injuries Compensation Tribunal. The Tribunal assesses compensation claims for persons who suffered an injury as a result of a criminal offence.²⁶³ The criminal injuries compensation scheme does not, however, offer compensation for pain and suffering related to the injury. It only covers any financial loss that has occurred due to the injury.²⁶⁴

All civil personal injury claims in Ireland are brought through the Personal Injury Assessment Board (PIAB). PIAB is an independent State body which is created for the purposes of assessing personal injuries and offering compensation.²⁶⁵ The law which governs the body outlines civil actions which may be brought before PIAB. These include workplace accidents, motoring accidents and public liability accidents, but excludes injuries arising from medical negligence.²⁶⁶ Investigations relating to the injury may be carried out by any appropriate person appointed by the court to give expert evidence which assesses a matter of the claim.²⁶⁷ Medical assessments are carried out by medical professionals which normally refers to the claimant's treating practitioner who completes the medical report which accompanies the claim application.²⁶⁸ Additionally, the Personal Injuries Guidelines,²⁶⁹ as published by the Judicial Council, outline the appropriate compensation for a variety of personal injury claims, including head injuries.²⁷⁰ Within the classification of head injuries, the Guidelines outline several categories including most severe brain damage, severe brain damage, serious and moderate brain damage, minor brain damage or head injury, established epilepsy and other epileptic conditions.

Within the scope of personal injury cases relating to brain injuries, brain imagining techniques are frequently used to quantify the brain injury. Brain imagining techniques such as MEG scans or structural MRI may be used to determine brain injuries in patients who have suffered blunt head trauma.²⁷¹ Therefore, including such scans in a personal injuries case is common practice. Although the majority of cases that go through PIAB are resolved through settlement or assessment, some claims may still be brought to court.²⁷² In Oliver Bennett v John Codd and Wallace Taverns Ltd,²⁷³ for instance, neuroscientific evidence was relied upon by the Court to determine appropriate damages. In this case, the medical evidence provided in relation to the claimant's brain injury included a report prepared by a consultant neurosurgeon, with CAT CT scans of the brain identifying an injury to the claimant's brain. Therefore, the use of neuro-imaging techniques is used within the scope of assessing damages in personal injury cases and to determine the injury for the purpose of the claim.

²⁷³ Oliver Bennett v John Codd and Wallace Taverns Ltd [2020] IEHC 554, [2020] 11 JIC 0301.



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²⁶³ Department of Justice. (2022) *Criminal Injures Compensation Scheme*.

²⁶⁴ Citizen Information. (2022) *Compensation for Victims of Crime*.

²⁶⁵ Personal Injury Assessment Board. (2022) *Personal Injury Assessment Board*.

²⁶⁶ Personal Injuries Assessment Board Act 2003, s 3.

²⁶⁷ Civil Liability and Courts Act 2004, s. 20.

²⁶⁸ Personal Iniury Assessment Board. (2022) *Personal Iniury Assessment Board*.

²⁶⁹ The Judicial Council. (2021) *Personal Injuries Guidelines*. Dublin: The Judicial Council.

²⁷⁰ Prior to April 2021, The Book of Quantum was the set of guidelines used to establish compensation in relation to personal injury claims.

²⁷¹ Lewine, J.D. et al. (2007) 'Objective Documentation of Traumatic Brain Injury Subsequent to Mild Head Trauma. Multimodal Brain Imaging With MEG, SPECT, and MRI', Journal of Head Trauma Rehabilitation, 22 (3). ²⁷² Personal Injury Assessment Board. (2022) *Personal Injury Assessment Board.* [2020] IEHC 554. [2020]

D4.2

A recent report published by the Law Reform Commission outlines various recommendations, including proposed legislation to cap general damages in personal injuries cases.²⁷⁴ This may have somewhat of an impact on the amounts individuals may receive in damages following personal injuries claims, but is unlikely to have a direct impact on the extent to which brain imaging techniques are relied upon by claimants.

3.3.3 Use in evidence and procedural law

Similar to Irish criminal law, evidence and procedural law in Ireland is derived from several sources. The Irish Constitution is the fundamental source governing the admissibility of evidence in Irish courts, as individuals have constitutional rights to due process that must be guaranteed in legal proceedings. Some important Acts governing evidence law in Ireland include the Criminal Evidence Act 1992 and the Criminal Procedure Act 2010, the latter of which revises a swathe of antecedent criminal procedure legislation. One of the key elements of this provision, which is considered in greater depth below, relates to the admissibility of expert evidence.

Personal injuries are governed by the Personal Injuries Assessment Board Act 2003 and the Personal Injuries Assessment Board (Amendment) Act 2019, which outline the process by which personal injury claims are dealt with in Ireland. Furthermore, the Civil Liability and Courts Act 2004 outlines the procedural aspects of personal injuries. More recently, the Criminal Justice (Forensic Evidence and DNA Database System) Act 2014 was introduced to close legislative gaps in evolving evidence law. The Juries Act 1976 governs laws considering the jury in Ireland. As is true with Criminal law in Ireland, much of the current legislation has been enacted from existing precedent derived from English and Irish case law.

Admissibility of Evidence

In the context of evidence admissibility, neuroscientists may act as expert witnesses in examining various neurological concerns of participants in a trial. This may be done by utilizing neurotechnologies such as brain scans. The Irish courts include expert evidence in a way that aids the court in enhancing knowledge on topics which may be outside of general knowledge. Irish criminal procedure laws provide definitions of expert evidence and expert witnesses. Expert evidence is defined as evidence of fact or opinion given by an expert witness who possess appropriate qualifications or experience about the matter to which the witness's evidence relates.²⁷⁵ Additionally, expert evidence is restricted to only that evidence which is required to enable the Court to determine the proceedings.²⁷⁶ The admissibility of expert evidence has also been confirmed in case law (for example see *AG v Ruddy* [1960]). The Irish courts finds expert evidence is generally permitted to opine on art, science or medicine,²⁷⁷ and the expert witness must demonstrate specialist knowledge which entails their entitlement to give opinion evidence.²⁷⁸ It is necessary for the expert evidence to be relevant in the circumstances of the case.²⁷⁹

Historically, Irish courts were very reluctant to admit expert evidence in the context of insanity or mental illness. This is as expert opinion should be used to inform the jury and not determine the ultimate issue.²⁸⁰ In some cases, courts refused expert evidence which did not establish the defence of insanity,²⁸¹ and the evidence was found to be irrelevant. However, as Ireland has gradually evolved to

²⁸¹ DPP v Kehoe 1985 WJSC-CCA 150, [1985] IR 444, DPP v Egan 1989 WJSC-CCA 1250, [1989] IR 681.



²⁷⁴ Law Reform Commission. (2020) *Report: Capping Damages in Personal Injuries Actions*. Dublin: Law Reform Commission.

²⁷⁵ Criminal Procedure Act 2010, s 34 (9).

²⁷⁶ Rules of the Superior Courts (Conduct of Trials) 2016, order 39 (58) (1).

²⁷⁷ AG (Ruddy) v Kenny [1960] 94 I.L.T.R. 185. Also found in *Flynn v Bus Atha Cliath* [2012] IEHC 398, [2012] 10 JIC 1101. The court confirmed the entitlement of experts to express opinion.

²⁷⁸ CDG v JB [2018] IECA 323, [2018] 10 JIC 0309.

²⁷⁹ Law Reform Commission. (2008) *Consultation Paper: Expert Evidence*. Dublin: Law Reform Commission, pp 38.

²⁸⁰ Fennell, C. (2020) *The Law of Evidence in Ireland*. 4th edn. London: Bloomsbury Publishing. Ch 7.

include expert testimony, the Law Reform Commission created a set of recommendations on the main duties of expert evidence.²⁸² Such duties include the duty to provide truthful and impartial expert evidence, state facts and assumptions, taking reasonable care in drafting written reports and confining their evidence to matters within the scope of their expertise.

Ireland seems to be moving towards a gradual acceptance of expert testimonies, with careful consideration given on how it may be admitted in a court setting. This is particularly important in the context of application of neuroscientific evidence in court. In *DPP v. Ramzan*, for instance, the Supreme Court upheld the decision of the trial judge and the Court of Appeal to exclude the expert testimony of a consultant clinical neuropsychologist.²⁸³ However, as observed by the Court of Appeal, this was not a restriction on the admissibility of such evidence per se, but rather borne of the requirement within s.5 of the Criminal Law (Insanity) Act 2006 that "*at least one* of the witnesses called in support of a defence of insanity must be a consultant psychiatrist."²⁸⁴ This indicates that neuroscientific evidence in the form of expert testimony provided by clinical experts may be admitted in addition to the evidence of a consultant psychiatrist in support of a defence of insanity, so long as such witnesses "have relevant evidence to give pertaining to an issue or issues of fact".²⁸⁵

Another point of useful comparison may be the evolution of the use of DNA evidence in Irish evidence laws. The Irish Courts have considered the application of DNA evidence in several cases in which it was used as a basis to identify the perpetrator of a crime.²⁸⁶ It was found that DNA evidence could not make sufficient evidential basis upon which a jury could identify the applicant.²⁸⁷ The Irish Supreme Court went further, giving guidance on the matter of DNA evidence.²⁸⁸ The Court set out general principles of evidence at the law/science interface. The Court held that, where evidence is given to the jury, it must be noted that the evidence is given by an expert and forms opinion evidence. Thus, juries should be reminded of the approach weighting expert evidence.

Recent developments in relation to DNA evidence can in some basic principles be applied to any potential neurotechnologies such as using brain scans to determine the perpetrator. The Irish law certainly leaves the possibility for future adoption of expert neuroscientific evidence, particularly when considering the now widespread adoption of DNA evidence within criminal trials. The extent of its adoption will seemingly be confined to opinion evidence, and as such would be clarified to the jury. Furthermore, considering the Law Reform Commission's recommendations on the main duties of expert evidence, we may see further development in law outlining the strictness of requirements for the admissibility of neuroscientific evidence. Although it seems at present that the Courts are generally reluctant to admit such evidence, as indicated by the case of *Ramzan*, the unfolding and changeable character of the common law may eventually lead to the admissibility of relevant, impartial, and expert neuroscientific evidence.

3.4 Liability for harms

Neurotechnologies, like any other product or device, are subject to national and European laws related to liability for harms when made available on the Irish market. Liability for harms is closely related to safety regulation, with both seeking to control activities that create a risk of harm.²⁸⁹ Yet there are some

²⁸⁹ Shavell, S. (1984) 'Liability for Harm Versus Regulation of Safety' *The Journal of Legal Studies: The University of Chicago Press*, 13 (2), p. 357-74, [Online]. Available at: <u>http://www.jstor.org/stable/724240</u>.



 ²⁸² Law Reform Commission. (2016) *Report: Consolidation and Reform of Aspects of the Law of Evidence*.
 Dublin: Law Reform Commission, pp. 7-8.

²⁸³ DPP v Ramzan [2018] IESCDET 34, [2018] 2JIC 0512.

²⁸⁴ DPP v Ramzan [2016] CCA 42/12, [31].

²⁸⁵ Ibid.

 ²⁸⁶DPP v O'Callaghan [2013] IECCA 46, [2013] 7 JIC 3105, DPP v Wilson [2017] IESC 54, [2019] 1 IR 96.
 ²⁸⁷ DPP v O'Callaghan [2013] IECCA 46, [2013] 7 JIC 3105.

²⁸⁸ DPP v Wilson [2017] IESC 54, [2019] 1 IR 96.

important distinctions. Safety regulation seeks to mitigate the risk of harm *ex ante*, i.e., before products are allowed to be sold on a market. Liability for harms is a regime that applies *ex post*, i.e., following the occurrence of harm and for the purpose of compensating the affected party.²⁹⁰ Irish law on liability for harms is informed by European legislation, as well as the common law tradition. This section examines the legal implications for neurotechnologies in relation to liability for harms, considering tort law, contract law and criminal law.

3.4.1 Liability for harms under tort law

The primary piece of legislation for products liability in Ireland is the Liability for Defective Products Act 1991, which implements the European Products Liability Directive.²⁹¹ The Act provides that a producer is liable in damages in tort for damage caused by a defective product.²⁹² Liability under the Act is tortbased, as opposed to criminal.²⁹³ In the context of neurotechnologies, this means that a producer of neurotechnological products would be liability in tort for any damages caused wholly or partially due to a defect in their product.

Furthermore, neurotechnologies are likely to fall within the remit of the European Medical Devices Regulation (MDR).²⁹⁴ A medical device is used for a medical purpose and used in a physical manner, as supposed to a pharmacological, immunological or metabolic manner.²⁹⁵ The MDR seeks to regulate devices intended for medical purposes. With the increased commercialisation of medical products and devices, and the potential commercialisation of neurotechnologies, it is uncertain to which extent the MDR will apply. If neurotechnologies are developed for both medical and non-medical purposes, such devices would need to comply cumulatively with the requirements applicable to devices for both purposes.²⁹⁶ However, if a neurotechnological device is developed purely for the purpose of its commercial use, it may fall outside the scope of the MDR. Annex XVI of the MDR sets out the list of groups of products without an intended medical purpose that still fall within the scope of the MDR.²⁹⁷ Neurotechnological devices that require an invasive surgical procedure such as a brain implant, are covered.²⁹⁸ Furthermore, 'equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields ...', such as EEG, would also be covered.²⁹⁹ However, there may be a

²⁹⁵ *Regulatory information / Health Products Regulatory Authority*, [Online]. Available at: <u>http://www.hpra.ie/homepage/medical-devices/regulatory-information</u>.

²⁹⁹ Ibid Article 2 (1) and Annex XVI, para. 6.



²⁹⁰ Kolstad, C.D., Ulen, T.S. and Johnson, G. V. (1990) 'Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?' *The American Economic Review*, 80 (4), pp. 888-901, [Online]. Available at: <u>https://www.jstor.org/stable/2006714</u>.

²⁹¹ Liability for Defective Products Act 1991, no. 28; Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC) (07.08.1985, OJ L210/29); *Product Liability and Safety in Ireland: Overview / Thomson Reuters Practical Law*, [Online]. Available at: <u>https://uk.practicallaw.thomsonreuters.com/w-012-</u> <u>9208?transitionType=Default&contextData=(sc.Default)&firstPage=true.</u>

²⁹² Liability for Defective Products Act 1991, no. 28, schedule 1, article 1; *Product Liability and Safety in Ireland: Overview*, [Online]. Available at: <u>https://uk.practicallaw.thomsonreuters.com/w-012-</u>9208?transitionType=Default&contextData=(sc.Default)&firstPage=true.

²⁹³ Product Liability and Safety in Ireland: Overview / Thomson Reuters Practical Law, [Online]. Available at: https://uk.practicallaw.thomsonreuters.com/w-012-

^{9208?}transitionType=Default&contextData=(sc.Default)&firstPage=true.

²⁹⁴ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (5.5.2017, OJ L117/1).

²⁹⁶ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (5.5.2017, OJ L117/1), preamble, para. 12, article 1 (3).

²⁹⁷ Ibid Article 2 (1) and Annex XVI.

²⁹⁸ Ibid Article 2 (1) and Annex XVI, para. 2.

need to update Annex XVI if a neurotechnological device is developed that would fall outside the scope but should be deemed to fall within the scope of the MDR.

As a common law jurisdiction, Irish law also recognises the doctrine of tort of negligence. This implies that a party, such as a manufacturer or seller, may be liable for the tort of negligence for defective products if (i) there was a duty of care, (ii), there was a breach of that duty, and (iii) the breach caused damaged to the injured party.³⁰⁰ The foundation for the Irish tort of negligence originates from English common law, and includes the case of *Donoghue v Stevenson* (1932).³⁰¹ In relation to neurotechnologies, this means that manufacturers and sellers of neurotechnological devices are likely to have a duty of care towards end-users. Such a duty may be breached, for example, if a manufacturer fails to ensure such devices are safe, or to issue safety warnings.³⁰²

3.4.2 Liability for harms under contract law

The primary pieces of legislation in relation to liability for harms under contract law in Ireland are the Sale of Goods Act 1893 and the Sale of Goods and Supply of Services Act 1980. Furthermore, the EU Directive on the sale of consumer goods also applies in Ireland.³⁰³ Interestingly, the Irish implementation of the EU's sale of goods Directive, does not include the six-month time limit of the Directive within which the lack of conformity must become apparent. As such, sellers liability is subject to the normal contractual limitation period of six years.³⁰⁴

Goods delivered under a contract of sale, must confirm to that contract of sale.³⁰⁵ Lack of conformity gives rise to the consumer right to have the goods brought into conformity, such as by repair or replacement.³⁰⁶ As such, sellers of neurotechnological devices are liable to conform to the contract of sale of such devices. Failure to do so, gives rise to the consumer right to have a device repaired or replaced; have the price reduced; or have the contract rescinded.³⁰⁷ Which solution is most suitable in the case of failure to conform to a contract of sale for neurotechnological devices, requires a case-by-case assessment.

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³⁰⁷ Ibid Article 3.



³⁰⁰ Product Liability and Safety in Ireland: Overview / Thomson Reuters Practical Law, [Online]. Available at: https://uk.practicallaw.thomsonreuters.com/w-012-

^{9208?}transitionType=Default&contextData=(sc.Default)&firstPage=true.

³⁰¹ Donoghue v Stevenson [1932] A.C. 562, [1932] UKHL 100, 1932 S.C. (H.L.) 31, 1932 S.L.T. 317, [1932] W.N. 139.

³⁰² Product Liability and Safety in Ireland: Overview / Thomson Reuters Practical Law, [Online]. Available at: https://uk.practicallaw.thomsonreuters.com/w-012-

³⁰³ S.I. No. 11/2003 European Communities (Certain Aspects of the Sale of Consumer Goods and Associated Guarantees) Regulations 2003, which implement Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees (7.7.1999, OJ L171/12).

³⁰⁴ Product Liability and Safety in Ireland: Overview / Thomson Reuters Practical Law, [Online]. Available at: https://uk.practicallaw.thomsonreuters.com/w-012-

^{9208?}transitionType=Default&contextData=(sc.Default)&firstPage=true.

³⁰⁵ Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees (7.7.1999, OJ L171/12), article 2 (1). ³⁰⁶ Ibid Article 3.

3.4.3 Liability for harms under criminal law

In relation to criminal liability for harms caused by neurotechnological devices, the European Communities (General Product Safety) Regulations 2004 is the primary piece of legislation in Ireland.³⁰⁸ The Regulations provide an offence for the placement of unsafe products onto the market.³⁰⁹ Furthermore, failure to notify the Director of Consumer Affairs (Ireland's national consumer authority) of unsafe products may also constitute criminal liability.³¹⁰ In relation to neurotechnologies, this means that producers and product distributers of neurotechnological devices may face prosecution if they introduce neurotechnological devices that are unsafe.

Irish law does not provide for the offence of corporate manslaughter. The concept of corporate manslaughter implies that companies and organisations may be found guilty of corporate manslaughter for serious management failures resulting in a gross duty of care breach which caused a person's death.³¹¹ Whilst the Corporate Manslaughter Bill 2016 was introduced to the *Seanad Éireann* to create an 'indictable offence of corporate manslaughter by an undertaking', the Bill lapsed with the dissolution of the Dáil and the Seanad.³¹² Should this Bill, or a new legislative initiative, be reintroduced to the Irish Parliament, this would mean that companies and other undertakings producing neurotechnological devices may be held criminally liable for grossly negligent management causing death.

³¹² Corporate Manslaughter (No. 2) Bill 2016 (Bill 64 of 2016) / Houses of the Oireachtas, [Online]. Available at: https://www.oireachtas.ie/en/bills/bill/2016/64/.



³⁰⁸ S.I. No. 199/2004 European Communities (General Product Safety) Regulations 2004 which implements Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (15.1.2002, OJ L11/4).

³⁰⁹ Ibid s. 4 (1).

³¹⁰ Ibid s. 8 (3).

³¹¹ See, for instance, the UK's Corporate Manslaughter and Corporate Homicide Act 2007, c. 19, s. 1.

4. Overview of gaps and challenges

The novel and emerging nature of neurotechnologies means that legal frameworks may not adequately cover all aspects and uses of neurotechnologies. This section sets out the key legal challenges identified in relation to the adequate regulation of neurotechnologies.

Human rights law implications

• Neurotechnologies have the potential to impact human rights in many ways, both positively and negatively. In relation to some rights in particular contexts, neurotechnologies have the potential to enhance the enjoyment of rights, such as when neurotechnologies provide innovative treatment options that positively impact the right to health. In other situations, however, the use of neurotechnologies may interfere with protected human rights, for instance if use in the courtroom violates the prohibition on self-incrimination as guaranteed under international human rights law. The Irish Constitution lays down various human rights, and further unenumerated constitutional rights have emerged through case law, including the right to bodily and psychological integrity.³¹³ In the context of rehabilitative treatment of criminal offenders, this right has the effect of requiring that proposed neurotechnological medical interventions could only occur with the voluntary consent of the offender to participate in such treatment.³¹⁴

Privacy and data protection implications

- o The interpretation of the right to privacy under the ECHR, to which Irish courts are required to take account of in the interpretation and application of Irish law,³¹⁵ might offer some protection to brain and other neural data generated through the use of neurotechnologies. In this context, such data might be considered analogous to genetic and biometric data, including cellular samples, DNA profiles and dactyloscopic data, the collection and/or retention of which has been determined by the ECtHR in various cases before it to constitute a prima facie interference with the right to respect for private life.³¹⁶ An additional aspect, most relevant to the clinical use of neurotechnologies, is the interpretation by the ECtHR of the right to privacy under Article 8 to protect information relating to an individual's health, including mental health.³¹⁷
- The primary use case of neurotechnologies is in a healthcare context for clinical treatment and research purposes. In relation to the latter, the Health Research Regulations outlines the various procedural requirements with which healthcare research is required to comply in order to safeguard the rights of data subjects to privacy and data protection, including a conditional obligation to obtain the "explicit consent" of the data subject prior to commencing the research.³¹⁸ Whilst this requirement can be disapplied by attaining a consent declaration from the HRCDC, it has been suggested that the threshold and requirements for this may impose a

³¹⁸ Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, Reg.3(1)(e).



³¹³ Bunreacht na hÉireann, Article 40 (3) (i) and (ii).

³¹⁴ Whelan, D. (2007) 'Fitness for Trial in The District Court: The Legal Perspective', *Judicial Studies Institute Journal*, 2 (1).

³¹⁵ European Convention on Human Rights Act 2003, s.4.

 ³¹⁶ See, e.g., *Case of S. and Marper v. The United Kingdom* (Application nos.30562/04 and 30566/04) (4
 December 2008); *Case of Gaughran v. The United Kingdom* (Application no.45245/15) (13 February 2020).
 ³¹⁷ See, e.g., *Case of Surikov v. Ukraine* (Application no.42788/06) (26 January 2017); *Case of Mockute v. Lithuania* (Application no.66490/09) (27 February 2018).

significant and potentially insurmountable procedural burden on researchers, with resultant implications for the viability of conducting healthcare research in Ireland.

Use in legal systems

o The discussion in Section 3.3 (see above) indicates an emerging trend towards the use of neurotechnologies in the Irish legal system; a trend also reflected in other national legal systems. Although these technologies may be helpful for a variety of trial purposes, including to determine the applicability of the defence of insanity in criminal cases, or to establish brain injury in civil law cases, careful consideration must be given to the protection of individual rights in relation to such proceedings, which are guaranteed under both domestic and international human rights law. The ICCPR, for instance, stipulates the equality of all before the law and guarantees the right to a fair and impartial trial in which the accused has the right to be presumed innocent until proven guilty.³¹⁹ The Irish Constitution also contains specific provisions relating to the trial of offences,³²⁰ including the right of trial by jury in criminal law cases.³²¹ In considering the current and future application of neurotechnologies in the courtroom, it is necessary to ensure that any such use is consistent with the protection of these established rights to due process.

Liability for harms caused by neurotechnologies

- The primary piece of legislation for products liability under tort in Ireland is the Liability for Defective Products Act 1991, which implements the European Products Liability Directive.³²²
- Furthermore, neurotechnologies are likely to fall within the remit of the European Medical Devices Regulation (MDR).³²³ Whilst various neurotechnological devices are likely to fall within the MDR, there may be a need to update Annex XVI if a neurotechnological device is developed that would fall outside the scope but should be deemed to fall within the scope of the MDR.
- As a common law jurisdiction, the doctrine of tort of negligence is also relevant to the regulation of liability for harms resulting from neurotechnologies in Ireland.
- The primary pieces of legislation in relation to liability for harms under contract law in Ireland are the Sale of Goods Act 1893 and the Sale of Goods and Supply of Services Act 1980. Furthermore, the EU Directive on the sale of consumer goods also applies in Ireland.³²⁴
- In relation to criminal liability, the European Communities (General Product Safety) Regulations 2004 is the primary piece of legislation in Ireland.³²⁵
- Whilst the Corporate Manslaughter Bill 2016 was introduced to the Seanad Éireann to create an 'indictable offence of corporate manslaughter by an undertaking', the Bill lapsed with the

³²⁰ Bunreacht na hÉireann, Article 38.

³²⁵ S.I. No. 199/2004 European Communities (General Product Safety) Regulations 2004 which implements Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (15.1.2002, OJ L11/4).



³¹⁹ International Covenant on Civil and Political Rights (entry into force 23 March 1976) G.A. Res 2200A (XXI), Article 14.

³²¹ Ibid Article 38(5).

³²² Liability for Defective Products Act 1991, no. 28; Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC) (07.08.1985, OJ L210/29); *Product Liability and Safety in Ireland: Overview / Thomson Reuters Practical Law*, [Online]. Available at: <u>https://uk.practicallaw.thomsonreuters.com/w-012-</u> <u>9208?transitionType=Default&contextData=(sc.Default)&firstPage=true</u>.

³²³ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (5.5.2017, OJ L117/1).

³²⁴ S.I. No. 11/2003 European Communities (Certain Aspects of the Sale of Consumer Goods and Associated Guarantees) Regulations 2003, which implement Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees (7.7.1999, OJ L171/12).

dissolution of the Dáil and the Seanad.³²⁶ Should this Bill, or a new legislative initiative, be reintroduced to the Irish Parliament, this would mean that companies and other undertakings producing neurotechnological devices may be held criminally liable for grossly negligent management causing death.

5. Conclusion

Whilst there are no dedicated Irish laws or policies that directly or comprehensively address all applications of neurotechnologies, this national legal case study on the Irish legal system has highlighted that neurotechnologies may have a variety of impacts on existing laws in the specific regulatory domains of human rights, privacy and data protection, use in legal systems, and liability for harms. Overall, it appears that Irish law generally permits the use of neurotechnologies, or at least does not establish explicit restrictions to the use of such technologies. This means that in a clinical context, for instance, neurotechnologies may be increasingly used for the purposes of healthcare treatment and research. Indeed, this may be viewed as consistent with the clear policy objective of the Irish Department of Health to improve the health and wellbeing of the population in Ireland, for which it envisions technological innovation and digitisation as key enablers. A pathway in the future towards increased and more widespread use of neurotechnologies in the provision of healthcare within the Irish healthcare system can thus be envisaged; a trend as already indicated by the accessibility under the TAS Scheme of neurotechnology-based treatment, such as deep brain stimulation (DBS), for the purposes of treating neurological disorders, such as dystonia.³²⁷ Outside of this primary use case, an emerging application of neurotechnologies is in the courtroom, prospective uses of which include to determine the applicability of the defence of insanity in criminal cases and to establish and quantify brain injury in civil law cases. Whilst Section 3.3.3 (above) indicates that Irish courts are generally reluctant to permit the application of neuroscientific evidence in legal proceedings, the increased admissibility of such evidence in other jurisdictions, such as the US, may serve as an influence for domestic inclusion. Indeed, it is generally considered that legal and policy developments occurring internationally and within supranational organisations, such as the EU, are capable of exerting great influence on the direction of law and policy at the level of nation states.³²⁸ In considering the potential for future regulation, most impactful may be the development of technology-neutral laws that are flexible, adaptable and capable of responding to the continual research and development innovations made in relation to both neuroscience and neurotechnologies.

³²⁸ See generally, Bradford, A. (2012) 'The Brussels Effect', *Northwestern University Law Review*, Vol.107, pp.1-68. Available at: https://scholarship.law.columbia.edu/faculty_scholarship/1966.



³²⁶ Corporate Manslaughter (No. 2) Bill 2016 (Bill 64 of 2016) / Houses of the Oireachtas, [Online]. Available at: https://www.oireachtas.ie/en/bills/bill/2016/64/.

³²⁷ *Deep Brain Stimulation* / Dystonia Ireland, [Online]. Available at: <u>https://www.dystonia.ie/forms-of-dystonia/treatment-options/deep-brain-stimulation/</u>.

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D4.2

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