

Volume 9, Issue 3, December 2012

BANKING (ON) THE BRAIN: A REPORT ON THE LEGAL AND REGULATORY CONCERNS

Aisling McMahon,^{} Shawn H.E. Harmon^{**}*

DOI: 10.2966/scrip.090312.376



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^{*} Doctoral Candidate , School of Law, University of Edinburgh

^{**} Lecturer in Regulation & Risk, University of Edinburgh; Deputy Director, J Kenyon Mason Institute for Medicine, the Life Science and Law, University of Edinburgh; Research Fellow, Innogen, ESRC Centre for Social and Economic Research on Innovation in Genomics, University of Edinburgh

1. Introduction

Whether and how discourses emerging from humanities and popular culture are encoded in the legal regulation of biomedicine is a question that was recently explored by the ‘Banking (On) The Brain’ project funded by the Arts and Humanities Research Council (AHRC).¹ The Project sought to cast new light on the symbiosis, or lack of symbiosis, between culture, law and science, using brain banking as the case study. Brain banking is the collection and storage of post mortem brain tissue to create a research resource for investigations into neurological diseases.² This Project was structured around three broad questions:

- In which ways and to what extent does science reflect conceptions of the brain emanating from key Arts and Humanities’ (“A&H”) fields?
- To what extent do these conceptions shape the law?
- In what ways and to what extent might the scientific knowledge generated within these regulatory regimes impact upon A&H and popular understandings of the brain, and inform and influence the law itself?

Using these questions as an overarching framework for analysis, and drawing on collaborative contributions from within and beyond the A&H, the Project examined the regulatory regime for brain banking in the UK. In particular, it sought to articulate:

- What is the legal framework applicable to brain banking in the UK?
- What is the broader regulatory framework applicable for the day-to-day governance and management of a brain bank in the UK?
- What conceptions of the brain shape these frameworks?

This brief report offers an overview of the project and a summary of its more pertinent findings from a legal and regulatory perspective.³

2. Project Overview

The Project was led by a Project Team drawn from a number of disciplines across the University of Edinburgh. The Project Team were as follows:

- Dr. Shawn H.E. Harmon, Lecturer in Regulation & Risk, School of Law (PI)

¹ AHRC Grant No. AH/J011495/1, 12 February 2012- 30 September 2012, funded under the AHRC’s Science and Culture Exploratory Award Stream

² See, J. Bell et al, “Management of a twenty first century brain bank: experience in the BrainNet Europe consortium” (2008) *Acta Neuropathol* 497-507 at 499, where a brain bank is defined as a resource “whose essential purpose is to provide brain and spinal cord samples to a community of research users, who include not only those affiliated to the bank but also external users who are independent of the bank.”

³ For a full report which outlines all of the projects findings, see S. Harmon and G. Haddow, “Banking (On) The Brain: The Neurological in Culture, Law and Science” *Medical Law International* (forthcoming)

- Dr. Gill Haddow, Senior Research Fellow, School of Social and Political Science (Co-I)
- Dr. Martyn Pickersgill, Wellcome Trust Senior Research Fellow in Biomedical Ethics, School of Health in Social Science (Co-I)
- Prof. James Ironside CBE, Professor of Clinical Neuropathology, National CJD Surveillance Unit, Western General Hospital (Co-I)
- Prof. Graeme Laurie, Professor of Medical Jurisprudence, School of Law (Co-I)
- Dr. Heather Blenkinsop, School of Social and Political Science (RF)
- Ms. Aisling McMahon, Doctoral Candidate, School of Law (RF)

The Project resulted in the generation of a number of discipline-specific literature reviews whose drafting benefited from the input of multi-disciplinary discussions at two interactive workshops.

3. Project Workshops

Workshops were held on 4th April, 2012 and 19th September, 2012. They brought together experts within the medical/scientific and A&H fields and provided a forum which facilitated dialogue across disciplines. This enabled the identification of overlapping concerns or lack thereof perceived amongst A&H and the medical/scientific communities in this context.

The first workshop served as a platform to exchange various disciplinary perspectives on the topic of brain banking and the significance of the ‘brain’. This workshop commenced with a discussion of some of the practical aspects of brain banking which included an insight from the brain banking professionals of the main legal and governance frameworks which are interacted with in the day-to-day operation of a brain bank. It then explored the differing conceptions of the brain across A&H and medical/science disciplines with a particular focus on its conception within sociological and legal literatures. The second workshop, organised at the end of the Project, provided a forum to discuss preliminary findings and areas of interest arising from literature reviews and facilitated further discussion specifically on the conception of the brain in philosophical and historical literatures.

4. Summary of Key Findings

Briefly, the key findings in relation to the three overarching questions pursued by the Project were as follows:

1. To what extent does science reflect A&H conceptions of the brain?

Although there is no overt mirroring of A&H conceptions of the brain by science, some subtle influences could be discerned. Particularly, the A&H conception of the brain as the ‘seat of the self’ has led to the conflation of brain function with the self in some discourses.⁴ Brain banking, like many other modern scientific enquiries,

⁴ For further discussion of such claims, see; N. Rose, “Neurochemical Selves” (2003) 41 *Society* 46-59, F Vidal, “Brainhood: Anthropological Figure of Modernity” (2009) 22 *History of Human Sciences* 5-36, W. Glannon, “Our Brains are Not Us” (2009) 23 *Bioethics* 321-329, E. Fein, "Innocent Machines:

proceeds by reducing the object of study, in this case the brain, to its smallest components in order to understand it (*i.e.*: it adopts a functional and atomistic approach).⁵ This, in turn, has led to claims in some quarters that the neural connections in the brain hold the key to understanding human behaviour and, of particular relevance to law, understanding criminal behaviour.⁶

2. To what extent do these conceptions shape the law?

Claims in some A&H and science discourses about the significance or salience of the brain have not been reproduced to the same extent in the legal scholarship, and has certainly been absent in regulatory construction. There is no bespoke regulatory framework for brain tissue and the law does not seem to treat the brain as 'special' in the brain banking context. Instead, the legal framework is concerned with ensuring that the donor has the required capacity to donate the tissue, and such discussions refer to the concept of 'illnesses of the mind' which is broader than some neuro-scientific claims of the brain as self. The brain has been a subject of legal debates, however, in relation to the use of brain stem function as a means in the diagnosis of death⁷, and its significance is recognised by the awards in personal injury claims involving brain injury (particularly those with physical and functional repercussions).⁸

3. To what extent might scientific knowledge impact on popular understandings of the brain and/or inform/influence the law?

Reports in relation to scientific knowledge about and research on the brain are a common feature in popular media, however, as more radical claims tend to receive the most publicity, it is questionable the extent to which the public have a true understanding of neuro-scientific research and limitations thereof. Furthermore, the extent to which neuro-scientific evidence will inform/influence the law is still a matter of debate. This has been a focal point for the emerging field of neuro-law, which involves the collaboration of scholars in psychology, philosophy, neuroscience, and other disciplines with law, in an attempt to ascertain "how new discoveries in

Asperger's Syndrome and the Neurostructural Self." (2011) 13 *Sociological Reflections on the Neurosciences Advances in Medical Sociology* 27-49, A. Noe, *Out of Our Heads: Why You are Not Your Brain and Other Lessons from the Biology of Consciousness* (New York: Hill and Wang, 2010) and R. Tallis, *Aping Mankind Neuromania, Darwinitis and the Misrepresentation of humanity* (Acumen, 2011).

⁵ For further discussion, see R. Lewontin, *Biology as Ideology: The Doctrine of DNA* (New York: Harper Collins, 1991)

⁶ See, T. R. Chorvat, K. McCabe, "The brain and the law", in S. Zeki, O. Goodenough (eds.), *Law and the Brain*, (Oxford University Press, 2004), A.R. Damasio., *Descartes' error. Emotion, reason and the human brain* (New York, Putnam, 1994); H. Damasio, T. Grabowski, R. Frank, A.M. Galaburda, A.R. Damasio, "The return of Phineas Gage: Clues about the brain from the skull of a famous patient" (1994) 264(5162) *Science* 1102-1105, P.J. Eslinger, A.R. Damiso, "Severe disturbance of higher cognition after bilateral frontal lobe ablation: Patient EVR" (1985) 35(12) *Neurology* 1731 – 1741. For further discussion, see S. Zeki and O. Goodenough (eds.), *Law and the Brain*, (Oxford University Press, 2004).

⁷ For further discussion, see L. Whetstine, "The History of the Legal Definition(s) on Death: From the 18th Century to the 20th Century" in D Cippen (ed.), *End -of-Life Communication in the ICU: A Global Perspective* (New York: Springer, 2008) 65-78

⁸ Judge Mackey et al, *Guidelines for the assessment of general damages in personal injury cases complied for the Judicial Studies Board*, (Oxford University Press, 2010) 10th Edition

neuroscience should navigate the way we make laws, punish criminals and develop rehabilitation".⁹ The reaction to claims in relation to the significance of neuro-science for law has been mixed and whilst the potential of neuroscience from a legal perspective has been acknowledged by some¹⁰, caution has been urged,¹¹ particularly in relation to the claims that such developments will radically affect or revolutionise current laws.¹²

5. Legal and Regulatory Framework for Brain Banking: Key Findings

The project generated a number of findings in relation to the legal and regulatory framework for brain banking in the UK which are summarised below. Firstly, in relation to the legal framework applicable, a number of points were ascertained:

- The main legislative instruments applicable to the donation, storage and use of brain tissue are the *Human Tissue Act 2004* (applicable in Northern Ireland, England and Wales) and the *Human Tissue (Scotland) Act 2006* (applicable in Scotland). Also relevant are the nine Codes of Practices¹³ produced by the Human Tissue Authority (HTA) which give practical guidance to persons carrying out activities within the remit of the HTA and lay down the standards expected.
- One of the main differences between the legal framework applicable in Scotland and that applicable in the rest of the UK is that Scottish regulation relies on ‘authorisation’ rather than ‘consent’. As to the import of this distinction, *Millar et al* claim that “the concept of ‘authorization’ implies that an active decision has been taken by someone in a position of control, whereas ‘consent’ signals a rather more passive acceptance of a proposal to perform a PME”.¹⁴

⁹ T.M. Spranger, “Neurosciences and the Law: An Introduction” in T.M Spranger (ed.), *International Neurolaw: A Comparative Analysis* (Springer, 2012) 1-10 at 1

¹⁰ Royal Society Report, *Brain Waves, Module 4: Neuroscience and the Law*, (December, 2011) available at <http://royalsociety.org/policy/projects/brain-waves/responsibility-law/> (accessed 4 Dec. 12) which states at p. v that “Neuroscientists seek to determine how brain function affects behaviour... [t]he law is concerned with regulating behaviour, and so it is reasonable to ask whether and if so how, neuroscience could, or should, inform the law”.

¹¹ *Ibid*, See also S. Schleim, Brain in context in the neurolaw debate: The examples of free will and “dangerous” brains (2012) 35 *International Journal of Law and Psychiatry* 104-111

¹² For a discussion of some claims and uses of neuro-scientific evidence for law see; S. Zeki, O. Goodenough, *Law and the Brain* (Oxford University Press, 2004); K. Smith, “Taking Aim at Free Will” (2011) 477 *Nature* 23-25; L. Claydon, P. Catley, Neuro-scientific Evidence in the English Courts in T.M. Spranger (ed.) *International Neurolaw: Comparative Analysis* (Springer, Berlin Heidelberg, 2012) 310-317 and more.

¹³ The Codes of Practice cover; Consent, Donation of Solid Organ for Transplantation, Post Mortem Examination, Anatomical Examination, Disposal of Human Tissue, Donation of Allogeneic Bone marrow and Peripheral Blood Stem Cells for Transplantation, Public Display, Import and Export of Human Bodies, Body Parts and Tissue for Research. Available at <http://www.hpa.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm> (accessed 4 Dec 12)

¹⁴ T. Millar et al, “Post-mortem Tissue Donation for Research: A Positive Opportunity?” (2008) 17(10) *Journal of Nursing Studies* 644-649 at 645

- The principles of consent/authorisation are at the cornerstone of both Acts, largely due to the fact that the legal regimes were enacted against a background of public concern over reports of the retention of children's organs in some cases without knowledge of the parents.¹⁵ A move away from the presumption that consent to perform a PME entitled a healthcare practitioner to retain the brain for research was recommended in the Isaac's Report,¹⁶ where it was found that whilst some families were disturbed by the failure to obtain proper consent, others were offended by the act of brain/tissue retention itself. Significantly, consent and authorisation are positive concepts in the HTAs replacing the former 'lack of objection' to donation criteria in the Human Tissue Act 1961.¹⁷
- Another difference is that the licensing scheme applicable in Northern Ireland, England and Wales is not operable in Scotland. However, in 2011 in Scotland it was decided to instigate a non-statutory accreditation scheme for the collection and storage of human tissue.¹⁸
- Overall, the two frameworks are broadly similar which facilitates the co-ordinated research on tissue and organs in the UK and allows the possibility of having brain banks which can share tissue across the UK.

Secondly, in relation to the governance framework for brain banking more specifically, the main findings were:

- All brain banks in the UK must abide by relevant procedures for ethical approval and the MRC guidelines. Ethical approval must be obtained from the relevant Research Ethics Committee prior to embarking on research and NHS Research and Development approval must also be obtained. All UK brain banks are also members of the MRC Brain Banks Networks, which operates to ensure high standards of operation in brain banks, and agrees common policies and procedures that are compliant with legal requirements.
- Importantly, the MRC Brain Bank Network Codes in combination with the practice of brain banking professionals produces a governance framework which exceeds hard law. Differences can be observed between black letter law

¹⁵ See, Royal Liverpool Children's Inquiry, *Report/The Royal Liverpool Children's Inquiry* (London,: Stationery Office, 2001)

¹⁶ HM Inspector of Anatomy, *Isaacs Report: The Investigation of Events that Followed the Death of Cyril Mark Isaacs* (London: Stationery Office, 2003)

¹⁷ Crown Office and Procurator Fiscal Service, *Death and the Procurator Fiscal : Information and Guidance for medical practitioners*, (October, 2008) available at <http://www.copfs.gov.uk/sites/default/files/Publications/Resource/Doc/13546/0000506.pdf> (accessed 4 Dec 12)

¹⁸ See Letter from Chief Medical Officer Harry Burns detailing the "Accreditation Scheme for the collection and storage of NHS tissue in Scotland" available at [http://www.sehd.scot.nhs.uk/cmo/CMO\(2011\)07.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2011)07.pdf) (accessed 4 December 2012)

and practice particularly in the area of consent/authorisation for donation of brain tissue. The HTAs provide no specific veto for family members to overrule the donors consent/authorisation to donate, however, the *HTA Code of Practice on Consent* suggests that practitioners should take into account the effect of going ahead with donation in light of family objections.¹⁹ It was observed at the workshops that practitioners would not go ahead with donation in the event of strong family discord.

- Some of the remaining governance difficulties encountered by modern brain banks include; absence of adequate funding mechanisms for brain banks,²⁰ absence of standard evaluation protocols for the evaluation of brain tissue banks and lack of international standard operating procedures or codes of conduct for brain banks.²¹

5. Conclusion

One of the principal aims of the Project was to explore how the science, law, cultural nexus operates in the context of brain banking. Specifically, it sought; to develop a greater understanding of whether and how the governance and regulation of brain banking is reflective of cultural ideas about the brain and personhood; and to ascertain, whether as a corollary, the regulation and science it empowers influences or reshapes those broader understandings. Through multi-disciplinary research, the Project investigated these questions and developed a better understanding of the differing conceptions of the brain in the A&H and scientific communities, much of which attributes some special significance to the brain. The Project identified, perhaps surprisingly, the absence of a similar significance devoted by law to the regulation of brain tissue in the brain banking context, which is treated in the same way as other tissue. Nonetheless, the brain features as a subject of concern in legal debates around death, injury compensation, and in the emerging field of neuro-law. However, within neuro-law there has in some instances been a lack of understanding of some of the limits of neuro-science and its related technologies, and the practice and meaning of law. There is arguably a disjoint in thinking between the regulation of scientific practices around the brain and popular conceptions of the brain which requires further exploration.

¹⁹See, Human Tissue Authority, *Code of Practice 1: Human Tissue Act: Consent* (September, 2009) at para. 76 which states that "...the Healthcare professional should also consider the impact of going ahead with a procedure in light of strong opposition of the family, in spite of the legal basis for doing so." In relation to the donation of children's organs in light of family opposition/disagreement the Code states at para. 95 that "...careful thought should be given as to whether to proceed if a disagreement arises between parents or family members. Any previously stated wishes of the deceased child should be considered, taking into account their age and understanding."

²⁰ H.A. Kretzschmar, "Brain banking: opportunities, challenges and meaning for the future" (2009) 10 *Nature* 70-78 at 76

²¹ R. Ravid, Standard Operating Procedures, ethical and legal regulations in BTB (Brain/Tissue/Bio) banking: what is still missing? (2008) 9 *Cell Tissue Banking* 151-167; See also, MB. Graeber, "Editorial: Twenty-first century brain banking: at the crossroads" (2008) *Acta Neuropathol* 493-496 at 494

Acknowledgements:

The authors would like to acknowledge the contribution of the Project Team to this report. The Project Team would like to acknowledge the support of the Arts and Humanities Research Council in funding this Project. The Project Team would also like to thank all those who gave their time, experience and insights, without which the Project could not have progressed as successfully as it has.