INTRODUCTION

During the last fifty years, an increasing range of human material has been ‘biobanked’, including blood spots, tissue, and DNA. More recently, the phenomenon of ‘brain banking’ (BBing) – the collection and storage of post-mortem brain tissue to create a research resource for investigation into neurological (especially neurodegenerative) disorders such as Alzheimer’s Disease and Dementia – has become de rigueur. This at a time when social and policy concerns abound regarding the problems of an ‘ageing population’. Indeed, the desire to understand and act upon the brain – an object of increasing ‘salience’ and ‘biovalue’ – drives much techno-scientific and biomedical innovation, including developments such as brain imaging, scanning, and surgery. Brain research, however, raises a number of concerns which vex not only regulators but also scientists and healthcare professionals who are involved in BBing. Key issues include (but are not limited to):

- commodification of the body and the self;
- consent to donate and control of usage;
- stewardship of, and access to, the resource;
- security of data; and
- commercialisation of products generated from publicly-funded and altruistically supplied brain banks (BBs).

While much has been written about the socio-ethical and legal concerns that arise from biobanking generally, some crucial questions remain unanswered: Is banking the brain fundamentally different from banking other parts of the body such as DNA or blood spots? If so, why so? Is the brain somehow ‘special’, and, if so, is this ‘specialness’ reflected in the law? For example, in science and philosophy, the brain was a contested ‘site’ of personhood.

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1 This is, in part, because people are living longer; estimates suggest that 30% of babies born today will live to be 100 years old: K. Christensen et al., “Ageing Populations: The Challenges Ahead” (2009) 374 Lancet 1196-1208.
Science is increasingly telling us (so some claim) that the brain is the site of personhood. However, many people would not necessarily acknowledge that pre-eminence. Indeed, we often feel ourselves as being concentrated just behind the eyes. When someone says “look at me”, we look at his or her face – usually the eyes, expecting to encounter there the person, or at least his or her clearest self-manifestation.5

The ‘Banking (On) The Brain’ project, AHRC Grant No. AH/J011495/1, 12 February 2012 – 30 September 2012 (Project), funded by the AHRC’s ‘Science in Culture’ stream, attempted to deal with such difficult questions within the broader context of a normative question for law:

How should the regulation of science respond to the culturally driven values and discourses uncovered by, and undertaken within, arts and humanities (A&H) disciplines?

What follows is a brief articulation of the multidisciplinary discussions at the two workshops undertaken within the Project, followed by a summary of some of its key findings.

THE PROJECT

The Project Team, all affiliated with the University of Edinburgh, was comprised of the following:

- Dr. Shawn Harmon, Lecturer in Regulation & Risk, School of Law (PI)
- Dr. Gill Haddow, Senior Research Fellow, School of Social & 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)
- Ms. Aisling McMahon, PhD Student, School of Law (RF)
- Dr. Heather Blenkinsop, School of Social & Political Science (RF)

As can be seen from the composition of the Project team, the Project was a multidisciplinary study geared toward interdisciplinary learning. The Project was aimed at (1) integrating the learning of a range of A&H fields, and, through close association with scientific researchers, (2) taking some first steps in determining whether and how discourses emerging from A&H disciplines and popular culture are encoded in biomedical regulation relevant to the brain or BBing. It was structured around three broad questions:

1. To what extent does science reflect A&H conceptions of the brain?
2. To what extent do these conceptions shape the law?
3. To what extent might scientific knowledge impact on popular understandings of the brain and/or inform/influence the law?

The ultimate objective of the Project, however, was to glean some insight into three related regulatory questions, namely:

1. What is the legal framework applicable to BBers in the UK?

2. How are the day-to-day operations of BBs managed as a going concern?
3. What conceptions of the brain inform the law and legislation?

The Project generated a number of discipline-specific literature reviews and, as noted, hosted two interactive workshops to discuss findings and shape ongoing investigations. The workshops had the ancillary ambition of forging an enduring network of Edinburgh-based experts interested in BBing and neuroscience and neurolaw more broadly. The first workshop was held on 4 April 2012 and the second on 19 September 2012. Participants in these workshops and/or partners in the emerging network are as follows:

- Prof. Jeanne Bell, Professor of Neuropathology, Western General Hospital, UoE
- Dr. Francine Benes, MD, Harvard University, USA
- Dr. Heather Blenkinsop, School of Social & Political Science, UoE
- Dr. Ken Boyd, Senior Honorary Professorial Fellow and Honorary Joint Theme Head for Medical Ethics, College of Medicine & Veterinary Medicine, UoE
- Dr. Liz Campbell, Senior Lecturer, Criminal Law & Evidence, School of Law, UoE
- Ms. Muriel Cassie, Member of Lay Public, Edinburgh
- Dr. Jacob Copeman, Social Anthropology, School of Social & Political Science, UoE
- Prof. Sarah Cunningham-Burley, Professor of Medical & Family Sociology, Centre for Population Health Science, UoE
- Dr. Gayle Davis, Wellcome Lecturer, History of Medicine, School of History, Classics & Archaeology, UoE
- Prof. Ian Deary, Professor of Psychology, School of Philosophy, Psychology & Language Sciences, UoE
- Dr. Murray Earle, Programme Developer in Medical Law & Ethics, Distance Learning Initiative, School of Law, UoE
- Dr. Peter Falkai, Georg-August-Universität, Germany
- Dr. Lydie Fialova, Fellow in Medical Ethics, College of Medicine & Veterinary Medicine, UoE
- Dr. Gill Haddow, Senior Research Fellow, School of Social & Political Science, UoE
- Ms. Amy Hardie, Head of Research, Scottish Documentary Institute, College of Art, UoE
- Dr. Shawn Harmon, Lecturer in Regulation & Risk, School of Law, UoE
- Xiuyuan Hu, Patent Lawyer, LLM Research Student, UoE
- Thomas Insel, NIH, USA
- Dr. James Ironside CBE, Professor of Clinical Neuropathology, National CJD Surveillance Unit, Western General Hospital, UoE
- Joel Kleinman, NIH, USA
- Dr. Graeme Laurie, Professor of Medical Jurisprudence, Director of the Mason Institute, School of Law, UoE
- Chris Lerpiniene, Research Nurse, Linchpin Project on Post Mortem Brain Tissue Post-Intra-cerebral Haemorrhage, UoE
- Daniel Lightfoot, Autism Speaks, USA
- Prof. Susan Manning, Gierson Professor of English Literature, Director of Institute for Advanced Studies in the Humanities, UoE
- Dr. Claire McKechnie, Department of English Literature, Medical Humanities Research Network, UoE
- Ms. Aisling McMahon, PhD Student, School of Law, UoE
• Tracey Millar, Research Nurse Co-ordinator, MRC Sudden Death Brain & Tissue Bank, Department of Pathology (Neuropathology), UoE
• Dr. Martyn Pickersgill, Wellcome Trust Senior Research Fellow in Biomedical Ethics, Centre for Population Health Science, UoE
• Dr. Tom Russ, MRCPsych, Alzheimer Scotland Clinical Research Fellow, Alzheimer Scotland Dementia Research Centre, UoE
• Prof. Thomas Schulze, MD, Georg-August-Universität, Germany
• Dr. Colin Smith, MD FRCPsPath, Centre for Clinical Brain Studies, Dept. of Pathology, UoE
• Dr. Camilla Stoltenberg, Norwegian Institute of Public Health, Norway
• Dr. Steven Sturdy, Head of Science Technology and Innovation Studies, UoE
• Dr. Tillmann Vierkant, Psychology & Language Studies, School of Philosophy, UoE

WORKSHOP DISCUSSIONS

The discussions at the workshops were open and wide-ranging, and can be summarised under the following themes:

Context

It was suggested that Brain Banks (BBs) work more efficiently when they are grounded on a hypothesis, even if that hypothesis is quite broad; you need to know why you are setting up a BB. Most of the 10 BBs in the UK are focussed around a disease, and have been set up by a particular charity for research into a particular condition (HIV, CJD, etc.) or an emergent interest (ageing, cognitive function, etc.). In Edinburgh, there are three BBs: the Sudden Death BB; the HIV BB; and the CJD BB. While a pathologist can generally ascertain cause of death or contributory factors to death from a physical examination of one brain, investigations into how diseases affect populations require a collection of brain tissue. It is fundamentally important that the collection includes ‘normal’ brains in order to provide a control sample. Of course, this raises fundamental questions about what and how ‘normal’ is defined. It was reported in the meeting that ‘control brains’ have also demonstrated some early forms of pathology; raising the issue of secondary findings that are associated with any form of population tissue bank.

Procuring and Preparing Brains

Brain tissue is often procured differently from other tissue and organs. Most brain donations are characterised by performance of a post-mortem examination (PME), and this is not necessarily the case for other tissue or organ donation scenarios (where they have been donated for the treatment of an individual). It was reported that individuals have refused to donate tissue for transplant yet agreed to donate brain tissue for research. Further, infected brains are still valuable, and are considered a ‘dangerous substance’ the handling of which requires specialist protective clothing (which also, importantly, protects the tissue from outside contamination). The HIV virus, for example, can remain alive and active in brain tissue for 72-96 hours post mortem.

In typical PMEs, the brain is examined for signs of physical and biological disease. One half is then cut and frozen whilst the other is fixed in a solution to make it firmer for examination – this is called ‘fixed tissue’ and is necessary for preparation of histological
slides for microscopic investigation.\(^6\) A diagnostic report is then prepared and fed back to the clinician who was responsible for requesting the PME. The majority of PMEs are not undertaken after hospital deaths, but rather after sudden deaths in the community, many of them natural but occurring suddenly and/or unexpectedly. Sudden or unexplained deaths are followed by a PME (or medical-legal autopsy) as a matter of course; in England and Wales they are handled by the Coroner, and in Scotland by the Procurator Fiscal. Essentially, a pathologist undertakes the PME at the behest of the legal authorities (not at the request of the clinician or family). Hence, type of death matters for the state of the brain (for example, sudden deaths are generally more suitable to BB).

**Brains in Culture and Public Expectations**

Bodies donated for anatomy training are not expected to be returned to the family whereas those that have undergone a PME at the behest of legal or hospital authorities generally are expected to be returned. In 2003, the Isaacs Report recommended a move away from the (old) presumption that consent to perform a PME entitled the healthcare professional to retain the brain for research.\(^7\) Such a move was particularly pressing and appropriate where the Coroner or Procurator Fiscal requested the PME in order to establish cause of death (and so familial consent was absent). It was discovered in the preparation of the Isaacs Report that, while some were only offended by failure to get proper consent, others were offended by the act of brain/tissue retention itself.

In the case of eye donation, fears around potential cosmetic disfigurement have been voiced. Cultural discourses around the brain being the seat of the soul, and the eyes being the window to the soul were noted, which led to questions as to whether it was the brain itself that likely provoked public reaction, or whether it was the removal procedures (ie: the incision) which caused alarm. In any event, it was agreed that the brain has some ‘iconic status’, and several observations of some sociological interest were discussed, namely:

- A noteworthy/unique situation is created when we use our brain to examine brains; the brain is ‘looking’ at itself and ‘thinking’ about itself. Parallels were drawn with Freud’s *Heimlich* and *Unheimlich* (familiar and unfamiliar), and the varying symbolic statuses and weights that have been given to the brain and the heart historically.

- ‘Illumination’ as a cultural trope and a visual metaphor was thought to be worth pursuing in relation to brain imaging (as was the question of whether this metaphor has informed any public or scientific conceptions).

- The relationship between the self and the brain may have been consolidated in the 1950s and ‘60s with the development and use of lobotomies, but questions persist as to when the brain becomes ‘self’ (24 weeks gestation?) or ends (having a fully functioning brain may not be a precondition of self, although not having a brain will end the self).

Ultimately, it is important to distinguish between identifying public perceptions of self/body

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\(^6\) Fresh brain tissue can be frozen so it can be prepared for neuro-chemical investigation, genetic analysis, and/or stem cell extraction. For a short film of London pathologist Steve Gentleman preparing and examining a brain from a patient who suffered from multiple sclerosis, see [http://news.bbc.co.uk/1/hi/health/8083597.stm](http://news.bbc.co.uk/1/hi/health/8083597.stm).

Brains in Practice and Regulation

First and foremost, and perhaps surprisingly given the sociological/cultural importance and status of the brain, the brain is not explicitly mentioned in UK legislation (i.e.: it is not singled out or identified as needing any significant or specific oversight). The brain is treated as any other tissue, although a difference between tissue and whole organs is acknowledged. The brain is only singled out insofar as it is associated with capacity; the law erects numerous and specific rules around consent and capacity/vulnerability, but this shifts the emphasis from the brain (as an object) to the self (as a subject).

The issue of a potentially ‘vulnerable individual’ with a ‘diseased brain’ giving consent to have their diseased brain banked and used for research was raised as a challenging area of legislation and regulation. A second important insight was that practices around securing brains and brain tissue are not reflective of the law insofar as they are more dependent on family cooperation and consent than the law requires (i.e.: family members have more say in how physicians proceed than they are given in the law). Indeed, in donation generally, family wishes typically override those of the individual (deceased) and of the procurement system.

The concept of ‘ownership’ does not typically arise for BBers, who rely more on concepts of ‘custodianship’, ‘stewardship’, or ‘guardianship’, but it was acknowledged that when a researcher develops a product derivative of his or her access to the tissue, the profits of that product belong to the researcher (or patent holder) and not to the individual who donated the tissue (or his/her relatives), nor to the BB. Consent forms typically characterise the donation as a gift and control of the tissue typically resides in the person who has done the work.

It was noted that increasing reliance on imaging technologies in research, including imaging of the brain, increases the possibility that findings of potential diagnostic importance will be made. This raises the issue of so-called ‘secondary findings’ (i.e.: findings not central to the research project for which the brain was scanned) and feeding back such information to participants. Policies on this issue have yet to be agreed. Related to this is the use of brain imaging to assess truthfulness or guilt in the (civil or criminal) litigation process, and the use of imaging to ‘measure’ intellectual functionality where a head/brain injury has occurred. It was noted that a range of scientifically unfounded expectations are emerging in this area.

KEY FINDINGS AND LESSONS

The Structuring Questions

Using the structural questions as our reporting architecture, we can report that the Project found the following.

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

The brain has been an object of inquiry for centuries, and views of the importance and function of the brain have changed: Galen considered it to be a set of cavities occupied by animal spirits; Descartes was more concerned with the mind, consciousness and the soul; he was critiqued by those who framed the brain as an anatomical object. Mid-18th century scholars associated brain function with thought and electricity. Mid-19th century scholars
began isolating parts of the brain associated with specific functions (speech). Modern BBing is reflective of the ‘biomedicalisation’ of society, a phenomenon advanced by the medico-scientific complex and popular desires for deliverance from all manner of conditions and states-of-being.  

Although the influence of A&H and cultural representations of the brain on scientific practitioners is not obvious, A&H conceptions have exerted a subtle influence on scientific thinking about the brain. What has emerged from their long-time interaction is a conception of the brain as the seat of 'self'; brain function is conflated with ‘self’. Neuroscience, of which BBing is a component, draws on the dominant medical paradigm of ‘disease’: physiological malfunctions can be separated from the person, causatively identified, and symptomatically relieved. BBing also adopts/advances the primary scientific ideology of atomism: the idea that we learn about nature and ourselves by reducing the object of study to its smallest components. Indeed, advances in imaging are leading to claims that it may be the ‘gorse’ of neural connections that are key.

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

Perhaps surprisingly given the sociological/cultural importance attributed to the brain, the brain has not featured strongly in legal scholarship. It has been the subject of debate regarding the diagnosis of death (particularly with the transition of the basis of that diagnosis from respiration to brain stem function), and its importance is reflected in awards for brain injuries (particularly those with a constellation of physical and functional repercussions), but it is treated like any other tissue/organ when it comes to regulation of science. In short, our cultural concerns over, or awe of, the brain does not seem to spill over into, or drive, the science or its regulation, which does not seem to treat the brain as ‘special’. UK legislation does not even explicitly mention the brain, addressing itself rather to ‘tissue’ and ‘organs’. Indeed, the law has mostly remained steadfastly focused on the self (as subject) rather than the brain (as object); it focuses on capacity and vulnerability and the need for conscious reflection. It resists the neuroscience fixation on brain as self by continuing to rely on ‘illnesses of the mind’, which permit wider sources of evidence than brain structure/function evidence.

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10  For more on the disease paradigm, see I. McWhinney, “Changing Models: The Impact of Kuhn’s Theory on Medicine” (1983) 1 Family Practice 3-8.


14  See the Human Tissue Act 2004, which applies to England, Wales, Northern Ireland, and the Human Tissue Act (Scotland) 2006, which applies to Scotland, and see the various HTA Codes of Practice.
3. To what extent might scientific knowledge impact on popular understandings of the brain and/or inform/influence the law?

Scientific metaphors associating the brain with machinery, particularly computers, and modularity, are dominating popular representations. Images of brains held in hands, bandaged brains, brains inserted with USB sticks are common. But genuine public understanding of neurologic knowledge is questionable, partly because it is the more radical and contested claims that are most widely disseminated. Claims that challenge principles fundamental to the law include claims that neuroscience will:

- demonstrate that ‘we are our brains’;
- alter conceptions of rationality and free will;
- permit technological/technical assessment of truthfulness/guilt;
- allow the measurement of intellectual functionality;
- prove the existence of ‘dangerous minds’.

Such claims exert a strong influence on public expectations and demonstrate that debates around ‘neurolaw’ need further and improved input from A&H.

The Regulation of Brain Banking

As previously noted, a primary objective for the Project was to determine how BBs are regulated in the UK, and how they are operated as going concerns. At the outset, we accepted the following definition of tissue bank:

A collection of human tissue or other biological material which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending.

With respect to BBs, we accept that a BB is a resource the essential purpose of which is to provide brain and spinal cord samples to researchers both affiliated with the bank and independent from the bank. Very briefly, we found as follows:

- BBing is governed primarily by the Human Tissue Act 2004 (England, Wales, Northern Ireland) and the Human Tissue Act (Scotland) 2006, neither of which expressly refer to brain or differentiate brain tissue from other bodily tissue or organs. Thus, again, while there are obvious technical or scientific issues thrown up in relation to the complexity and contextual location of the brain, no sense of ‘specialness’ or unique complexity is

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16 And members of the Project Team and the broader network it engaged with are pursuing that process, participating in the Biomedical Ethics Film Festival run by the Scottish Council on Human Bioethics, which, this year, focuses on neuroethics.


gleaned from its position in the regulatory environment.

- While the two instruments have much in common, the HTA 2004 erects a licensing scheme with which BBs must comply. The HT(S)A 2006 does not, but Healthcare Improvement Scotland has recently erected a non-statutory accreditation system designed to demonstrate the ‘highest possible professional standards’.

- Additionally, the HTA 2004 relies on ‘consent’ whereas the HT(S)A 2006 relies on ‘authorisation’. The latter is seen as a departure from passive acceptance; it is more active, reflecting the idea that consent for unspecified future studies cannot be ‘informed’ and is not properly ‘consent’. Both consent/authorisation form characterises donation as a ‘gift’. In practice, these divergences make no difference; practices are not standardised, but they are harmonised, a primary motivation being to facilitate tissue sharing within the UK.

- BBs in both jurisdictions are members of, and work to standards agreed by, the MRC Brain Banks Network, which formulates common policies and procedures so as to ensure high standards of operation. They must also obtain approvals from NHS Research & Development and relevant Research Ethics Committees, and such approvals can be applied for online through the Integrated Research Application System. REC oversight tends to focus on issues of consent/authorisation, compliance of use with originally claimed/anticipated purposes, and third party access, which is also addressed by the Acts.

- Importantly, the MRC Brain Banks Network Codes, combined with actor practices, produce a governance framework that exceeds hard law. For example, statutory provisions around consent/authorisation are very specific, placing decisional power with donors. However, practice more closely follows guidelines and the practicalities of promoting respect and harmony between doctor/nurse and patient/family. Thus, while legislation offers no veto for relatives of a deceased who has consented/authorised to the use of his/her brain/tissue, the Code urges caution, stating that the impact of going ahead in light of familial opposition should be considered (and BBers never proceed in the face of family discord).

- Governance issues which remain problematic include standard criteria for evaluating or auditing BBs, international operating procedures for exchanging specimens, and international standards of conduct. In some cases, however, when gaps are apparent, practice and experience offers some guidance (as in the case of consent). Thus, for example, while BBers cannot monitor how (foreign) researchers handle tissue or data provided from UK BBs, BBers come to know regular users and their practices/legislation.

Significantly, there are numerous ethical, legal and social issues relevant to BBing that overlap with, or reflect, those in other forms of tissue banking (eg: procurement, storage, etc).
access, unknown purpose), and a key aim is therefore to enhance dialogue between such banks in order to ascertain shared ethical, legal and social issues.

OUTSTANDING QUESTIONS OF INTEREST

Further regulatory questions ripe for exploration in greater detail include:

1. What is the state of the neuro-legal discourse, and the state of play for neuro evidence?

2. Can we say that the different legal status attributed to humans, animals and plants respectively are based on the brain and its capacities?

3. Do the many scientific/medical/technical uncertainties (mysteries) around the brain and its operation cause legal uncertainties/problems?

4. What is the state of the law with respect to neuro enhancement?

5. At what point does the BBer’s stewardship or curator responsibilities to handle the tissue in a certain way transfer to the researcher, and how is or might that be monitored?

Some social or sociological questions worthy of further or follow-on exploration include:

1. What is the definition of (what counts as) a ‘normal brain’, and how does this affect the classification of diseases and disorders?

2. How have public perceptions of BBing changed over time?

3. Is the brain as emotive as the eyes – why or why not? Has the brain come to be seen as ‘uncanny’ in the Freudian sense? How and for how long has the division between ‘mind’ and ‘brain’ been created?

4. What is the link between the brain and the self? How are public debates/discourses regarding the relationship between the ‘brain’ and the ‘self’ unfolding?

5. How are researchers approaching neuroethics and issues of ‘medicalization, and what is the impact of brain images/imaging on wider expectations and perspectives?

CONCLUSION

Through cross-disciplinary investigations and discussions around the governance of BBing, this Project explored interactions between science and culture, addressing questions pertaining to conceptions of the brain embedded within BB practice, the impacts of these on law, and the legal and cultural traction of the knowledge produced by BBing. It found that the brain is salient in legal debates around death and injury compensation, but is treated like any other tissue/organ when it comes to science regulation. BBs are governed by de jure law and by de facto regulation emergent from codes of conduct and routinized practice. Despite resonance of issues and concerns between BBs and other types of biobanks, dialogue about the ethical, legal and cultural aspects and implications of the work in these domains remains
limited. More broadly, neurological knowledge is contributing to the development of ‘neurolaw’, a discursive realm within which there is often a poverty of understanding of both the scope and limits of neuroscience and BBs, as well as the practice and meanings of law. The arguable dichotomy that exists between scientific practices around the brain and popular cultural (even facetious) manifestations of the brain, as captured by this Project, are admirably reflected in Figures 1 and 2.24

Image 1: Bain Slice

![Image 1: Bain Slice](http://www.guardian.co.uk/science/gallery/2012/mar/28/human-brain-dissection-in-pictures/?picture=387992576&index=6)

Image 2: Brain Cap

![Image 2: Brain Cap](http://www.boredpanda.com/brain-hat-by-alana-noritake/)

From a more methodological perspective, this Project demonstrated how the ambiguities and ambivalences that differences between intellectual traditions might produce can be leveraged to animate new interdisciplinary conversations, initiatives, and innovations.

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