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### Banking (on) the Brain

From Consent to Authorisation and the Transformative Potential of Solidarity

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# BANKING (ON) THE BRAIN: FROM CONSENT TO AUTHORISATION AND THE TRANSFORMATIVE POTENTIAL OF SOLIDARITY

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**Abstract:** Modern technologies and biomedicine ambitions have given rise to new models of medical research, including population biobanking. One example of biobanking is brain banking, which refers to the collection and storage of brain and spinal cord samples for research into neurological diseases. Obviously, brain banking involves taking brains and tissue from deceased people, a fact which complicates the role of recruiters and makes consent a poor tool for stakeholders. After contextualising brain banking and considering the public health issues at stake, this paper explores the legal definitions and demands of, and actual processes around, consent in England/Wales/Northern Ireland and authorisation in Scotland, articulating and evaluating their conceptual and practical differences. It then argues for an expanded but improved operation of ‘authorisation’ in the brain banking (and broader biobanking) setting, adopting ‘solidarity’ as our foundation and the improvement of the ‘public good’ our objective.

**Keywords:** Authorisation – Consent – Brain Banking – Posthumous Donation – Autonomy – Solidarity – Human Tissue

## I. INTRODUCTION

Modern technologies and ambitions for biomedicine have given rise to new models of medical research. One such model is population biobanking, which is the practice of collecting tissue and data into a repository that can be used as a research tool by multiple researchers over a period of time. However, despite widespread pursuit of, and support for, biobanking, considerable uncertainty persists around how to most optimally structure the governance of, and participation in, biobanks. Significant debate has centred around how best to recruit participants, and whether consent could ever be ‘informed’.<sup>1</sup> Some have argued for a more ‘open’ or ‘broad’ consent, and some for approaches that view consent as an ongoing process rather than a one-off event,<sup>2</sup> and others have argued for a retreat from

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<sup>1</sup> See, e.g., V Árnason, ‘Coding and Consent: Moral Challenges of the Database Project in Iceland’ (2004) 18 *Bioethics* 27- 29; B Knoppers, ‘Biobanking: International Norms’ (2005) 33 *J Law, Med & Ethics* 7-14; G Hengesson et al, ‘Ethical Framework for Previously Collected Bio Bank Samples’ (2007) 25 *Nature Biotechnology* 973-976; J Forsberg et al, ‘Changing Defaults in Biobank Research Could Save Lives Too’ (2010) 25 *Eur J Epidemiol* 65-68; J Allen & B McNamara, ‘Reconsidering the Value of Consent in Biobank Research’ (2011) 25 *Bioethics* 155-166.

<sup>2</sup> See, e.g., T Caulfield et al, ‘Research Ethics Recommendations for Whole-Genome Research: Consensus Statement’ (2008) 6 *PLoS Biology* e73; A McGuire & L Beskow, ‘Informed Consent in Genomics and Genetics Research’ (2010) 11 *Ann Rev Genomics & Human Genetics* 361-381.

consent (and consent language) altogether,<sup>3</sup> claiming that the more pertinent issues are those of 'control' and the advancement of the 'public good'. For a variety of reasons, it is argued, the consent paradigm's focus on the position and wellbeing of the individual participant/donor and his or her autonomy sits uncomfortably in the biobanking model, which is prospective, purposively indeterminate, and aimed at furthering the interests of, and benefit to, the community as a whole.<sup>4</sup>

This lack of congruity is heightened in brain banking because one is there dealing with 'participants' who are deceased at the time of their donation.<sup>5</sup> The result is that third parties are more often and more directly drawn into the recruitment interaction. Participants are typically recruited in one of the following ways:

- an individual decides to donate, and records their wishes in an Advance Directive or some other format, and their relatives are engaged and counselled after their death;
- an individual is approached by a donor programme or their palliative care team, and agrees to donate, making their wishes known, and their relatives are engaged and counselled after their death;<sup>6</sup>
- an individual makes no decision about donation or at least fails to inform anyone of his/her wishes surrounding donation, and an individual's relatives may be approached about donation after their death, in which case the relatives become the primary decision-makers.

This recruitment process raises some important practical questions which are (or can be) influenced by the recruitment model used:

1. Who *should* consent in the absence of the expressed wishes of the deceased?
2. If the known wishes of the deceased conflict with those of the family, who prevails?
3. If re-consent is needed for new research, who should provide this, especially if the deceased gave the original consent?

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<sup>3</sup> S Harmon, 'Semantic, Pedantic or Paradigm Shift? Recruitment, Retention and Property in Modern Population Biobanking' (2009) 16 Euro J Health Law 27-43. See also G Hengesson et al, n 1 above, and T Caulfield et al, 'Debate: DNA Databanks and Consent: A Suggested Policy Option Involving an Authorization Model' (2003) 4 BMC Medical Ethics, doi:10.1186/1472-6939-4-1.

<sup>4</sup> S Harmon, *ibid.* Similar arguments have been made in the context of organ donation for transplantation purposes: see A Cronin & J Harris, 'Authorisation, Altruism and Compulsion in the Organ Donation Debate' (2010) 36 J Med Ethics 627-631.

<sup>5</sup> Brain banking refers to the collection and storage of brain and spinal cord samples for research into neurological diseases: see J Bell et al, 'Management of a Twenty-First Century Brain Bank: Experience in the BrainNet Europe Consortium' (2008) 115 Acta Neuropathol 497-507.

<sup>6</sup> For more on these, see A Schmitt et al, 'How a neuropsychiatric brain bank should be run: A consensus paper of BrainNet Europe II' (2007) 114 J Neural Transim 537-537. For examples of disease-specific banks, see <http://www.ukmtissuebank.imperial.ac.uk/> and <http://www.parkinsonstissuebank.org.uk/>.

This paper follows from the AHRC-funded 'Banking (On) The Brain' (BOTB) project.<sup>7</sup> It examines the current framework for recruitment to brain banks in the UK. At the outset, it must be acknowledged that post mortem examination (PME) rates are declining, which translates into an inability to secure brains and brain tissue for research (ie: hindered recruitment).<sup>8</sup> Particular difficulties have been encountered in obtaining unaffected or 'normal' brain tissue, which acts as a necessary control in the investigation of disease;<sup>9</sup> without sufficient quantities of *both* 'diseased' and 'normal' tissue, there is a real risk that research, which relies on numbers of statistical significance and control data, will be stifled or might lead to incorrect conclusions and improper solutions.<sup>10</sup> There are, of course, a variety of reasons for this decline, including historical ambivalence toward autopsies,<sup>11</sup> use of ownership models by families to claim possessory rights in bodies,<sup>12</sup> and the organ retention scandals of the late 1990s.<sup>13</sup> To these we would add the legislative frameworks under which recruitment now takes place.

In the following pages, after contextualising brain banking and justifying its characterisation as supporting the public good, we consider 'consent' under the *Human Tissue Act 2004* (HTA 2004),<sup>14</sup> and 'authorisation' under the *Human Tissue (Scotland) Act*

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<sup>7</sup> Banking (On) The Brain, AHRC Exploratory Award No. AH/J011495/1, February-September 2012, funded under the AHRC's Science and Culture Stream.

<sup>8</sup> See, e.g., C Petri, 'Decrease in the Frequency of Autopsies in Denmark After the Introduction of a New Autopsy Act' (1993) 5 *Qual Assur Health Care* 315-8; L Eriksson & C Sunstrom, 'Decreasing Autopsy Rate in Sweden Reflects Changing Attitudes Among Clinicians' (1993) 5 *Qual Assur Health Care* 319-23; J Lund & G Tierney, 'Hospital Autopsy: Standardised Questionnaire Survey to Determine Junior Doctors' Perceptions' (2001) 323 *BMJ* 21-22; C Hulette, 'Brain Banking in the United States' (2003) 62 *J Neuropathol Exp Neurol* 715-722; G O'Grady, 'Death of the Teaching Autopsy' (2003) 327 *BMJ* 802-803, NHS Implementation Sub-Group, *Can Cross-Sectional Imaging as an Adjunct and/or Alternative to the Invasive Autopsy be Implemented Within the NHS?* (London: Crown, 2012).

<sup>9</sup> T Millar et al, 'Tissue and Organ Donation for Research in Forensic Pathology: The MRC Sudden Death Brain and Tissue Bank' (2007) 213 *J Pathology* 369-375, at 374. Families of deceased patients affected by a neurological disease are much more likely to authorise donation, or comply with the deceased's desire to donate.

<sup>10</sup> *Ibid*, at 369.

<sup>11</sup> See R Richardson, *Death, Dissection and the Destitute* (London: Phoenix Press, 1988).

<sup>12</sup> The unstable history of notions of property in relation to cadavers is exemplified by an evolution of cases: , e.g., *R v Stewart* (1840) 12 *Ad. & El.* 773; *R v Fox* (1841) 2 *QB* 246; *R v Sharpe* (1857) 169 *ER* 959; *R v Feist* (1858) *Dears. & B.* 590; *Foster v Dodd* (1867) 3 *QB* 67; *Williams v Williams* (1882) 20 *Ch D* 659; *Dobson v North Tyneside HA* (1996) 4 *ALL ER* 474, *R v Kelly* (1999) 2 *WLR* 384.

<sup>13</sup> See, e.g., K Mason & G Laurie, 'Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey' (2001) 64 *Mod Law Rev* 710-729; S Dewar & P Boddington, 'Returning to the Alder Hey Report and its Reporting: Addressing Confusions and Improving Inquiries' (2004) 30 *J Med Ethics* 463-469. The Royal College of Pathologists Higher Specialist Training Committee, *RCP Exam Guidelines - 2012*, at <[http://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/A/Exams\\_Autopsy\\_July\\_2012.pdf](http://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/A/Exams_Autopsy_July_2012.pdf)> [17 September 2013], indicates that, in the wake of the organ retention scandal, physicians are hesitating to ask for autopsies, and, further, only 12% of junior doctors are informed when an autopsy is to take place, only 6% attend autopsies, and many are declining to take higher specialist training in autopsies, resulting in a general decline in skills.

<sup>14</sup> This applies to England, Wales, and Northern Ireland, though note that on 2 July 2013, the Welsh government adopted the *Human Transplantation (Wales) Act 2013*, which implements a 'soft opt-out' system for organ donation, whereby individuals will be presumed to have consented for their organs to be donated unless they have opted out. Under this system, donation will not take place if a relative or longstanding friend of the deceased objects on the basis of the deceased's views so long as a reasonable person would conclude that the relative or friend knows that the most recent prior-to-death view of the deceased on the matter of

2006 (HTSA 2006). In doing so, we draw on secondary regulation from the Human Tissue Authority (HTA),<sup>15</sup> and have reference to recruitment strategies deployed by brain bankers. After exploring the demands and consequences of consent in England/Wales/Northern Ireland and authorisation in Scotland, we argue for a more uniform shift from ‘consent’ to ‘authorisation’, with the caveat that we must ground ‘authorisation’ on a wider value base than currently prevails. We close by making a case for improving the operation of authorisation in the biobanking and brain banking context by operationalising ‘solidarity’, which would facilitate a shift in thinking about donation. It would retreat from the contested concept of donation as an altruistic gift, advancing the view that donation is rather a contribution to the wider social fabric (ie: to individual health and the health of future generations) that is owed.

## II. PUBLIC GOODS AND PUBLIC HARMS

In this section we argue that health is an important and valued ‘public good’ and we demonstrate that brain and neurological diseases are a serious and growing challenge to health. We also point to the instrumental role that brain banks – by providing well-curated samples of human tissue to a community of researchers – play in advancing knowledge about brain development and conditions that affect the brain, and developing effective treatments for same. These realities are important for justifying brain banking and the adoption of legal measures to support it.

### A. Health as a ‘Public Good’

A ‘public good’ is an end, outcome, or commodity which is ‘non-rivalrous’,<sup>16</sup> or ‘non-excludable’,<sup>17</sup> or both (ie: one person’s use or enjoyment of such goods will neither negate nor diminish another person’s enjoyment).<sup>18</sup> Applying these criteria in the health context, we can say that one person’s health does not necessarily diminish someone else’s health, and one’s achievement of health (or rather one’s possession of health and vitality) does not in the normal course limit others’ achievement of it; nobody in a population can be excluded from benefiting from a reduction in the risk of infectious disease, for example, and one person benefiting from this reduction in risk does not prevent anyone else from also

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consent for donation was that of opposition: see s. 4(4)). This Act comes into effect in 2015, and it is only applicable in relation to the donation of organs for transplantation, not organs donated for research purposes.

<sup>15</sup> As authorised by HTA 2004, s. 26(1), the HTA has produced nine Codes of Practice which articulate standards of conduct for persons carrying out activities within the remit of the HTA. The existing codes pertain to 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 and research, and can be found at <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm> [17 September 2013].

<sup>16</sup> Something is ‘non-rivalrous’ if one’s use of it does not diminish another’s use.

<sup>17</sup> Something is ‘non-excludable’ if its use cannot be or should not be limited to certain people.

<sup>18</sup> For more on public goods, see B Prainsack & A Buyx, *Emerging Biotechnologies: Technology, Choice and the Public Good* (London: Nuffield Council on Bioethics, 2011) at 4.6. For a critique on the report, see A Dawson & M Verweij, ‘Solidarity: A Moral Concept in Need of Clarification’ (2012) 5 *Public Health Ethics* 1-5.

benefiting.<sup>19</sup> Of course, these claims might be complicated when there is a need to access limited healthcare resources to achieve that health, but, as will be argued below, this public/private divide is blurring and becoming irrelevant to the characterisation of health as a public good.<sup>20</sup>

Some go so far as to argue that health is a *global* public good because enhanced mobility, international trade linkages, information flows, and cross-border environmental threats have accelerated the extra-national transmission of disease and of behavioural and environmental health risks/determinants.<sup>21</sup> While we concur with this broader identification of public goods, it is not essential to our argument. Further and relatedly, while we concede that the substance of what is meant by in the 'public good' may evolve over time,<sup>22</sup> and that some manifestations of it might not easily co-exist,<sup>23</sup> we take it as uncontroversial that health is also in the public good. In this sense, we take 'in the public good' to mean an activity which will bring about some real social welfare enhancing benefit to a community or society at large.

Individual and community health are the fount of all other social ambitions and achievements; without health and some level of vitality, very little can be accomplished (ie: no wealth-generation activities like labour, production or innovation, and no social activities such as democratic engagement or cultural generation). Health is an important – and arguably the *most* important – constituent element of individual and community existence, and all societies must engage with and promote health or they risk failure. The fundamental importance of individual and community health is reflected by the amount of critical thought, political attention, social and legal architecture, and public money directed at their realisation. With respect to money note that the NHS typically represents one of the largest single national budget expenditures,<sup>24</sup> and its 2011/12 budget was £106 billion (approximately 8.4% of GDP).<sup>25</sup>

Of course, while most will agree that health is 'in the public good', rational agents may well disagree about how to define health or health benefits. This may give rise to

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<sup>19</sup> Paraphrased from R Smith, 'Global Public Goods and Health' (2003) 81 WHO Bull 475. Arguments have also been made that surveillance of infectious diseases is a public good (W McNeill, *Plagues and Peoples* (NY: Anchor Books, 1976), and M Zacher, 'Global Epidemiological Surveillance: International Cooperation to Monitor Infectious Diseases' in I Kaul, I Grunberg & M Stern (eds.), *Ibid*, 266-283, and that actions aimed at controlling new environmental threats are public goods (A McMichael & A Haines, 'Global Climate Change: The Potential Effects on Health' (1997) 315 BMJ 805-809).

<sup>20</sup> L Chen, T Evans & R Cash, 'Health as a Global Public Good' in I Kaul, I Grunberg & M Stern (eds) *Global Public Goods: International Cooperation in the 21st Century* (Oxford: OUP, 1999), 284-304.

<sup>21</sup> L Chen, T Evans & R Cash, *Ibid*, at 289. See also, R Smith, 'Global Public Goods and Health' (2003) 81(7) WHO Bulletin of the 475. For more on public goods in the global context, see, D Dalrymple, 'Scientific Knowledge as a Global Public Good: Contributions to Innovation and the Economy' in Steering Committee (eds.), *The Role of Scientific and Technical Data and Information in the Public Domain* (Washington DC: National Academies Press, 2003) 35-51.

<sup>22</sup> For example, 'public welfare' was used as a justification to allow the compulsory sterilisation of the so-called 'unfit', which included those suffering from mental illness, in *Buck v Bell* (1927) 274 US 200.

<sup>23</sup> G Laurie, P Mallia et al, 'Managing Access to Biobanks: How Can We Reconcile Individual Privacy and Public Interests in Genetic Research?' (2010) 10 Med Law Int 315-337.

<sup>24</sup> Public health spending in England, for example, has increased to £4.7 billion (including pharmaceuticals but excluding secondary prevention): Department of Health, *The NHS Belongs to the People: A Call to Action* (London: NHS England, 2013), at 15.

<sup>25</sup> Up from £437 million at its foundation in 1948: R Harker, *NHS Funding and Expenditure* (London: House of Commons Library, 2011).

difficulties in some contexts, but less so in the present one. If we accept that brain disease, and particularly degenerative brain and neural conditions, are rising and are affecting significant levels of the population, then it becomes much less contestable to state that the pursuit of treatments for such conditions is in the public good. How to decide on the type of research which should be pursued (ie: which conditions should be prioritised outside those which affect significant numbers) is a separate issue, but is nonetheless addressed briefly below.

## **B. Brain Diseases as a Pressing Public Harm**

To state the obvious, health is diminished by injury and disease. Thus, we require social systems (ie: policies, practices, institutions, instruments) for monitoring, maintaining, and restoring health. In the UK, we have, *inter alia*, the NHS. Like most free-at-point-of-service public health systems, the NHS began as an ambitious dream of universal care (and caring) which would serve to raise the relative welfare of society.<sup>26</sup> While ambitions for and expectations placed on the NHS have perhaps declined from their lofty antecedents, it is still expected to deliver reasonable health to the public through effective interventions delivered fairly and efficiently by competent professionals.

Of course, questions persist as to what this might mean in practice, particularly in light of the following:

- increasingly expensive technologies and treatments (from new, narrowly targeted and expensive drugs to IVF, etc.);
- increasingly aged populations (imposing the treatment pressures of long-term and degenerative conditions); and
- decreasing numbers of system contributors (in the form of taxable employed citizens).

Questions also persist about the implications of privatisation of some services traditionally provided by the NHS, a main point of concern being the consequences of such on standards of care,<sup>27</sup> and sharpening of health inequalities.<sup>28</sup> Answers to these questions are not obvious, but also are not pertinent to the argument.

What is clear is that the NHS faces many difficult challenges as a result of changing demographics, demands, and disease patterns. Neurodegenerative and other neurological diseases in particular are cited as pressing concerns. In 2011, in the 27 EU countries plus Norway, Iceland and Switzerland (population: 514 million), disorders of the brain – defined as including mental and neurological illnesses – were estimated as costing €798 billion per

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<sup>26</sup> See W Beveridge, 'Social Insurance and Allied Services – 1942' (2000) 78 WHO Bull 847-855.

<sup>27</sup> See K Stacey, 'NHS Privatisation with a Bill', *Financial Times*, London, 17 April 2013, at <<http://www.ft.com/cms/s/0/3bdd3b3e-a77d-11e2-9fbc-00144feabdc0.html#axzz2cLLlcmPs>> [17 September 2013], G Plummer, 'Arms' race over £5bn in NHS work', *Financial Times*, London, 29 July 2013) at <<http://www.ft.com/intl/cms/s/0/6424b29e-f60a-11e2-a55d-00144feabdc0.html>> [17 September 2013], D Campbell, 'NHS privatisation fears deepen over £1bn deal', *Guardian*, London 26 July 2013, at <<http://www.theguardian.com/society/2013/jul/26/nhs-privatisation-fears-deepen-deal>> [17 September 2013].

<sup>28</sup> See Secretary of State for Health, *Government's Response to the Health Committee Report on Health Inequalities* (London: HMG, 2009).

year.<sup>29</sup> This represents 25% of the direct healthcare costs in Europe, with indirect costs adding to this figure.<sup>30</sup> A recent report estimated that the total cost of brain disorders in the UK in 2010 was €134 billion which included indirect costs, direct non-medical and direct healthcare costs.<sup>31</sup> In fact, the NHS is said to be facing a ‘neurological time bomb’ due to expanding disease burdens and patient demand.<sup>32</sup> The picture is similarly bleak at a global level, as it has been estimated that disorders of the brain account for 13% of the global disease prevalence, a level which surpasses both cardiovascular diseases and cancer.<sup>33</sup> And quite aside from the resource implications of these disorders, the human impact is profound; they have life-altering health and functionality implications for the patients, and cause social and relational fallout for families.

Ultimately, individual and community health are seriously threatened by diseases of the brain, and will be increasingly threatened in the future, and this in turn will place more and more pressure on already straining healthcare systems around the world.<sup>34</sup> As such, we can strongly claim that they are a pressing public harm which should be met by the pursuit of rationally connected public actions to bolster the public good that they diminish.

### III. BRAIN BANKING AND INTERESTS IN CADAVERS

In this second section we argue that brain banking is such an action; it is in the public interest (ie: it supports in a very direct way the public good that is health), and any effort to regulate brain banking must be cognizant of the relative strengths of the interests at stake.

#### A. *Brain Banking in the ‘Public Interest’*

The above harm snapshot justifies our claim that it is in the ‘public interest’ to actively facilitate health research, and, more specifically, research into the workings of, and disorders affecting, the brain. We define ‘public interest’ as the aggregate interest of a populace and both the main objective and justification for democratically empowered political structures.<sup>35</sup> So acts ‘in the public interest’ are acts which are ‘in the public good’

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<sup>29</sup> A Gustavsson, M Svensson, F Jacobi et al, ‘Cost of Disorders of the Brain in Europe 2010’ (2011) 21 Eur Neuropsychopharmacology 718-779.

<sup>30</sup> Ibid, at 765. A study conducted in 2003 claimed that disorders of the brain accounted for nearly 35% of Europe’s entire disease burden: J Olsen & M Leonardi, ‘The Burden of Brain Disease in Europe’ (2003) 10 Eur J Neurol 471-477.

<sup>31</sup> N Fineberg, P Haddad et al, ‘The Size, Burden and Cost of Brain Disease in the UK’ (2013) 27 J Psychopharm 761-770. The authors noted that this estimate of costs should be seen as conservative as some conditions such as body dysmorphic disorder could not be included in the analysis due to limitations of data.

<sup>32</sup> N Trigg, ‘NHS facing neurology disease time-bomb’, *BBC News*, London, 17 January 2012, at <<http://www.bbc.co.uk/news/health-16581674>> [17 September 2013].

<sup>33</sup> P Collins et al, ‘Grand Challenges in Global Mental Health’ (2011) 475 Nature 27-30. Indeed, global burden of disease studies, which examine all disease groups, shows that higher proportions of global disease burdens will be attributed to brain disorders: C Murray & A Lopez (eds.), *The Global Burden of Disease* (Harvard: WHO, 1996).

<sup>34</sup> See H Kretzschmar, ‘Brain Banking: Opportunities, Challenges and Meaning for the Future’ (2009) 10 Nature Rev Neuroscience 70-78, at 71.

<sup>35</sup> For more on public interest, see, e.g., P Napoli & N Creskill, *Foundations of Communications Policy: Principles and Process in the Regulation of Electronic Media* (NY: Hampton Press, 2001); L-S Ho, *Public Policy and Public Interest* (London: Routledge, 2011); A McHarg, ‘Reconciling Human Rights and the Public Interest:



(ie: which have real welfare-enhancing potential for publics).

We recognise that defining ‘publics’ or ‘the public’ to which benefit should accrue in a given context, and how many individuals an act needs to benefit for it to be deemed in ‘the public interest’, may give rise to controversy; in fact the difficulty of drawing boundaries on the ‘public’ in other contexts has been noted in detail elsewhere.<sup>36</sup> Nonetheless, given that brain diseases are non-discriminatory of ‘publics’ in the sense that they may affect any individual regardless of ethnicity, socio-economic background, gender, age, etc., the ‘public’ which may be affected by illnesses of the brain will be significant and will encompass the vast majority of the population. It follows that research on the brain is firmly within the public interest in the broadest sense.

Of course, with advances in genomics and the predictability of illnesses, including illnesses of the brain, the ‘public’ which may be affected by such diseases may be said to decrease. Similarly, in the rare diseases context, one might argue that the public affected is much smaller, making it questionable whether pursuing treatments on such diseases is in the broader public benefit. However, both these claims can be countered. First, predictability is often not nearly as objective or accurate as the term suggests. Many factors can diminish or negate the predictability claimed in relation to genetic testing, including lifestyle and environmental factors, both of which might be imposed on the individual. Second, from an impact perspective, rare diseases have consequences for people well beyond the number of those afflicted. They place all manner of burdens and hardships on families and loved ones, sometimes both well before and well after onset of the disease in the patient. Thus, research on the brain does not just benefit those who may suffer from illness, rather it has an important relational aspect. All told, while the parameters of the ‘public’ can and have been contested elsewhere, it is reasonable to say that, given the prevalence, potential for harm and relational aspect of brain diseases, brain banking (and associated research) transcends the boundaries of the obviously concerned ‘publics’ and touches on a significant portion of the ‘public’.

Ultimately, while we recognise that it can be difficult (or rather a matter of contestation) to define what is truly in the ‘public interest’, or what it means to respect the ‘public interest’,<sup>37</sup> we take it as relatively uncontroversial that it is in the public interest to actively promote and support public goods, and, as we have shown, health is a public good. Further, brain banking is an integral part of (brain and neurological) health research and thus it is in the public interest to maintain and support the donation of tissue to such banks.<sup>38</sup> Obviously, this argument is premised on the assumption that the banking

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<sup>36</sup> See; J Reardon, ‘The Human Genome Diversity Project: A Case Study in Coproduction’ (2001) 31 *Soc Studies Science* 357-388; J Reardon, ‘Race Without Salvation: Beyond the Science/Society Divide in Genomic Studies of Human Differences’ in B Koenig et al (eds), *Revisiting Race in a Genomic Age* (NJ: Rutgers U Press: 2008) 304-319; J Reardon, ‘Creating Participatory Subjects: Race, Science and Democracy in a Genomic Age’ in S. Frickel & K Moore (eds), *The New Political Sociology of Science: Institutions, Networks, and Power* (Madison: U Wisconsin Press: 2006) 351-377.

<sup>37</sup> M Häyry & T Takala, ‘American Principles, European Values and the Mezzanine Rules of Ethical Genetic Databanking’ in M Häyry, R Chadwick, V Arnason & G Arnason (eds.), *The Ethics and Governance of Human Genetic Databases* (Cambridge: CUP, 2007) 14-36.

<sup>38</sup> One might go further and argue that health research and the knowledge it generates is a public good in itself, but we need not go this far. For a discussion of knowledge as a public good, see J Stiglitz, ‘Theory of Local Public Goods’ in M Feldstein & R Inman (eds.), *The Economics of Public Services* (NY: Halsted Press, 1997).

undertaking and the research it facilitates is both ethically robust and scientifically sound. On this point, it should be noted that the operation of all tissue banks in the UK, including brain banks, is dependent on having the appropriate ethics approval from a relevant Research Ethics Committee, as well as NHS Research & Development approval.<sup>39</sup> A licensing scheme also applies under the *Human Tissue Act 2004* to all tissue banks in England, Wales and Northern Ireland,<sup>40</sup> ensuring that each bank meets appropriate ethical and safety standards. Scotland has also recently adopted a non-statutory accreditation scheme for the collection and storage of human tissue in NHS Scotland. Developed in consultation with NHS Scotland R&D Directors, NHS Scotland tissue bank managers, public partners, and Healthcare Improvement Scotland, the scheme seeks to ensure tissue banks adopt the highest possible professional standards.<sup>41</sup> Additionally, all brain banks in the UK are part of the UK Brain Bank Network, which seeks *inter alia* to put in place common 'gold' standards for brain banking, including harmonised procedures for consent and stewardship across the UK.<sup>42</sup> Finally, researchers seeking to obtain tissue from MRC-funded brain banks must also apply to the bank for permission. This usually results in an assessment of the application based on its scientific merits, as well as the likelihood of it giving rise to ethical issues.<sup>43</sup> Ethically approved research using samples obtained from ethically robust brain banks will generate knowledge that will:

- contribute to deeper understandings of the brain and human body;
- illuminate the causes and progression of diseases;
- contribute to more effective and less invasive cures, treatments, and/or management strategies for the afflicted; and
- inform more cost-efficient and effective ways of structuring and delivering healthcare system responses.

Further, the knowledge created will be probed and built-upon thereby expanding human

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For arguments against scientific knowledge being a public good, see M Callon & G Bowker, 'Is Science a Public Good?' (1994) 19 *Sci Tech & Human Values* 365-424, and T Kealey, 'The Myth of Science as a Public Good', Lecture to the Oxford Libertarian Society, Christ Church College, University of Oxford, 22 May 2009. For a discussion of the public interest in the context of organ transplantation, see J Harris, 'Organ Procurement: Dead Interests, Living Needs, Cadaver Organs Should be Automatically Available' (2003) 29 *J Med Ethics* 130-134.

<sup>39</sup> Such approval can be applied for online through the Integrated Research Application System, available at <https://www.myresearchproject.org.uk/SignIn.aspx>.

<sup>40</sup> See HTA 2004 ss16-25.

<sup>41</sup> Chief Medical Officer, 'Letter on the Accreditation Scheme for the Collection and Storage of NHS Tissue in Scotland' (2011), available at [http://www.sehd.scot.nhs.uk/cmo/CMO\(2011\)07.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2011)07.pdf), at para. 1

<sup>42</sup> For more see <http://www.mrc.ac.uk/Ourresearch/Resourceservices/UKBrainBanksnetwork/index.htm>.

<sup>43</sup> *Ibid.* Should the solidarity model proposed *infra* be adopted, further methods of ethical approval may be considered in order to ensure research conducted from such samples is in pursuit of knowledge and/or conditions of a pressing social/medical nature. Should there be financial or tissue shortages, mechanisms prioritising certain pursuits/interventions may also need to be pursued. Methods of public engagement might be investigated to extend to publics a more active role in such decisions. In any event, the precise contours of such a framework requires further investigation and is beyond the scope of this paper. It is enough for our argument to highlight the already stringent mechanisms of ethical approval that are required, and to note that these may and could be strengthened to align more closely with public objectives, thereby giving the 'public' a more active role in the process as befits the solidarity model.

knowledge beyond that envisioned by the initial cost and contribution.<sup>44</sup> The long-term aggregate impact of brain banks will be to reduce human suffering and to promote (and realise) better health and human functionality.<sup>45</sup> In fact, biobanks (of which brain banks are just one genre) have already been defended as valuable resources for the public interest:

[W]e offer the following proposition: scientifically sound, ethically robust research using biobanks is manifestly in the public interest. We would, in fact, go further and suggest that there is a positive moral obligation to promote the use of these research resources in ways that, in turn promote the public interest. This can only happen through access. The imperative, then, is to promote access on sound scientific, ethical, and legal principles.<sup>46</sup>

While brain banks have already been instrumental in furthering our understanding of central nervous system function and neurological diseases like Alzheimer's, Parkinson's, and Multiple Sclerosis,<sup>47</sup> and in recognising new types of diseases,<sup>48</sup> their benefits are not necessarily expected to be enjoyed by the individuals who participate/donate. A long view of the research investment is evident, wherein the collective is prioritised over the individual. In this way, brain banks serve as mechanisms of intergenerational justice (ie: the present generation contributes positively to the utility and better health of future generations). In our view, this enhances the status of brain banks as being in the public interest for it permits greater benefits to emerge for a wider community over time.

We concede that the state's obligation to foster brain banking depends on its rational connection (or necessity) to the public good sought to be advanced (eg: health for individuals and publics). In this respect, it is notable that while technological advances allow improved disease progress monitoring in living brains, cell cultures, and animal models,<sup>49</sup> developments have not rendered the need for examination of cadaveric brains obsolete.<sup>50</sup>

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<sup>44</sup> It is re-used and reconsidered, a process which further verifies knowledge and *adds* value to it: M Callon & G Bowker, n 38 above, who, at 401, argue that scientific knowledge '... is a durable good, not destroyed or altered by its use. Even better, the more it is used the more its value increases because it proves its fecundity, widens the scope of its applications, and becomes richer'.

<sup>45</sup> For a discussion of the scientific knowledge being generated by such networks, see M Callon & G Bowker, in 38 above, and M Callon, 'Four Models for the Dynamics of Science' in S Jasanoff et al (eds.), *Handbook of Science and Technology Studies* (Newbury Park: SAGE, 1994) 29-63.

<sup>46</sup> See G Laurie & P Mallia, n 23 above, at 322.

<sup>47</sup> See, e.g., H Kretzschmar, n 34 above; A Kutzelnigg et al, 'Cortical Demyelination and Diffuse White Matter Injury in Multiple Sclerosis' (2005) 128 *Brain* 2705-2712; S Roemer et al, 'Pattern specific loss of aquaporin-4 immunoreactivity distinguishes neuromyelitis optica from multiple sclerosis' (2007) 130 *Brain* 1194-1205; B Trapp et al, 'Axonal transection in the lesions of multiple sclerosis' (1998) 338 *New Eng J Med* 278-285; B Serami et al, 'Dysregulated Epstein-Barr virus infection in the multiple sclerosis brain' (2007) 204 *J Experimental Med* 2899-2912.

<sup>48</sup> D Murphy & B Ravina, 'Brain Banking for Neurodegenerative Diseases' (2003) 9 *Current Opin Neurol* 459-463.

<sup>49</sup> See J Bell et al, n 5 above, at 498, and H Kretzschmar, n 34 above, at 71.

<sup>50</sup> J Bell et al, *ibid*, at 498, and J Burton, 'Clinical, Educational and Epidemiological Value of Autopsy' (2007) 369 *Lancet* 1471-1480. Cadaveric brains are obtained at post mortem examinations, at which the brain is divided in two; one section is stored in formalin for neuropathologic diagnosis, whilst the other is frozen and stored at -80°C in the brain bank to be distributed to requesting members of the scientific community who have fulfilled relevant ethical and legal criteria: H Kretzschmar, n 34 above, at 71 and 75, and S Harmon & G

If anything, given its support of genetics and functional genomics – which themselves have given rise to techniques which facilitate better understandings of disease pathogenesis and potential therapeutic targets – PME and removal of tissue for brain banks is more crucial than ever for investigating neurological diseases and providing evidence of the efficacy of therapies.<sup>51</sup> Thus, it is vital that we have sufficient samples available in order to advance neurological understandings. In summary, the public's interest in brains is strong and the connection between procuring them, generating relevant scientific and health knowledge, and improving health is all rationally (indeed closely) connected.

The presence of commercialisation might be used to undermine the characterisation of brain banking as in the public interest. Private (commercial) entities do and will continue to play an integral role in the realisation of improved health. The realities of drug innovation are that it is time and cost-intensive beyond the capacity of purely public support. This, combined with the large and potentially lucrative market for neurological treatments means that commercial entities will be interested and involved in brain and neurological research, and, to a lesser extent, in the formation and maintenance of brain banks to support that research. However, commercial involvement does not negate the public nature of the problem, the public interest in brain banking (and research), nor the public good character of health.<sup>52</sup>

The primary consequence of commercial involvement is that some (or all) of the eventual treatments may be subject to patent protection (or intellectual property enclosure), thereby rendering them temporarily excludable, or selectively available through licensing strategies or pricing regimes. This is, of course, not ideal; it means that individuals will be asked/encouraged/required to donate for the public good in the absence of an assurance that their donation will result in something instrumental that will be immediately available to everyone equally. However, two matters serve to undermine this challenge. First, although the interplay of regimes is such that intellectual property diminishes access, this diminishment must be viewed as temporary. The fact is that the knowledge will eventually fall completely into the public domain, and in the preceding period treatments *will* be available to patients, though their availability might be narrowed by costs to the bearers of healthcare funding (eg: taxpayers and/or individuals). Second, given the gravity of the health problem society faces, it behoves us to work within the confines of the legal order that has evolved in this context, even if this means that sub-optimal availability of treatments (which we readily admit, but which is not at all remedied by using the contested involvement of the intellectual property regime to deny the existence of brain banking as being in the public interest).

Given the ambiguous role of commercialisation, scientific knowledge is sometimes described as an 'impure' public good, in the sense that if there is patent or other IP protection the knowledge becomes temporarily excludable (and therefore fails the non-

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Haddow, 'Banking (On) the Brain: The Neurological in Culture, Law and Science' (2012) 12 *Med Law International* 79-91, at 83.

<sup>51</sup> J Bell et al, *ibid*; H Kretschmar, *ibid*; T Miller et al, n 9 above; J Bell, J Nicoll et al, 'Neuropathology of Human Alzheimer Disease after Immunization with Amyloid-beta Peptide: A Case Report' (2003) 9 *Nat Med* 448-452. See also, e.g., N Cairns & P Lantos, 'Brain Tissue Banks in Psychiatric and Neurological Research' (1996) 49 *J Clinical Path* 870-873; C Hulette, 'Brain Banking in the United States' (2003) 63 *J Neuropathol Exp Neurol* 715-722.

<sup>52</sup> A point already made by L Chen, T Evans & R Cash, n 20 above.

excludability criteria).<sup>53</sup> Some have pointed to general public misgivings around commercial involvement in and profit arising from such research, noting the common perception of donation as a 'gift' and the concomitant assumption that it will not be associated a financial return to another.<sup>54</sup> To alleviate these misgivings, they have advanced benefit-sharing models based on the Newfoundland and Labrador Model.<sup>55</sup> This model requires a proposal for benefit sharing to be provided along with the application for ethical approval. Obviously, a similar framework could inform brain bank resource access, thereby ensuring not only that only approved research which was deemed to be in the public interest is carried out, but also that measurable benefits are returned to the community, even when private enterprises are accessing the resource.

In any event, our claim is simply that health research conducted using samples provided by brain banks has the potential to generate knowledge which will facilitate the understanding of diseases and the development of treatments. This is undoubtedly of benefit to individuals and to levels of community health and functionality.<sup>56</sup> Hence, it is in the public interest to promote the generation of such knowledge and brain banks and associated research should therefore be actively encouraged, or at the very least not unnecessarily impeded.

## **B. Ranking the Stakeholders' Interests**

Before proceeding to a critique of how the law supports brain banking, it is important to consider who has or may assert an interest in the material that is the 'life-blood' of brain banks (ie: cadavers and their brains). We suggest that the (formerly) living individual, the surviving family, and the public may all assert some interest, and the relative strength and foundation of that interest is considered below.

The first interest-holder is the deceased individual. While alive, that individual had interests and rights enforceable against others, including the state and family members, though none of these rights would have been absolute. Additionally, the deceased can, while alive, express testamentary wishes in relation to a variety of matters which will be enforceable after death through the estate using legal/state mechanisms (eg: disposition of property, use of personal likeness, disposition of body, etc.), although again there are limits

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<sup>53</sup> See J Stiglitz, 'Knowledge as Global Public Good' in I Kaul, I Grunberg & M Stern (eds.), *Global Public Goods: International Cooperation in the 21st Century* (Oxford: OUP, 1999, 308-325, at 310. Reforms aimed at more open access to scientific knowledge arguably contribute to the 'purity' of scientific knowledge (from a public interest perspective). For a discussion of the importance of open access models in the biobank context, see A Marks & K Steinberg, 'The Ethics of Access to Online Genetic Databases: Private or Public' (2002) 2 *Am J Pharmacogenomics* 207-212.

<sup>54</sup> Haddow et al, 'Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal' (2007) 64 *Soc Sci Med* 272-282.

<sup>55</sup> As proposed in D Pullman & A Latus, 'Policy Implications of Commercial Human Genetic Research in Newfoundland and Labrador: A Report for the Newfoundland and Labrador Department of Health and Community Services (St John's: DOHCS, 2003).

<sup>56</sup> Of course, one might question whether any public good is realised without some private and/or commercial contribution and therefore interference. As such, the interplay of commercial interests here makes no difference to the characterisation of health as a 'public good', or to brain banks as being in the 'public interest'.

as to what can be expected/demanded.<sup>57</sup> In complying with these wishes/instructions, we might claim that we are vindicating the individual's autonomy, but this is not entirely accurate. Presumably, an autonomous decision was made while alive, but at the time of (posthumous) enforcement, it is not autonomy that we are vindicating for the deceased ceases to 'be' and nothing can physically or emotionally harm or improve his or her position. This has led to compelling arguments that all of the deceased's autonomy and interests (together with the ability to personally enforce them) evaporate at death, and there are no obvious residual interests to defend.<sup>58</sup> Bolstering this position is jurisprudence to the effect that human rights cannot be claimed or enforced by or on behalf of someone who is not living.<sup>59</sup>

One might argue that it is a dignity-based respect for the deceased that compels us to comply with the deceased's wishes (and to legislate compliance through instruments like the HTA 2004 and HTSA 2006), but again the deceased remains indifferent to that dignity. He or she has none to claim or display. Ultimately, it might be more the survivors' remembrance of that (former) autonomy and dignity that is being respected. It is a claim by the survivors to that intangible that connects the past to the present and the future (the deceased to the living and the as-yet unrealised descendants). While the maintenance of such connections has value, one might question whether they seriously serve to strengthen a deceased's interest in his or her cadaver, which must be viewed as weak. It might serve to favourably place the survivors' interests in the cadaver, but more tangible and legally recognisable interests might be desired for purposes of ranking claims.

With respect to survivors, it is the deceased's family who will, in the normal course, have the best interest in the cadaver. Grieving relatives and loved ones will have a strong emotional connection to the deceased, and thus, the current practice understandably seeks to put their interests centre-stage; this is a noble and compassionate response. However, while we acknowledge that family members can have enforceable (legal) interests in relation to the living individual (interests that are enforceable against the state, against others, and against the individual him or herself), those interests diminish upon the individual's death, or rather the right to enforce those interests diminish, often to the point of nullity (although we acknowledge that claims against an estate can persist). With respect to the actual corpse, family members might invoke ECHR Article 8 (right to private and family life) and/or Article 9 (right to freedom of thought, consciences or religion) to ensure its disposal in a certain way,<sup>60</sup> but the key point is that their legally recognised interest in the

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<sup>57</sup> In this regard, there is significant scholarship on the limits of the dead-hand: see, e.g., T Kester, 'Can the Dead Hand Control the Dead Body? The Case for a Uniform Bodily Remains Law' (2007) 29 *W New Eng Law Rev* 571, L Friedman, *Dead Hands: A Social History of Wills, Trusts and Inheritance Law* (Stanford: Stanford U Press, 2009).

<sup>58</sup> J Harris, 'Law and the Regulation of Retained Organs: The Ethical Issues' (2006) 22 *Legal Studies* 527-549, at 539. For more on posthumous interests, see, e.g., A Baier, 'The Rights of Past and Future Persons' in E Partridge (ed), *Responsibilities to Future Generations* (NY: Prometheus Books, 1980) 171-183; T Wilkinson, 'Individual and Family Consent to Organ and Tissue Donation: Is the Current Position Coherent?' (2005) 31 *J Med Ethics* 587-590; D Sperling, *Posthumous Interests: Legal and Ethical Perspectives* (Cambridge: CUP, 2008).

<sup>59</sup> See *Vo v France*, Case No. 53924/00, 08/07/2004 (ECtHR), wherein the court refused standing for an unborn foetus, stating that rights could only be held once the foetus was born alive.

<sup>60</sup> For example, see *Pannullo & Forte v France*, Case No. 37794/97, 30/01/2002 (ECtHR), and *Girard v France*, Case No. 22590/04, 30/09/2011 (ECtHR), wherein Article 8 was used by survivors of the deceased to have a body returned for burial.

cadaver is restricted to possession for disposal (eg: burial or cremation).<sup>61</sup> The operation of these provisions is aimed at vindicating the deceased's (and more often the survivors') rights to have spiritual/religious and ceremonial expectations/conditions met (and so ties into the dignity and memorial interests articulated above). However, even then it has been held that the public interest might override their interests and/or stated position.<sup>62</sup>

Finally, there is the public's interest in cadavers, which are grounded in state obligations to advance individual and public health, which, in turn, strengthen the social fabric and viability of communities. The state's interest in public health has long been considered an important public interest, and a legitimate target for state action.<sup>63</sup> The disposition of cadavers as part of that action ensures that cadavers are properly/safely disposed of so as not to pollute public spaces and essential utilities, and the state's allocation of cadavers for use serves to:

- contribute to medical training so our incoming physicians understand anatomy and how to handle the body;<sup>64</sup>
- improve the evidence-base around cause of death and the efficacy of treatments, thereby improving healthcare decision-making;<sup>65</sup>
- improve the evidence-base around clinical counselling and healthcare decisions, thereby reducing the chance of clinical misunderstandings and/or errors;<sup>66</sup> and
- advance human knowledge, particularly life science knowledge and understandings of drug pathways and mechanisms, thereby facilitating new cures and treatments.<sup>67</sup>

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<sup>61</sup> See J Harris, n 58 above, at 533.

<sup>62</sup> In *Regina v Greater Manchester North District Coroner, Ex parte Worch* [1987] QB 627, wherein a practising Jew was found dead after a car crash, the Coroner was held to be justified in conducting a PME despite this being contrary to Jewish law because it was necessary to determine whether the deceased had died of natural causes prior to the crash or had been killed in the crash.

<sup>63</sup> Its interest in maintaining public health has long supported public authorities' overriding power in relation to the burial of human bodies: see s. 46, *Public Health (Control of Diseases) Act 1984*, as amended.

<sup>64</sup> See, e.g., R Charlton, 'Autopsy and Medical Education: A Review' (1994) 87 H R Soc Med 232-236; J Hooper & S Geller, 'Relevance of the Autopsy as a Medical Tool: A Large Database of Physician Attitudes' (2007) 131 Arch Pathol & Lab Med 268-274.

<sup>65</sup> See the remit and ambitions for the National Institute for Health and Clinical Excellence (NICE), at [http://www.nice.org.uk/aboutnice/whatwedo/what\\_we\\_do.jsp](http://www.nice.org.uk/aboutnice/whatwedo/what_we_do.jsp) [17 September 2013]. Studies show that, in cases of multiple causes of death, a majority of death certificates are inaccurate in the absence of PME, with many of the undiagnosed causes of death considered treatable: see M D'Amico et al, 'Ill-defined and Multiple Causes on Death Certificates: A Study of Misclassification in Mortality Statistics' (1999) 15 Eur J Epidemiol 141-148, and M Nashelsky & C Lawrence, 'Accuracy of Cause of Death Determination Without Forensic Autopsy Examination' (2003) 24 Am J Forensic Med Pathol 313-319.

<sup>66</sup> Studies show that adequate PMEs combined with case discussion at hospital level can improve safety and better inform practice choices: D Hoyert, *Vital and Health Statistics: The Autopsy, Medicine, and Mortality Statistics*, Series 3 (Maryland: DOH, 2001). A study of neonatal autopsies in south-east Scotland showed that PMEs generated new information in 26% of cases, and in 3% of cases that new information proved crucial for counselling: M Brodie et al, 'Ten Years of Neonatal Autopsies in a Tertiary Referral Centre: Retrospective Study' (2002) 324 BMJ 761-763.

<sup>67</sup> See, e.g., L Calabrese & A Fleischer, 'Thalidomide: Current and Potential Clinical Applications' (2000) 108 Am J Med 487-95; M McDermott, 'The Continuing Decline of Autopsies in Clinical Trials: Is there a way

Indeed, the value of PME's has led some to argue that medical authorities should reject the classification of PME's as elective and adopt them as a professional obligation,<sup>68</sup> although this might have unsustainable resource allocation consequences.

The state's interest in health also engages some of its responsibilities under human rights law, most particularly those implicated by the so-called 'right to health'; the right to the highest attainable standard of physical and mental health, and to a standard of living adequate for health and basic needs is contained in numerous international instruments.<sup>69</sup> This right may be inferred from Article 2 of the European Convention on Human Rights (1950), which states:

Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.

Importantly, the 'right to health' is increasingly seen as essential to achieving equitable societies. It has informed health policy reforms,<sup>70</sup> and constitutional provisions linked to the right to life, to dignity, and to physical integrity.<sup>71</sup> In combination with the legal and social entitlements that Europeans generally enjoy (and expect),<sup>72</sup> the effect of this right is that individuals have higher aspirations than ever before for achieving and sustaining good health, including health in old age,<sup>73</sup> and this will surely continue in future generations.

To make this right effective, the state, through health authorities, must make suitable and timely treatment options available. To date, jurisprudence drawing on the right to health has imposed on states and health authorities the obligation to:

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Back?' (2004) 89 Arch Dis Child Fetal Neonatal Ed F198-F199; B Cunha et al, 'Renal Transplant with Bronchiolitis Obliterans Organizing Pneumonia (BOOP) Attributable to Tacrolimus and Herpes Simplex Virus (HSV) Pneumonia' (2012) 41 Heart Lung 310-315.

<sup>68</sup> R Hill, R Anderson & R Vance, 'The Autopsy: A Professional Obligation Dissected' (1990) 21 Hum Pathol 127.

<sup>69</sup> Instruments include the Universal Declaration of Human Rights (1948), UN General Assembly Res. 217A (III), UN GAOR, 3d Sess., UN Doc. A/810, 1948, Article 25; the WHO Constitution (1948), adopted at the International Health Conference, New York, June-July 1946, Preamble; the International Covenant on Economic, Social and Cultural Rights (1966), 993 UNTS 3, Articles 9 and 12 and General Comment 3; the International Convention on the Elimination of All Forms of Racial Discrimination (1966), 660 UNTS 195; the Convention on the Rights of the Child (1990), 1577 UNTS 44; the Declaration of Alma-Ata (1978), at <[http://www.who.int/publications/almaata\\_declaration\\_en.pdf](http://www.who.int/publications/almaata_declaration_en.pdf)> [17 September 2013]; the Ottawa Charter for Health Promotion (1986), at <<http://www.who.int/healthpromotion/conferences/previous/ottawa/en/>> [17 September 2013]; the Bangkok Charter for Health Promotion in a Globalised World (2005), at <[http://www.who.int/healthpromotion/conferences/6gchp/hpr\\_050829\\_%20BCHP.pdf](http://www.who.int/healthpromotion/conferences/6gchp/hpr_050829_%20BCHP.pdf)> [17 September 2013].

<sup>70</sup> Uganda Ministry of Health, *Review of the HSSPII in Relation to Human Rights and Gender as Part of the Third-Term Review for the Health Sector, Second Draft* (Kampala: Ministry of Health, 2008).

<sup>71</sup> H Hogerzeil et al, 'Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?' (2006) 368 Lancet 305-311.

<sup>72</sup> Including strong mobility rights, increasing levels of education, widely available information about technological capabilities and geographic inequalities, and rising desires for varied, self-actualising leisure opportunities.

<sup>73</sup> E Rynning, 'The Ageing Populations of Europe: Implications for Health Systems and Patients' Rights' (2008) 15 Euro J Health Law 297-306.



- ensure that hospitals employ competent staff who are trained and work to a professional level within systems that protect patients;<sup>74</sup>
- avoid putting an individual's life at risk through the denial of care that they would have made available to the larger population.<sup>75</sup>
- restructure national healthcare systems to improve care.<sup>76</sup>

Essentially, states and health authorities are expected to achieve more and to deliver better health outcomes (usually with fewer resources), and this will be true with respect to burdensome and widely experienced neurological diseases. The use of cadavers is a vital component of fulfilling that expectation. Indeed, the importance of deceased donation was recently emphasised in the *Human Transplantation of Organs (Wales) Act 2013*, which introduces a soft opt-out system for organ donation for transplantation in Wales. Interestingly, s. 2 of the Act imposes a duty on Welsh Ministers to 'promote transplantation as a means of improving the health of the people of Wales'. This marks a firm commitment to improving the health of people through cadaveric donation. Similar arguments could be made to justify promotion of donation for research; while such donation does not have the immediate and personal effect as in transplantation, it has the potential to generate knowledge which could improve the condition of generations (and may reduce the demand for transplantation which now wildly exceeds supply).

Given the above, we argue that the public (ie: the collective as represented by the state) has the greatest/strongest interest in cadavers and their disposition. The deceased's interests and those of the surviving family might be personal, sentimental, or community-bonding, and they are largely dignity-based. By contrast, the public's interests are utilitarian, instrumental, and pressing. They are solidly grounded in human rights responsibilities and expectations, but they are also community-bonding. Realisation of those public interests will generate great advantage for a great number of people, and will also enhance the dignity of those people (by giving them better health, better lives, and better deaths).

#### IV. THE REGULATORY FRAMEWORK FOR BRAIN BANK RECRUITMENT

The above demonstrates that, when crafting regulation governing the life sciences – which are strongly linked to advances in healthcare and health – it is vital that we think about:

1. the 'public good' and how we can better advance it;
2. what we expect of medical research and the scientific knowledge generated therefrom;
3. whether we are willing to contribute sufficiently to the enterprise to fulfil the great expectations we have placed in it.

As part of that exercise, it is axiomatic that the applicable legal framework be designed to

<sup>74</sup> *Savage v South Essex Partnership NHS Foundation* [2008] UKHL 74 (HL).

<sup>75</sup> *Cyprus v Turkey* (2002) 35 EHRR 30 (ECtHR).

<sup>76</sup> *Tutela Decision*, T-760/2008, 31 July 2008, Colombian Constitutional Court.

shape behaviour to facilitate the public good, not frustrate it, and to recognise and accurately reflect the interests at stake. In terms of shaping behaviour, the legal framework should facilitate donation by ensuring that an individual's express wish to donate is carried out and not overridden by third party interests. Individuals should be made aware that in the event of uncertainty there would be a presumption in favour of donation. This would encourage individuals to think seriously about donation and facilitate wider (and maybe deeper) public thinking around medical research.

In other contexts, rewards are provided in order to encourage donation such as providing cheaper healthcare for those who donate samples for research purposes.<sup>77</sup> However, such schemes have been challenged on grounds that they may be exploitative or derogatory of 'true' consent.<sup>78</sup> While we do not necessarily agree with this challenge, we do not recommend a rewards system for brain donation in part because of the difficulties arising from the fact that the donor would be deceased at the time of donation. An important aspect of our approach is the attitudinal shift that solidarity could bring: individuals would come to better appreciate the individual obligations that they bear and to recognise donation as a contribution to health, including their own, all of which might result in stronger community sentiment toward donation. In short, for the public good to be truly acknowledged in biolaw, the legal framework must be designed to (strongly) encourage individual contribution.<sup>79</sup>

Given all of the above, two questions are implicated: (1) How has the law been fashioned? (2) How is it working to support brain banking? In this section, we explore those questions, focusing on the regulatory frameworks in England/Wales/Northern Ireland and Scotland respectively. After articulating the conceptual foundation of the legal regimes, we examine the consent and authorisation models more closely, highlighting intended differences, and then the problematic role of families in brain bank recruitment, which tends to negate those differences.

### **A. Conceptual Foundations of the Legislative Frameworks**

The existing framework for the donation of human tissue, including brain tissue, emerged as a result of public concern (and outrage) over non-consensual post mortem removal and retention of organs in both England and Scotland.<sup>80</sup> Investigations undertaken at the time

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<sup>77</sup> An example of this is the HFEA-accepted practice of 'egg-sharing' where a range of benefits may be offered by fertility clinics to women undergoing infertility treatment if they donate ova to other couples or for research purposes. This generally involves a reduced fee for fertility treatment. For more see <http://www.hfea.gov.uk/1411.html>. See also, A McNab, 'HFEA Statement on Donating Eggs for Research' (2007), available at <http://www.hfea.gov.uk/471.html>. Though payment for donation is prohibited, donors can receive £750 per cycle of donation to cover expenses and loss of earnings, see <http://www.hfea.gov.uk/donating-for-research.html>.

<sup>78</sup> For a discussion of these arguments and the experiences of donors in the context of egg-sharing, see E Haines, K Taylor I Turkmendag, 'Eggs ethics and Exploitation? Investigating Women's Experiences of an Egg Sharing Scheme' (2012) 34 *Sociology of Health & Illness* 1199–1214.

<sup>79</sup> Recall that the public's compelling interests in cadavers are currently being met with declining PME rates with the result that brain banks struggle with recruitment.

<sup>80</sup> For the Scottish investigations, see Audit Scotland, *Organ Retention Validation Review: Performance Audit* (Edinburgh: Audit Scotland, 2002). For the English investigations, see Bristol Royal Infirmary Inquiry, *Interim Report: Removal and Retention of Human Material*. (London: Crown, 2000); Royal Liverpool Children's Inquiry, *The Royal Liverpool Children's Inquiry: Summary and Recommendations* (London: Crown, 2001); Chief

found that the brain was the organ most often retained, although most brains were retained for diagnostic rather than research purposes.<sup>81</sup> They were retained as a result of genuine beliefs that retention was in the 'public interest', and erroneous beliefs that the Coroner or Procurator Fiscal could authorise retention of organs which had no bearing on the cause of death.<sup>82</sup> Interestingly, the primary cause of distress was the lack of information and consultation rather than the retention itself.<sup>83</sup> In any event, the public outcry resulted in a heavy emphasis by policymakers and legislative reformers on ensuring disclosure and clearer decisional frameworks for post mortem retention of tissue. The resultant legislative frameworks were heavily shaped by 'autonomy' and 'risk', concepts that place the individual at the centre of all things and emphasise the need to 'protect' people 'from' the medical establishment and the harms that might follow from research participation.

Autonomy acknowledges the human capacity (and desire) for self-determination and self-rule. It values people as physical, psychological, economical and legal entities individuated from others, and respect for autonomy involves creating spaces for individuals to make decisions relating to themselves with as little interference (or coercion or duress) as possible.<sup>84</sup> It therefore serves as a foundation for rights relating to physical integrity, freedom from coercion, and privacy.<sup>85</sup> Risk is the potential or probability of some event or occurrence happening that is negative or harmful to individuals and communities (eg: something that destroys, damages, injures, unbalances, challenges, questions, or affronts).<sup>86</sup> Risk discourses have increased in society as people, driven by autonomy, wish to control more and more of the lived environment and their destinies within it. As this has happened, the regulatory concern with risk has also climbed, with much regulation aimed at minimising deviations from the (agreed) norm.<sup>87</sup>

Given the above, the doctrines of consent and, latterly, authorisation have emerged. In the medical context, consent grew from a desire to protect individuals against harm or unwanted invasions of bodily integrity.<sup>88</sup> In the research context, it developed with the goal of ensuring respect for individuals and avoiding a repetition of the medico-scientific

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Medical Officer, *The Removal, Retention and Use of Human Organs and Tissue from Post Mortem Examination* (London: DOH, 2001); Chief Medical Officer, *Report of a Census of Organs and Tissues Retained by Pathology Services in England* (London: DOH, 2001); and Health Services Directorate, *Report at Post-mortem Examination and Disposal of Human Materials in the Chief Medical Officer's Census of NHS Pathology Services* (London: DOH, 2000).

<sup>81</sup> See Department of Health, *The Investigation of Events that Followed the Death of Cyril Mark Isaacs*, (London: Crown, 2003). (Isaacs Report) In Chief Medical Officer, *ibid*, it was reported that brains accounted for 44% of all retained organs from 1970-1999.

<sup>82</sup> See Isaacs Report, *ibid*, at 7 and 175.

<sup>83</sup> T Millar et al, n 9 above, at 374.

<sup>84</sup> See, e.g., T Beauchamp & R Faden, *The History and Theory of Informed Consent* (Oxford: OUP, 1986), G Dworkin, *The Theory and Practice of Autonomy* (Cambridge: CUP, 1988); T Beauchamp & J Childress, *Principles of Biomedical Ethics*, 4th ed (Oxford: OUP, 1994).

<sup>85</sup> O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: CUP, 2002), at 23.

<sup>86</sup> See, e.g., P Slovic, *The Perception of Risk* (London: Earthscan, 2001), D Lupton, *Risk* (London: Routledge, 1999).

<sup>87</sup> See, e.g., B Massumi, 'Everywhere You Want to Be: Introduction to Fear' in B Massumi (ed), *The Politics of Everyday Fear* (Minneapolis: U Minn Press, 1993) 3-38, D Lupton, *Medicine as Culture: Illness, Disease and Bodies in Western Societies* (London: SAGE, 2003).

<sup>88</sup> See J Harris, n 58 above, at 531-532; M Sutrop, 'Viewpoint: How to Avoid a Dichotomy Between Autonomy and Beneficence: From Liberalism to Communitarianism and Beyond' (2011) 269 *J Internal Med* 375-379, at 376.

atrocities committed during World War II.<sup>89</sup> It has evolved as a means to facilitate the exercise of individual autonomy with respect to actions relating to one's body (offering individuals some control over the risks to which they expose themselves), and authorisation has inarguably taken up that same cause. In both cases, a key ambition is to inform individuals and allow them to make decisions relevant to risks, and their inclusion in regulation typically contains mandated assessments of risk or harm manifestation. It must also be acknowledged that consent has a double effect in that obtaining it serves not only to protect patients but also to protect medical practitioners such as doctors, researchers, etc. from unwanted litigation.<sup>90</sup> In the HTA 2004 and the HTSA 2006, the doctrines of consent and authorisation respectively replaced the 'lack of objection' criteria contained in the *Human Tissue Act 1961*.<sup>91</sup>

## **B. Decisional Mechanisms under both Acts**

The HTA 2004 relies on a traditional consent model in that, after provision of relevant information addressing risks and benefits of the particular intervention (here donation), the 'appropriate consent' must be given. The 'appropriateness' is determined having reference to whether the statutorily required person has given the consent, and this depends on whether the subject (or donor) is an adult, an adult without capacity, or a child. For example, under s. 3(6), the appropriate consent of an adult is manifested as his or her decision in force immediately before death. If no such decision was made (or is known), then the appropriate consent is the decision of his or her 'nominated person' under s. 4. If he or she has not nominated a decision-maker, then the appropriate consent is that of the person who stands in the most authoritative 'qualifying relationship' to him or her immediately prior to death. The ranking of qualifying persons is set out in s. 27(4) as follows: spouse or partner; parent or child; brother or sister; grandparent or grandchild; child of a person the person concerned brother or sister; stepfather or stepmother; half-brother or half-sister; friend of long-standing. The Act offers nothing by way of criteria for shaping individual choices.

As with consent, 'authorisation' under the HTSA 2006 is a decisional model driven by autonomy, risk, and the individual, and authorisation must be given by the 'appropriate person'. This varies depending on whether the donor is an adult, a child 12 years or over, or a child under 12 years.<sup>92</sup> Like the consent model, authorisation draws heavily on risk.<sup>93</sup> The

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<sup>89</sup> T Caulfield et al, n 2 above.

<sup>90</sup> This follows on from the *Bolam* principle whereby 'a doctor is not negligent if he acts in accordance with a practice accepted at the time as proper by a responsible body of medical opinion': *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582. This, in turn, means that if consent which is deemed to be in accordance with the current practice by a reasonable body is obtained, then the doctor will not be liable in negligence. In the Scottish context, see *Hunter v Hanley* 1955 SLT 213.

<sup>91</sup> See Crown Office and Procurator Fiscal Service, *Death and the Procurator Fiscal: Information and Guidance for Medical Practitioners* (2008), para. 16.1, at <http://www.copfs.gov.uk/sites/default/files/Publications/Resource/Doc/13546/0000506.pdf> [6 March 2013]. Parenthetically, neither the HTA 2004 nor the HTSA 2006 specifically refer to brains or brain tissue, or indeed to any specific type of organ or tissue. What is significant is the origin of the tissue (from humans) and the status of the donor at the moment of donation; brain tissue is considered to be tissue from a deceased person.

<sup>92</sup> For guidance on the appropriate person, see HTSA 2006, ss. 6-10.

<sup>93</sup> Although, as noted elsewhere, the individual risks associated with participating in biobanks are minimal, and are not at all commensurate with participation in more tradition trial-based research: see B

term 'authorisation', however, was preferred over that of consent because it was felt to better capture the actual interests and circumstances at play. The influential McLean Report<sup>94</sup> defended its preference as follows:

- Authorisation would reinforce the belief (in everyone concerned) that individuals could and should make decisions about their own bodies, and that these decisions should be enforced.<sup>95</sup>
- While 'authorisation' better captures the right of donors (or relatives) to receive full information, it preserves their right to decline certain details while still being able to make an enforceable/lawful decision; authorisation better balances the need for decision-makers to receive *sufficient* information to make a judgment and for staff to be more sensitive around the provision of information.<sup>96</sup>
- The common law requirement that parental decisions relating to children be in the child's 'best interests' put parents in an untenable position with respect to tissue/organ donation because 'best interests' would be difficult to demonstrate. Authorisation better describes the obligations and powers which come with parenthood insofar as it signals their rights against third parties who might try to interfere with family relationships.<sup>97</sup>

In short, 'authorisation' was erected as an autonomy-based approach which has the primary goal of ensuring that the wishes of the deceased are enforced, but which has the ancillary aim of reducing the amount of information which decision-makers need in order to make an enforceable decision, whether that decision-maker is the deceased who may give authorisation prior to death, or surviving family members thereafter. So conceived, 'authorisation' is more suitable than 'consent' in the brain banking context, which implicates deceased individuals, for at least four reasons.

First, a key ambition of consent, in addition to those noted above, is to protect the physical integrity interests of the living.<sup>98</sup> However, this ambition has little relevance in the cadaveric context. The reality is that the human corpse does not remain intact but rather naturally decomposes.<sup>99</sup> Thus, there can be no legitimate interest in physical integrity after death. Moreover, because bodies must be buried or cremated, there can also be no expectation of inviolability. As such, one of the primary interests intended to be protected

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Prainsack & A Buyx, 'A Solidarity-Based Approach to the Governance of Research Biobanks' (2013) 21 *Med Law Rev* 71-91. This might be viewed as doubly true where the participation occurs after death.

<sup>94</sup> Independent Review Group, *Retention of Organs at Post-Mortem: Final Report* (Edinburgh: Department of Health, 2001). (McLean Report)

<sup>95</sup> Ibid, at 41.

<sup>96</sup> Ibid, at 41.

<sup>97</sup> Ibid, at 29-31.

<sup>98</sup> See, e.g., K Mason & G Laurie, n 13 above, at 717, J Harris, n 58 above, at 531, O O'Neil, 'Some Limits on Informed Consent' (2003) 29 *J Med Ethics* 4-7; J Wilson, 'Is Respect for Autonomy Defensible?' (2007) 33 *J Med Ethics* 353-356; A McGuire et al, 'DNA Data Sharing: Research Participants' Perspectives' (2008) 10 *Genetics Med* 46-53; and J Mason & G Laurie, *Mason and McCall Smith's Law and Medical Ethics*, 8th ed (Oxford: OUP, 2011).

<sup>99</sup> J Harris, n 58 above, at 547.

by consent is not directly engaged in deceased donation,<sup>100</sup> and therefore, it may not be the most appropriate legal mechanism.

Second, as articulated in the McLean Report, authorisation is intended to emphasise that the decision to donate does and should originate from the person's own volition. It is intended to signal a firmer commitment to respecting the expression that the individual made when alive. Indeed, it has been emphasised that authorisation is intended to more clearly convey the idea that people have the right to express during their lifetime their wishes about what should happen to their bodies after death, and that they should be able to expect that those wishes will be respected.<sup>101</sup> This suggests a more active role for the donor and a greater commitment to self-determination.<sup>102</sup>

Third, it serves to ease the informational burden on all parties. This is appropriate in two respects. First, decisions need to be taken very soon after a person's death; the brain deteriorates quickly so donation must be carried out within the first few days.<sup>103</sup> Authorisation acknowledges that the donor and/or relatives may not want to receive detailed information about the donation procedure, and it gives recruiters discretion about the amount and specificity of information which they provide to donors/relatives should these parties agree to this, though of course recruiters must still give sufficient information to allow a decision to be made. Second, it acknowledges that some information around the purposes of tissue use (and thus possible longer term risks) cannot be known at the time of recruitment or donation (ie: it better caters for situations where research uses may not be fully known and where research may develop in a different manner than originally conceived).<sup>104</sup> In both cases, it signals that donation is still permitted provided the authorising person has *sufficient* information to make a decision.

Fourth, and following on from the third reason, authorisation diminishes the need for re-contact, or reduces the circumstances under which re-contact and new authorisations will be necessary, which, in the brain banking case, would necessarily implicate third parties. Indeed, the Organ Donation Taskforce has opined that consent requirements are not fulfilled where relatives have to make the decision and are unclear as to what the donor would have wished.<sup>105</sup> The Taskforce claimed that the process is more appropriately viewed as an act of 'authorisation',<sup>106</sup> again reinforcing the distinction between the two concepts.

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<sup>100</sup> See E Patridge, 'Posthumous Interests and Posthumous Respect' (1981) 91 *Ethics* 243-264; W Waluchow, 'Feinberg's Theory of "Preposthumous" Harm' (1986) 25 *Dialogue* 727-734.

<sup>101</sup> Scottish Executive Health Department, *Human Tissue Act 2006: A Guide to its Implementation for NHS Scotland* (Edinburgh: SE, 2006) para. 8.

<sup>102</sup> Currently, such expressions are often undermined by third parties, prompting the question of whether we should ever let others make determinations over another's body. In the event that we do, and clearly the HTA 2004 and HTSA 2006 provide that we do, the question of to whom that power falls is one that we may not have answered correctly. For more on deceased donation, see K Mason & G Laurie, n 13 above.

<sup>103</sup> The interval between death and post-mortem varies depending on legal and resource constraints. In the MRC Sudden Death Brain and Tissue Bank, the interval was measured at between 28-140 hours with a mean of 70 hours: T Millar et al, n 9 above, at 372. For a discussion on the effect of post mortem delay on tissue, see I Ferrer et al, 'Brain Banks: Benefits, Limitations and Cautions Concerning the Use of Post-Mortem Brain Tissue for Molecular Studies' (2008) 9 *Cell Tissue Banking* 181-194.

<sup>104</sup> T Caulfield, R Upshur & A Daar, 'DNA Databanks and Consent: A Suggested Policy Model Involving an Authorization Model' (2003) 4 *BMC Med Ethics* 1-4.

<sup>105</sup> Organ Donation Taskforce, *The Potential Impact of an Opt Out System for Organ Donation in the UK* (London: Crown Printer, 2008), at 1.12.

<sup>106</sup> *Ibid*, at 7.5.

To alleviate the third party involvement complication, one might draft consent forms very broadly so as to cover many potential uses, but this challenges the ‘informedness’ on which consent is founded.

The consequence of the above is that there are important conceptual differences between consent and authorisation. While both advance the ethical interests of decisional integrity, they do not demand uniform or common practices; they might be viewed as ethically ‘equivalent’ rather than ‘equal’, and so might be held up as an example of ‘harmonised’ rather than ‘standardised’ approaches to conduct (ie: as non-standardised practices that are equally acceptable and effective).<sup>107</sup> Unfortunately for recruiters in Scotland, the HTA and Scottish authorities (and perhaps patients) seem to view consent and authorisation as convergent and standardised, and so performed in largely the same manner with the same steps and tools. While the regulator’s aim is to ensure ‘continuation of the arrangements for sharing organs and tissue across the UK,’<sup>108</sup> the result is that authorisation does not do the work it might otherwise accomplish; like consent, it leaves significant scope for family interference in donation decisions, thereby prioritising family affecting interests over those of the donor and the public.

### **C. Divergence Between Rules and Practice**

The lapse of time between the deceased’s expression of giving and the act of donation, combined with the absence of the donor at the actual time of the donation, results in a peculiar operation of consent/authorisation whereby the donor can become, and often is, marginalised. Unless an Advanced Directive is operable or the express wishes of the deceased are otherwise known to the physician(s) involved in the donor’s palliative care or post-palliative handling, brain bank recruiters will have to solicit and comply with the wishes of a third party, which usually means a family member or members. The difficulty of their job is compounded by the fact that decisions need to be taken very soon after a person’s death. These can be emotionally charged days, and the family may not be equipped to deal with decisions in relation to donation and dissection.

The statutes clearly identify the order of those who have decisional priority, placing the deceased at the top.<sup>109</sup> However, even in cases where a deceased person has expressed a clear wish to donate his or her brain or other tissue, those wishes will not be carried out by physicians/researchers in the face of objections by family members.<sup>110</sup> In short, despite

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<sup>107</sup> Human Tissue Authority, *Code of Practice 1: Consent* (London: HTA, 2009), para. 16.

<sup>108</sup> Organ Donation Taskforce, n 105 above, and see also Nuffield Council on Bioethics, *Human Bodies: Donation for Medicine and Research* (London: NCB, 2011), para. 2.15.

<sup>109</sup> See s. 27(4) HTA 2004 and s. 50 HTSA 2006.

<sup>110</sup> Even in the case of publicly-authorized PMEs, a family member must consent to tissue retention for research purposes. There are three types of post mortem examinations: (1) Coroner / Procurator Fiscal Autopsies: performed at the instigation and under the authority of the coroner (England/Wales) or procurator fiscal (Scotland) where cause of death is not known and so no death certificate can be issued; (2) Hospital Autopsies: performed when the cause of death is known and a death certificate can be issued, but specific clinical questions relating to diagnosis or treatment modalities are implicated; (3) Family Autopsies: performed at the request of the family. While no family consent (or knowledge) is required to undertake a Coroner’s or Procurator Fiscal’s autopsy, the public authority is *functus officio* thereafter so consent *is* required before the pathologist can retain tissue for research. Family consent is also required under the other types of autopsies, which also require consent for the conduct of the autopsies themselves. If families demand return of the body and its associated tissue, they have a right to possession for the limited purpose of burial or cremation.

an absence of any statutory veto, family members (sometimes regardless of where they rank in the decisional hierarchy) may still, and do, veto deceased donation decisions properly made and recorded,<sup>111</sup> a scenario which has been described as a 'double veto'.<sup>112</sup> This of course does nothing to respect the decision of the deceased who, while alive, made a reasoned and morally conscious decision about their death and the disposition of their body (and its parts); presumably, they wanted to contribute in some way to society through research in keeping with their duties under the social contract model. It also fails to recognise and enforce the statutory hierarchy of authority in situations where there are conflicting positions amongst the survivors.

While this deferential seems unjustified under both consent and authorisation models, it is particularly contrary to the latter, which is intended to signal a stronger commitment to carry out a deceased donor's wishes. The McLean Report was adamant that those wishes should be paramount, stating that they should be respected 'unless there is reason to believe that the deceased had a change of mind before death.'<sup>113</sup> Indeed, the McLean Report was specifically critical of the old practice of giving priority to family wishes:

very often interpretation of the law has gone beyond its strict requirements. Doctors will virtually always ask relatives actively to agree to the use of the dead body, rather than, simply asking about the wishes of the deceased. While this practice is understandable given the circumstances, *it fails spectacularly to respect the competently expressed wishes of the person now deceased.*<sup>114</sup> [emphasis added]

It recommended that:

the expressed wishes of the individual adult, competently made before death, should take priority over the wishes of surviving relatives. The current legal requirement to discover whether or not this agreement has been withdrawn should remain, but it must be clear that the relatives have no legal role in circumstances where the deceased had made known, and not retracted, his or her wishes.... An important concomitant of this recommendation to be a campaign directed at those who may wish to make such a declaration to encourage them to discuss their wishes freely and fully with those who will ultimately be asked about the deceased's intentions...<sup>115</sup>

Despite the above, this deferential approach has both some commendable practical consequences and some regulatory support. With respect to the former, it is a pragmatic and sensitive approach to dealing with bereaved families. Medical practitioners have no wish to compound the emotional difficulties of mourning families, and they have strong self-

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<sup>111</sup> BOTB Project, Roundtable Workshops, 4 April 2012 and 19 September 2012.

<sup>112</sup> The individual donor gets a veto (eg: a right to refuse donation despite the family desiring them to do so), and family members get a veto (eg: a right to effectively block donation despite an express wish to donate by the deceased): see T Wilkinson, n 58 above, at 587.

<sup>113</sup> See Scottish Executive Health Department, n 101 above, at 39.

<sup>114</sup> Ibid, at 39-40.

<sup>115</sup> Ibid, at 40.



interest in not embroiling themselves in unseemly disputes over the use of a deceased family member's body, particularly with the retained body parts scandal so recently in the past. Thus, as a simple matter of relational harmony and reputational preservation, and indeed as an act of solidarity with the bereaved family, this approach makes sense on the ground. In the context of organ donation for transplantation, the Scottish government has stated:

Few, if any, transplant surgeons would go against the wishes of a family. Whilst there are unlikely to be any repercussions against a surgeon who removed organs in the face of family objections from a person who wished to be a donor, there are few surgeons who would add to the stress of a grieving family by acting contrary to their wishes. Negative publicity from such an act would also have a detrimental effect on organ donation.<sup>116</sup>

Additionally, this approach permits an operational flexibility, allowing the physician (or recruiter) to exercise personal and professional judgment about how to proceed in each case. In short, sensitivity and respect are cornerstones of the interaction; not respect for the deceased but for those who remain. Such respect should be a fundamental element of the physician's (and recruiter's) professional duties, and a formative part of the professional team's interactions with patients and families. It reflects a valuable civility that has been encouraged by the post-paternalistic turn in medical culture; whereas practitioners once decided with little or no consultation what was in the interest of the patient, patients now are expected to be more actively involved in treatment decisions through conversations about their care/treatment.

With respect to regulatory support, the deferential approach is acknowledged by the HTA's *Code of Practice I: Consent*. Applicable to both the English/Welsh/Northern Irish and Scottish frameworks, it states that if a deceased person or nominated representative has consented to donation but those close to the deceased object, a healthcare professional should discuss the matter sensitively with the parties, should encourage the objector(s) to accept the wishes of the deceased, and should be informed that they have no right to veto these wishes.<sup>117</sup> It goes on to state, that in such circumstances a practitioner should consider 'the impact of going ahead with a procedure in light of strong opposition of the family, despite the legal basis for doing so.'<sup>118</sup> This inconsistency (between statute and practice guidance) is also evident in the *Code's* guidance relating to child donation in cases where the wishes of the parents or guardians conflict. It states that it is sufficient for one person in a position of parental responsibility to give consent to donation of a deceased child's tissue/organs, but then advises that:

The issue should be discussed fully with relatives and careful thought should be given as to whether to proceed if a disagreement arises between parents

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<sup>116</sup> Scottish Government, *Organ Donation: Transplant Pack* (2003), at <<http://www.scotland.gov.uk/Publications/2003/11/18095/25897>> [17 September 2013] See also <<http://www.organdonationscotland.org/faqs-and-common-myths>> [17 September 2013].

<sup>117</sup> See Human Tissue Authority, n 107 above, at para. 76.

<sup>118</sup> *Ibid*, at para. 76. For more on consent and deceased donors, see Royal College of Pathologists, *Guidelines for the Retention of Tissues and Organs at Post-Mortem Examination* (London: RCP, 2000).

or family members. Any previously stated wishes of the deceased child should be considered, taking into account their age and understanding.<sup>119</sup>

The real-world consequence is that, regardless of whether HTA 2004 ‘consent’ or HTSA 2006 ‘authorisation’ is relied on, neither legal mechanism is strictly enforced in the face of objections by family members, or conflicts within the family.<sup>120</sup>

## V. SOLIDARITY AND AN EMPHASIS ON THE ‘PUBLIC’ IN BRAIN BANKING

Although both the HTA 2004 and HTSA 2006 are grounded on autonomy and risk, and on the decisional authority of the individual, with authorisation intended to be even more autonomy-confirming than consent, practices on the ground have served to erode the differences between consent and authorisation, and to weaken the operation of both mechanisms insofar as recruiters are challenged by survivor opposition in the face of deceased consent/authorisation. While this might be seen to contribute to a more cooperative decision-making process around the use of bodies, it has had the real-world effect of blocking donation in the face of *any* objections by survivors. Ironically, the autonomy interest that frames the whole regime gets frustrated and the regulation fails to deliver on its promise to the deceased and the scientific undertaking. We suggest an approach more sensitive to the obvious and important ‘public interest’ aspects of brain banking, which are currently under-emphasised in the legislation and under-operationalised in practice.<sup>121</sup>

### A. *A Value Foundation to Support the Public Interest*

To make a real impact, the public interest must be given a role more in keeping with its significance (ie: given the increasingly high statistics and incidence of brain disease, it is imperative that research in this area is actively supported and that the public benefits are both emphasised and realised). There is thus a need to recognise the ‘public’ as an important stake-holder in the donation framework. This can only be achieved if the value-base underpinning the human tissue use regime is broadened.<sup>122</sup> In particular, ‘solidarity’ should be deployed as an action- and decision-guiding value in relation to the dead body; indeed, it should be given a prominence that is at least equivalent to other guiding values, including autonomy.<sup>123</sup> Solidarity has been defined as encompassing the following

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<sup>119</sup> See Human Tissue Authority, n 107 above, at para. 95.

<sup>120</sup> See BOTB, n 111 above.

<sup>121</sup> A fact discussed by participants in the Banking (On) The Brain Project: BOTB, *ibid*.

<sup>122</sup> For arguments in support of expanding our ethical frame, see S Harmon, ‘Solidarity: A (New) Ethic for Global Health Policy’ (2006) 14 *Health Care Anal* 215-236; T Schrecker, ‘Benefit-Sharing in the New Genomic Marketplace: Expanding the Ethical Frame of Reference’ in B Knoppers (ed), *Populations and Genetics: Legal and Socio-Ethical Perspectives* (Boston: Martinus Nijhoff, 2003) 405-421; M Häyry, ‘European Values in Bioethics: Why, What and How to be Used?’ (2003) 24 *Theoretical Med* 199-214; D Callahan, ‘Principlism and Communitarianism’ (2003) 29 *J Med Ethics* 287-291; S Benatar, ‘Blinkered Bioethics’ (2004) 30 *J Med Ethics* 291-292; B Knoppers, ‘Of Genomics and Public Health: Building Public ‘Goods’?’ (2005) 173 *Cdn Med Asstn J* 1185-1186.

<sup>123</sup> We do not wish to be seen as overly critical of autonomy. Autonomy can and does serve the public good and is not necessarily contrary to public mores or community wellbeing. However, the over-individualisation of autonomy has the effect of erecting and encouraging the idea of a freestanding individual

interrelated and mutually enhancing virtue-propositions:<sup>124</sup>

- Solidarity prioritises community by recognising that individuals are naturally and irrevocably embedded in social contexts; they are in a state of interrelationship or interconnectedness with individuals, groups and society.
- Solidarity emphasises equality and active promotion of welfare through its grounding in compassion, fraternity and a genuine interest in the wellbeing of others, the ultimate goal being to construct, through personal and collective actions, both a just and decent or fair society.
- As a result of our inclusion in societies and the complex of social relationships and values that is needed to realise standards of decency and justice within societies, solidarity emphasises the virtue of duties over rights; duties flowing from and toward individuals and communities that may require collective interests and public goods to take priority over the interest of individuals or sub-collectives.

So conceptualised, solidarity helps us characterise participation in brain banking as a beneficial *opportunity*, if not an obligation, to contribute to individual and public health beyond one's lifetime; it characterises participation as a legacy which contributes to intergenerational justice by enabling the health of future generations, and, as such, is a means to advance human wellbeing more generally.<sup>125</sup> If solidarity is better integrated into the legislative regime and the decisions that it structures, a new interaction can be framed.<sup>126</sup> And this interaction might better close the gap between levels of claimed support for research and the opportunity to make a contribution, and actual participation in research.<sup>127</sup>

In a recent report commissioned by the Nuffield Council, the authors conceive of solidarity as signifying a collective commitment to carry 'costs' (financial, social, emotional,

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independent of the community and with few responsibilities to the community, or responsibilities for the consequences to the community of his or her individualist choices: W Gaylin & B Jennings, *The Perversion of Autonomy: Coercion and Constraints in a Liberal Society* (Georgetown: GUP, 2003), at 203.

<sup>124</sup> S Harmon, n 122 above.

<sup>125</sup> For more on intergenerational justice, see, e.g., H ten Have, 'Global Bioethics and Communitarianism' (2011) 32 *Theor Med Bioethics* 315-322, B Knoppers & Y Joly, 'Our Social Genome' (2007) 25 *Trends in Biotechnology* 284-288.

<sup>126</sup> For more on solidarity, see S Harmon, n 122 above, R Houtepen & R ter Meulen, 'New Types of Solidarity in the European Welfare State' (2000) 8 *Health Care Anal* 329-340; R Ashcroft, A Campbell & S Jones, 'Solidarity, Society and the Welfare State in the United Kingdom' (2000) 8 *Health Care Anal* 377-394; R Chadwick & K Berg, 'Solidarity and Equity: New Ethical Frameworks for Genetic Databases' (2001) 2 *Nat Rev Genet* 318-21; S Sternø, *Solidarity in Europe: The History of an Idea* (Cambridge: CUP, 2004); M Haÿry, 'Precaution and Solidarity' (2005) 14 *Cambridge Q Healthcare Ethics* 199-206; R ter Meulen, W Arts & R Muffels (eds), *Solidarity in Health and Social Care in Europe* (Dordrecht: Kluwer, 2010). For more on solidarity's many inclusions in international biolaw, see S Harmon, 'Ethical Rhetoric: Genomics and the Moral Content of UNESCO's 'Universal' Declarations' (2008) 34 *J Med Ethics* e24.

<sup>127</sup> Research shows that family members often derive some comfort from their loved ones' donation, but that the strongest support for donation comes from families who have lost a member to a particularly tragic circumstance such as a sudden accident or death by suicide: see T Millar et al, n 9 above, at 372, Table 2; J Bell et al, n 5 above, at 505.

or otherwise) to assist others that requires individual actions and collective commitment.<sup>128</sup> The report offers a 3-tier approach to how individuals might interact with solidarity:<sup>129</sup>

- Tier-1: Interpersonal: At base, solidarity is viewed as an expression of willingness to carry costs to help others with whom a person recognises similarity, sameness, or symmetry. It demands actions by individuals to help other individuals within a group or community who share certain things in common with them.
- Tier-2: Group Internalisation: This solidarity arises when certain action elements of solidarity become engrained in a group (ie: come to represent an aspect of ‘good conduct’), and so evolve into forms of institutionalisation. At this level, solidarity can be defined as ‘manifestations of a collective community to carry costs to assist others who are all linked by means of a shared situation or cause,’<sup>130</sup> and a common example of this is self-help or patient groups.
- Tier-3: Contractual/Legal: This tier is where the social norms of the previous tiers solidify into contractual or other legal norms; it is a fixed or enforced form of solidarity, examples of which include the welfare state, social welfare arrangements, statutorily-protected/enforced trade unionism, etc.

This framework is useful for thinking about where solidarity needs to be introduced and how it might be embedded to reorient public perceptions about, and the regulatory regime applicable to, brain banking, and we shall return to it below. Suffice to say presently, we believe that shifting both participation levels in biobanks and regulatory frameworks demands two interrelated movements: first, the public interest must be understood in a more active sense which not only recognises rights, but also duties (ie: it must be understood as demanding positive efforts on the part of individuals as a component of their social citizenship); and, second, the moral or value-foundation of the public interest (and public goods) must be given a more prominent role, both generally and in individual conversations (such as that between physician/recruiter and patient/family). Solidarity offers a valuable touchstone for undertaking or facilitating these movements.

## **B. Operationalising Solidarity in Brain Banking**

Conceptualising participation in brain banking as an act of solidarity justified (if not demanded) by the public interest encourages a shift toward greater consideration of the public good aspect of the enterprise. So grounded, the implications for brain banks might be that a system of *mandatory* donation to brain banks could be justified on utilitarian, virtue, and international human rights grounds.<sup>131</sup> While mandatory donation might be considered

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<sup>128</sup> See B Prainsack & A Buyx, *Solidarity: Reflections on an Emerging Concept in Bioethics* (London: Nuffield Council on Bioethics, 2011), at 5.3 and 5.4, a characterisation taken up by the authors of the report in subsequent publications.

<sup>129</sup> Ibid, at 5.7-5.13.

<sup>130</sup> Ibid, at 5.12.

<sup>131</sup> For arguments in favour of a duty to participate in research, see S Harmon, n 122 above; J Harris, ‘Scientific Research is a Moral Duty’ (2005) 31 *J Med Ethics* 242-248. The duty might be considered even

problematic by some, particularly in our prevailing individualistic social context, additionally so in this context given the deep personal and growing cultural significance of the brain,<sup>132</sup> it is not without its supporters. A mandatory system has been justified in other contexts on the grounds that individuals receive public health benefits stemming from brain and other life science research, and they must therefore be viewed as accepting those benefits on the understanding that they may need to contribute to the 'public good' by donating post mortem tissue for such research. Indeed, it has been argued that if we accept the benefits of medical research (eg: antibiotics and other medicines), then we have an obligation to contribute to social practice which produce those benefits.<sup>133</sup> Where that contribution is only made after death, the argument is even stronger,<sup>134</sup> although such a system would need to incorporate provisions permitting individuals to object to donation in keeping with other human rights (eg: freedom of religion), which would operate in exceptional circumstances.

Despite the defensibility of mandatory donation, we are not arguing for this, and the sheer cost and personnel demands would, in any event, make it unsustainable. Further, it should be acknowledged that brain banks do not require donation from *all* individuals; they merely need an increase in current donation rates, particularly of 'normal' brains. Thus, we propose a regime which gives *preference* to public needs, and which justifies those preferences with reference to the public good that is health, the public interest in its achievement, and acknowledgement of the 'social contract' which we all enter into. The social contract theory recognises that individuals gain benefits from society (and this is certainly so in a democratic welfare state with a free-at-point-of-service healthcare system), and it holds that individuals must therefore also give back to society.<sup>135</sup> As part of that, they must accept that their interests may sometimes be compromised for the 'public good'; and what less intrusive time to compromise those individual interests than after death when the compromise will mean nothing to the individual who is being asked/commanded to contribute? If we accept that individuals and society are in a contractual relationship in which each entity must not only receive but should also give, the question becomes: How can we better embed the notion that it is a social responsibility to support biobanking? Here we can draw on the 3-tier interaction set out by Prainsack and Buyx.

When individuals decide to participate in a biobank, it is an act of Tier-1 solidarity insofar as they do so with the acceptance that certain costs will be incurred by them (or their survivors) for the sake of communal benefit.<sup>136</sup> Increased participation will be facilitated by attitudinal change; people must be encouraged to internalise solidarity and to accept the responsibility to act, for values are most commonly operationalised when they

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stronger where, as here, there is no risk of harm to the individual participant (because he or she is already dead).

<sup>132</sup> A point which came up in the BOTB Project: see S Harmon & G Haddow, n 50 above.

<sup>133</sup> J Harris, n 131 above, at 243. He goes on to argue that individuals are already required to make contributions to the public good (eg: through taxation or jury service), and there is no reason why the same justification would not ground a contribution to research.

<sup>134</sup> See D Price, *Human Tissue in Transplantation and Research: A Model Legal and Ethical Donation Framework* (Cambridge: CUP, 2010) 53-63.

<sup>135</sup> See J Rawls, *A Theory of Justice* (Oxford: Clarendon Press, 1972).

<sup>136</sup> B Prainsack and A Buyx, n 128 above, at 6.18.

are internalised and embraced by publics.<sup>137</sup> This can be done through public campaigns highlighting the prevalence of brain conditions, the pivotal role of brain banks in the treatment of same, and the benefits of research participation.<sup>138</sup> While some question the propriety and effectiveness of ‘nudge’ policies,<sup>139</sup> their use of sociology, behavioural economics and social psychology is a practical way to rationally structure choice architecture so socially useful outcomes can be achieved.<sup>140</sup> It has already been pointed out that the problem of countervailing nudges must be overcome if such campaigns are to work.<sup>141</sup> Obviously, that countervailing push should not come from regulation. Indeed, we argue that the campaigns could be statutorily dictated, as has been done in Wales with respect to transplantation; the *Human Transplantation of Organs (Wales) Act 2013* imposes a duty on Welsh Ministers to promote transplantation and encourage donations deemed necessary for the improvement of the health of the people of Wales.<sup>142</sup>

Tier-2 solidarity is implicated by how the bank structures its decision-making, how it shapes its relationship and interactions with the public, and how it communicates.<sup>143</sup> The bank must view its donors (and more specifically their surviving family members) as partners in the research endeavour to whom the bank owes certain duties important to the maintenance of trust, and it must structure its governance and interactions as such.<sup>144</sup> This also has state implications. First, more optimal and transparent biobank structures and governance arrangements could be statutorily shaped. Second, a magnitude change in donation would demand a firm commitment by the state to provide sufficient financial support to ensure that resources and personnel are available to manage that increased donation.<sup>145</sup> This is particularly important because the agreement to donate (ie: to bear

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<sup>137</sup> So pointed out by C Casillas, P Enns & P Wohlfarth, ‘How Public Opinion Constrains the US Supreme Court’ (2011) 55 Am J Poli Sci 74-78, who claim that in some cases judges may follow public opinion rather than the letter of the law so as to maintain the legitimacy of law.

<sup>138</sup> In the past such campaigns have been successful, for instance, following a publicity campaign in Australia a consent rate of 58% was recorded as provided by bereaved families on the day of post mortem for donation of the whole brain: see L Azizi, T Garrick, C Harper, ‘Brain Donation for Research: Strong Support in Australia’ (2006) 13 J Clin Neurosci 449-452. For more on the use of nudge in the health arena, see M Quigley, ‘Nudging for Health: On Public Policy and Designing Choice Architecture’ (2013) 21 Med Law Rev 588-621.

<sup>139</sup> T Goodwin, ‘Why We Should Reject ‘Nudge’’ (2012) 32 Politics 85-92; Y Saghi, ‘Salving the Concept of Nudge’ (2013) 39 J Med Ethics 487-493; R Ashcroft, ‘Doing Good by Stealth: Comments on ‘Salvaging the Concept of Nudge’’ (2013) 39 J Med Ethics 494; L Bovens, ‘Why Couldn’t I be Nudged to Dislike a Big Mac’ (2013) 39 J Med Ethics 495-496; G Dworkin, ‘Lying and Nudging’ (2013) 39 J Med Ethics 496-497; B Welch, ‘Shifting the Concept of Nudge’ (2013) 39 J Med Ethics 497-498; A Wertheimer, ‘Should ‘Nudge’ be Salvaged?’ (2013) 39 J Med Ethics 498-499; Y Saghai, ‘The Concept of Nudge and its Moral Significance: A Reply to Ashcroft, Bovens, Dworkin, Welch and Wertheimer’ (2013) 39 J Med Ethics 499-501.

<sup>140</sup> Secretary of State for Health, *Healthy Lives, Healthy People: Our Strategy for Public Health in England* (London: HMG, 2010), at 24 and 30. For more on the operation of nudge politics, see R Thaler & C Sunstein, *Nudge: Improving Decision about Health, Wealth and Happiness* (London: Penguin, 2008).

<sup>141</sup> T Marteau, D Ogilvie, M Roland et al, ‘Judging Nudging: Can Nudging Improve Population Health?’ (2011) 342 BMJ 263-265.

<sup>142</sup> See s. 2, HTOWA 2013.

<sup>143</sup> B Prainsack & A Buyx, n 128 above, at 6.33.

<sup>144</sup> And for more on possibilities in this regard, see S Harmon, n 3 above; B Prainsack & A Buyx, n 93 above.

<sup>145</sup> Kretschmar, n 34 above, at 26, states that the cost per brain collected is estimated at €10,000-€15,000 for BrainNet Europe. For a discussion of resource implications of organ transplantation, see S McLean, *Autonomy, Consent and the Law* (London: Routledge, 2010), at 207; B Teo, ‘Is the Adoption of More

that cost) must be met with effective measures to make that donation meaningful. If efforts or resources are wasted, public mistrust could justifiably set in.

An example of how tier-3 might be engaged is when solidarity is used to shape statutory structures so that they are more reflective of public goods and the public interest.<sup>146</sup> The law should explicitly adopt solidarity as a guiding value in an effort to make a positive difference in recruitment practices and participation levels. Solidarity can be relied on to:

- more stoutly vindicate the wishes of a deceased to donate in the face of resistance by survivors (ie: the use of solidarity to better operationalise autonomy); and
- more openly override the deceased's (or survivors') decision to not donate in limited circumstances (such as when the individual has a rare disease that has become the target of research, or where brain banks make a specific call for 'normal' brains).

In furtherance of this, we suggest that 'authorisation' is the most appropriate decisional mechanism, and that, to work optimally, that mechanism must stipulate discourses which encourage all parties to consciously consider the public good of health, the public interest in (brain) banking, and the fundamental value of 'solidarity' in the exercise of their autonomy. In other words, it must inject some non-risk-based decisional criteria into the interaction in recognition of the fact that the individual risks of participating in biobanks are minimal (and not commensurate with participating in more traditional trial-based research).<sup>147</sup>

Additionally, parties must be assigned authority commensurate with their interest in the cadaver. Obviously, the first interest holder is the deceased insofar as she wishes to donate and has made that wish known. This conscious choice, made when the deceased was a living, rights-bearing individual with autonomy interests, benefits the many and so, despite the above-noted evaporation of interests upon death, should, in the round, be respected. Not only does this respect reflect the value we – the public – placed on the individual when she was alive, it might also be characterised (cautiously) as a 'memorial right', meaning a right that was held and exercised in life that should be (and can only be) vindicated after death. As such, it is important to acknowledge that it is the (deceased) individual's right, not the family's right, and it should be seen as vesting upon death with the public, thereby enhancing the possibility of vindication.<sup>148</sup>

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Efficient Strategies of Organ Procurement the Answer to Persistent Organ Shortage in Transplantation?' (1992) 9 Bioethics 113-129.

<sup>146</sup> Prainsack and Buyx offer the circumstance of data-sharing practices being imposed as contractual obligations for access to the resource as another example of tier-3 solidarity in action: see B Prainsack & A Buyx, n 128, at 6.34.

<sup>147</sup> For a brief discussion of the risks, see B Prainsack & A Buyx, n 93 above.

<sup>148</sup> Again, and importantly, we are not proposing a framework for mandatory donation, but rather a conceptual change to the framework founded on solidarity. Under such a framework, active individual contribution and attitudinal change surrounding donation and medical research generally are encouraged, and such is supported by the above.

In all other situations, the interest ranking must run from public, down to family, down to deceased. This acknowledges how decisional autonomy in relation to the corpse falls away upon the individual's death, and that the most interested remaining party is the public. Others – who have no strong principled interest in the corpse other than beliefs grounded in religion, superstition, or revulsion – should not hold a veto unless their objection is based on *reliable evidence* that the deceased objected to donation. Again, a provision similar to that in the *Human Transplantation of Organs (Wales) Act 2013* relating to families would be useful.<sup>149</sup> This position is supported by Harris, who argues that, if we are to presume anything of the deceased, we should presume that he or she would have wished to donate; it right to assume that the deceased had no interest in frustrating knowledge or increasing the probability of others' death.<sup>150</sup>

In addition to altering how donation is broached and supported, a solidarity approach would have implications for consent documents (and re-consent for new uses of the samples). Rather than over-emphasise risks, the consent process and its documentation would make greater efforts to highlight the benefits of donation and to inform parties about how the bank has structured its governance, oversight, and access policies so as to maximise utility and transparency, and to minimise and then appropriately manage risks. It would demand admitting to potential donors that neither recruiters nor bank custodians can know all possible uses or research directions, and that the donor would be agreeing to participate in a context of uncertainty.<sup>151</sup> It would emphasise the values and goals of the bank to which the donor would be contributing, and the Agreement to Participate could:<sup>152</sup>

- acknowledge that the donor has considered the possible advantages and disadvantages of participation, including worst-case scenarios;
- articulate that the surviving representative would be entitled to continue to dialogue with the bank on an ongoing basis; and
- stipulate that the bank can use the tissue for research purposes into future, including for unforeseen or changing research aims so long as they comply with the clearly stated values or mission of the bank.

This approach, which shares some characteristics with previously discussed 'consent as a propositional attitude' and 'participation as a public interest' approaches,<sup>153</sup> vindicates

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<sup>149</sup> See s. 4.4(4) HTOWA 2013, and discussion of this at n 14 above

<sup>150</sup> J Harris, n 58 above, 540.

<sup>151</sup> See B Prainsack & A Buyx, n 128 above, at 6.14 and 6.23. In such a case, as noted by the Prainsack and Buyx the initial disclosure must offer individuals information as to both the broad aims/aspirations of the brain bank and the known research questions currently pursued, its funding and governance structures, its process for dealing with personal information, its commercialisation strategy (if any), and a statement that the brain bank may be used for purposes which have not yet been envisaged but for which ethics approval would have to be obtained.

<sup>152</sup> For more on a solidarity-based approach to recruitment for biobanks and what such an approach might demand, see S Harmon, n 3 above, and B Prainsack & A Buyx, n 93 above.

<sup>153</sup> See S Harmon, *ibid*, for the latter, and O'Neill, n 85 above, for the former.



autonomy within a solidarity framework that grants banks the flexibility needed to remain viable and effective over time.

## VI. CONCLUSION

Neurological diseases are on the rise worldwide, and so research aimed at understanding and alleviating them will play an increasingly critical role in human health and wellbeing, and on the capacity of public healthcare systems to cope with demands. Brain banks are essential to that undertaking. However, for brain banks to deliver on their promises, there must be a shift in how we think about brain banking. The consent model under the HTA 2004 has a number of shortcomings, most notably the tension provoked by the individualistic nature of consent, which fails to offer any space for consideration of the community-enhancing aims of brain banking. While the authorisation model under the HTSA 2006 is arguably even more autonomy-centred, it might be viewed as an improvement.<sup>154</sup> However, its reliance on the same narrow value foundation as the HTA 2004 means that it also fails to express the values most advantageous to banking and to truly reifying the difference that authorisation was supposed to achieve.

The statutory frameworks would benefit (and so would the biobanking enterprise and society) from a greater emphasis on solidarity as a guiding value. Discussions which include explicit references to solidarity (in addition to autonomy and risk) remind us that we are part of a broader community, and that individuals have (and should fulfil) obligations toward that community. Incorporating solidarity into our legislative frameworks and recruitment practices would better respect the wishes of the deceased (in cases where those wishes are now being overridden by family members), and would better realise the public interest and public goods that are at play. In this regard, it behoves us to make every effort to maximise the public investment that has been made in these resources, and to advance the public interest that brain banks underwrite.

A solidarity-grounded regime might offer solutions to some of the recurrent challenges or practical questions faced by brain banks. Having reference to the questions posed in the Introduction, we might argue as follows:

- Who should consent in the absence of the expressed wishes of the deceased? Drawing on an assumption that people wish to contribute positively to society and to facilitate scientific knowledge as a public good (and indeed the public good), and that they are (or should be) supportive of ethical research and donation thereto (and this assumption is reinforced by their acceptance of the fruits of medical research), the Coroner or Procurator Fiscal should consent to donation for research when they have care of a cadaver, and they should be able to trump most objections raised by the family in other situations. In short, solidarity supports public authorities having greater power to

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<sup>154</sup> And the McCracken Report recommends that the Department of Health should review the HTA 2004 and consult on amendments to bring it more into line with the Scottish legislation, and that the HTA should pursue closer cooperation with other regulators to eliminate overlaps or inconsistencies in regulatory activities and ensure understood and seamless regulatory pathways: see Recommendations 15 and 16 of the J McCracken, *Review of the Human Fertilisation & Embryology Authority and the Human Tissue Authority* (2013), at 10, at <[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/216947/Justin\\_McCracken\\_report\\_of\\_review\\_of\\_HFEA\\_and\\_HTA.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216947/Justin_McCracken_report_of_review_of_HFEA_and_HTA.pdf)> [15 September 2013].

prevail if there is a variance of views as to what should be done with the deceased's brain when the deceased has been silent as to donation.

- If the known wishes of the deceased conflict with those of the family, who prevails? If there are conflicting views as between the deceased (wishing to donate) and surviving family members (wishing to preserve the corpse intact), there should again be a presumption in favour of donation which is in the 'public good'; indeed this does nothing more than vindicate the autonomous choice of the deceased, an outcome which the deceased would have expected (and presumably did expect when s/he was alive).
- If re-consent is needed for new research, who should provide this, especially if the deceased gave the original consent? The original provision of information should address this scenario squarely, and the Agreement to Participate should be drafted such that re-consent or re-authorisation is not required when new avenues of investigation emerge post-donation; it should ensure that the agreement to donate means donating to the brain bank, with all that that entails, not to a specific research target. The bank's governance structure, in turn, should be such as to ensure transparency of decision-making, clarity around and ease of access, and availability of information to the public (ie: it should have an accessible communications element).<sup>155</sup>

Obviously, a key component of the legal and decisional framework would be transparency. This is not a strong feature in existing regimes because neither the decisional hierarchies nor the factors which go into arriving at decisions are clear. Improved transparency would encourage solidarity and make clearer to people how biobanks aim to realise reciprocity, another important driving value in this field. By embedding solidarity in the legal framework for brain donation and shifting the focus from the risks of donation (which are limited in the cadaveric context) to the opportunity presented for individuals to contribute to the health and legacy of future generations, a more sustained commitment to, and realisation of, the public good will be possible, and could be actively encouraged.<sup>156</sup>

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<sup>155</sup> In this respect, we note Recommendation 4 of the McCracken Report, *ibid*, which encourages the HFEA and HTA to review and strengthen their arrangements for consulting with stakeholders on their approach to regulatory activities, and to ensure that issues raised with them and their responses are publicly available and discussed regularly in open meetings.

<sup>156</sup> The precise operational aspects of this framework is the subject of further investigation. Should such a framework be adopted, it would need continuous development and re-evaluation to ensure practice aligns with public perceptions and public interests as and if the stages of solidarity become embedded.