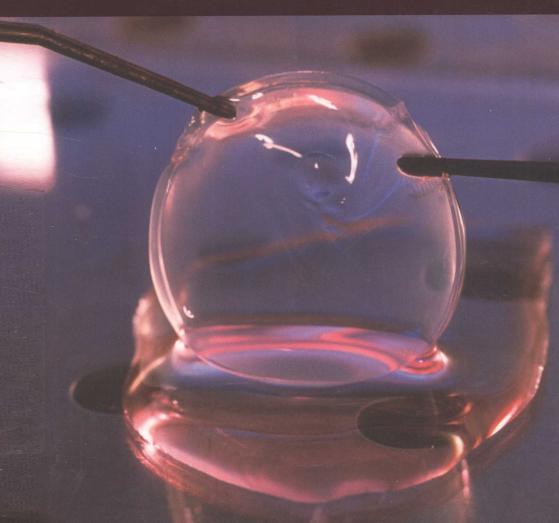
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Human Tissue in Transplantation and Research

A Model Legal and Ethical Donation Framework

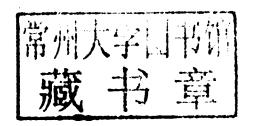
David Price



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Preface

This book is the culmination of many years of working in the fields of organ tissue transplantation and research in an academic and policy advisory context, leading me to a conviction of the urgent need for a unifying legal and ethical donation framework incorporating various central concepts and principles. The necessarily complex policy-making in this sphere is a function of the fact that humans themselves *are* the 'therapy' or 'research material' here, involved in a uniquely human activity. These are consequently areas which not only preserve but also reflect our humanity.

I am very grateful in the making of this book for the assistance received from the staff at Cambridge University Press, and in particular Finola O'Sullivan, Brenda Burke and Richard Woodham, and to Martin Wilkinson for his hugely helpful remarks in regard to two of the most substantial parts of the book. Mostly of course, my thanks and love are directed to my long-suffering wife Arlene, whose support is profoundly appreciated.

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Introduction

This is a book about policy, aimed at professionals, academics and strategists. It aspires to map out a broad, transferable contemporary 'model' framework to govern human organ and tissue donation for transplantation and research. It is my contention that existing systems, whilst well-meaning and considered, often serve – on account of deficiencies and anomalies – to defeat the very objectives which they have set out to achieve; to the detriment of patients, subjects and society in general. Deconstruction is consequently crucial, especially in the light of the controversies surrounding such activities and the ever-increasing challenges presented by them. Of course, differences of view are inevitable in spheres touching so closely upon intimate areas of human activity, but this is a field riven not only by divergence of perspective and emphasis, but also by misconception. These are areas of policy which have invariably developed in pragmatic, customary fashion, being science-, technology- and practice (and hence largely demand-) driven, partly by dint of necessity, but which require in the modern age a sure footing which can survive critical scrutiny. To be sure, legal and ethical principles will inevitably operate in a 'fuzzy' way in the real world, but there is nonetheless a need for clear concepts to cut through the increasing 'noise'. The challenges here are great, but so are the prizes. The need for human organs and tissues is one of the hallmarks of contemporary society and the gateway to interventions of incalculable benefit to mankind, either as forms of therapy or as precursors to the development of preventive, therapeutic and diagnostic strategies.

Whilst there are an increasing number of published works touching on the topics dealt with in this book, and including ethical analyses of the central issues, there are few which attempt to develop a modal framework

¹ In relation to post-mortem practice, the system was said to have operated over the previous thirty years on a 'custom and practice' basis; see Chief Medical Officer, *The Removal, Retention and Use of Human Organs and Tissue from Post-mortem Examination*, 2001, at www. doh.gov.uk/orgretentionadvice/orgretcmoadv2.htm. See also V. S. Leith, 'Consent and nothing but consent? The organ retention scandal' (2007) 29(7) *Sociology of Health & Illness* 1023 at 1032.

which cashes out these legal and ethical 'conclusions' and translate them into a workable and coherent form able to adequately guide practice. Indeed my own previous book in this sphere fell short of a wholly normative enterprise, being principally analytical in parts.² In this current work some of the areas of detailed discussion in that earlier work are omitted, and it is intended that the present volume 'build' upon the earlier one in normative terms.

An ethico-legal skeleton

The book seeks to knit together ethical and legal perspectives relating in particular to autonomy, consent, justice and property. The issue of consent has come to dominate contemporary debates with respect to the donation of human material, albeit without any shared or unifying vision as to what constitutes 'consent', or what interests consent is designed to protect. As Brazier notes, 'Consent is such a simple word' and is the more beguiling and elusive for that.³ Moreover, it has historically by no means been the norm. The perceived or actual failure to obtain proper consent has been at the heart of many controversies in the transplantation and research spheres, most visibly in the postmortem organ and tissue retention scandals which have lately arisen around the globe, and in particular in the UK,⁴ and in other analogous

² D. Price, Legal and Ethical Aspects of Organ Transplantation (Cambridge University Press, 2000) [Price, Legal and Ethical Aspects].

³ M. Brazier, 'Organ retention and return: Problems of consent' (2003) 29 Journal of Medical Fibirs 30 at 30

See Bristol Royal Infirmary Inquiry Interim Report, 2001, at www.bristol-inquiry.org.uk/ interim_report/index.htm (hearts of 170 dead children retained); Redfern Inquiry into the Liverpool Children's (Alder Hey) NHS Trust, at www.rlcinquiry.org.uk/download/index. htm (organs of 3,500 children retained); HM Inspector of Anatomy, Investigation of events that followed the death of Cyril Mark Isaacs, May 2003, at www.doh.gov.uk/cmo/ isaccsreport/ (24,000 brains in storage in Britain in 2003). A Census in England in 2000 revealed that 54,300 organs, body parts, still-births or foetuses were held following postmortem examinations carried out since 1970; see Chief Medical Officer, Report of a Census of Organs and Tissues Retained by Pathology Services in England, London: The Stationery Office, 2001. See also the Scottish Report, Final Report of the Independent Review Group on Retention of Organs at Post-Mortem in Scotland, 2000, and the Northern Ireland, Organ Retention Report, Belfast, 2001. Abroad, see the Madden Report on Post Mortem Practices and Procedures (2006) in Ireland, at www.dohc.ie/publications/pdf/madden. pdf; D. Tilmann, 'German prosecutor investigates the removal of dead babies' organs' (2000) 320 British Medical Journal 77; Organs Retained at Autopsy, Advice of the Australian Health Ethics Committee, NHMRC, 2001, Commonwealth of Australia, Canberra; U. Jensen, 'Property, rights, and the body: The Danish context' in H. Ten Have, J. Welie and S. Spicker (eds.), Ownership of the Human Body (Dordrecht: Kluwer Academic Publishers, 1998), 173 at 174 (retention of brains of thousands of psychiatric patients at Aarhus).

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contexts.⁵ The perceived benefits of such activities have often led to practice blinkered to wider ethical perspectives, and the possibility of profit from human body parts has in some other instances been the motivation for the witting or reckless failure to obtain necessary consent for removal and use.⁶ Human bodily resources are increasingly acquiring value and utility either in themselves or as the basis for the development of further biological materials, or merely as sources of biological or genomic information *per se*. This 'value' enhances the vulnerability and prospectability of our bodies and the need for donor, and indeed often community, interests to be properly protected.⁷ By virtue of their nexus to 'self', the retention and use of human material raises profound issues pertaining to the relationship between bodies and personal identity, and generates fundamental questions about who we are and what sort of society we wish to live in.

There is an ever-present tension between the imperative to generate sufficient body parts for societally and ethically crucial goods and the rights of individuals or their families to control the use of such materials. It is argued here that the need to satisfy the relevant demands for body parts cannot entirely justify a donation policy in itself, although it is recognised that a failure to satisfy the needs (of patients and professionals, respectively) is not only a major moral deficiency *per se* but will invariably fuel more and more extreme means of dealing with the deficit; which, in turn, produces a further policy dimension. Whilst a requirement for consent is becoming ubiquitous, different notions of 'consent' prevail in

⁵ Body parts from deceased former workers at nuclear power plants have allegedly been non-consensually retained and tested in both the UK and the US (Los Alamos) over many years; see O. Dyer, 'Inquiry will study claims that Sellafield workers' body parts were-removed without families' consent' (2007) 334 British Medical Journal 868; The Times, 18 April 2007, 19 April 2007, 20 April 2007 and 27 April 2007; L. Andrews and D. Nelkin, Body Bazaar: The Market for Human Tissue in the Biotechnology Age (New York: Crown Publishers, 2001), p. 20 [Andrews and Nelkin, Body Bazaar]. Body parts have frequently been merely 'retained' post-mortem; see, e.g., C. Abraham, Possessing Genius: The Bizarre Odyssey of Einstein's Brain (Cambridge: Icon Books, 2001); N. Stafford, 'German medical schools respond to claim they have stored Namibian skulls from colonial times' (2008) 337 British Medical Journal 1047.

Of course, the exploits of graverobbers and others supplying anatomy schools with whole corpses for profit were the catalyst for the passing of the anatomy legislation in the early nineteenth century. For a contemporary analogue, see http://news.bbc.co.uk/1/hi/world/africa/3039513.stm.

⁷ The interests of indigenous populations such as Native American Indians and Aborigines are being increasingly protected, e.g. Native American Graves Protection and Repatriation Act 1990 and the Aboriginal Heritage Act 1988 (South Australia) and the Heritage Conservation Act 1991 (Northern Territory). See R. Tsosie, 'Native American genetic resources and the concept of cultural harm' (2007) 35(3) Journal of Law, Medicine and Ethics 396.

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official policies, and widely varying laws, practices and perceptions exist around the world. In particular, presumed consent is a concept which, despite being a widespread legal phenomenon, continues to draw trenchant criticism from various quarters.

The relationship between 'donation' and the allocation or permitted use(s) of organs and tissues to patients or users is a crucial one. Especially contentious is the extent to which the latter should be controlled by donors, professionals, or by society, with issues of justice, equity and utility juxtaposed against individual rights of disposition and control. This again introduces issues pertaining to the relationship between the donor and his or her (separated) body parts. The US President's Council on Bioethics has stated that 'In dramatic ways, the question of who, if anyone, owns a part of the body that is brought out of the body's interior and into the light of the laboratory or clinic has become a meaningful one'. The jurisprudence in common law jurisdictions has been loathe to recognise the existence of private property rights in human materials, especially in tissue sources themselves. 9 But as Magnusson observes 'To hold categorically that human tissue cannot be the subject of proprietary rights suggests that, in the absence of specific empowering legislation, such tissue could not be gifted, bought or sold, stolen or converted, bailed or patented. In a rapidly developing biotechnological age, a legal vacuum such as this would be very curious indeed.'10 A lack of a network of property rights emanating initially from the tissue source is unsustainable in the context of a true 'donation' scheme. This by no means necessarily implies a right to trade in such material, however. This is a separate and further matter beyond rights of exclusion, use and transfer per se.

There is a perceived conflict between sufficiently protecting donors' interests and the smooth and efficient running of the various services dependent upon the human material emanating from them. This is especially patent in the US jurisprudence relating to the use of human tissue for research but similar tensions can be seen in relation to the secondary use of tissue from living individuals for research across the board, e.g. archived pathology samples, newborn screening cards, etc. 11

⁸ President's Council on Bioethics, On the Body and Transplantation: Philosophical and Legal Context, Staff Discussion Paper, 2006/7 at 8-9.

The decision in Yearworth v. North Bristol NHS Trust [2009] EWCA Civ 37 (4 February 2009) is a very welcome recent exception.

¹⁰ R. Magnusson, 'Proprietary rights in human tissue', in N. Palmer and E. McKendrick (eds.), *Interests in Goods* (London: Lloyds of London Press, 1993) 237 at 237.

Research on pathological specimens has led to important discoveries such as helicobacter pylori bacteria as the cause of peptic ulcers. The distinction between further pathological examination and 'research' is itself blurred. Their conflation has historically been

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The post-mortem organ retention scandals in the UK and elsewhere likewise generated the perception of professional and public interests being at odds, 12 but this must be seen in the light of either the professional failure to adhere to contemporary ethical or legal standards or the failure of the prevailing standards to comport with appropriate presentday values. 13 Whilst in many situations there was a failure to comply with the mandates of the law, in others both law and existing ethical standards supported the retention and subsequent use of tissues removed at postmortem for various purposes, including research, without proper consent. 14 There was apparently no evidence of any general unwillingness to allow such (research) practices, however, where consent was first obtained. Subject to some necessary accommodations, conflict is not inevitable if openness and transparency exist and a shared, partnership approach is adopted. As the Retained Organs Commission (ROC) remarked 'If adequate ethical principles govern organ retention enforced by effective laws and regulations, neither medicine nor science should suffer.'15

Ambit

This book focuses on the use of human material for transplantation and research rather than for 'treatment' purposes more broadly. It thus

considered good practice and is to some degree unavoidable. The ability to look back at retained autopsy material has helped to define vCJD, AIDS and the causes of cot death, cerebral palsy and epilepsy.

- The majority apparently support the retention of organs and tissue for research postmortem provided informed consent had been obtained; see Retained Organs Commission, Qualitative Research to Explore Public Perceptions Regarding Retention of Organs and Tissue for Medical Practice, Teaching and Research, Research Report, London, 2002.
- Whilst in some instances such practices were lawful, 'staying within the law is not enough practice needs to reflect what the community regards as acceptable in the environment in which autopsies are now performed'; see Australian Health Ministers' Advisory Council, The National Code of Ethical Autopsy Practice, Australian Department of Human Services, 2002 at 5.
- The Chief Medical Officer's Report remarked that 'The law governing organ retention is unclear, ambiguous and ageing. It was poorly understood and, as a result, not well applied'; see Chief Medical Officer, The Removal, Retention and Use of Human Organs and Tissue from Post-Mortem Examinations, Stationery Office, London, 2001. By contrast, in various jurisdictions, including many Australian States and Territories, consent for hospital post-mortem examination was by law explicitly stated to be sufficient to permit the retention and use of body parts for transplantation or research, e.g. section 28, Transplantation and Anatomy Act 1983 (South Australia). See also Report Into the Retention of Body Parts After Post-Mortems, Solicitor General South Australia, August 2001, Adelaide; and Interim Report into the Retention of Tissue and Organs Following Post-Mortems in NSW, New South Wales Health Department, February 2001, Sydney.

Retained Organs Commission, Remembering the Past, Looking to the Future, NHS, 2004, para.1.19.