Human tissue: ethical and legal issues

Preface

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Human tissue has held central place in the history of medicine. Human tissue also evokes strong emotional and spiritual responses. The great monotheistic religions of Judaism, Islam and Christianity hold different views about the human body and human tissue. The clinical and forensic uses of human tissue have been accompanied by complex ethical and legal issues.

During the twentieth century, there were remarkable advances in medical science in relation to human tissue. Blood transfusions were perfected and became common place, blood itself could be fractionated into various medicines and therapeutic products, transplantation of regenerative and non-regenerative tissue achieved high rates of success (though the supply of organs remains problematic), embryos were transferred to alleviate infertility through in vitro-fertilisation and, finally, stem-cell technology made claims to promising medical futures. By the close of the twentieth century, human tissue became a major source material for the knowledge-based genetics revolution. This revolution has been rightly described by Justice Michael Kirby as more significant than any of the other great twentieth century achievements of nuclear fission, interplanetary flight or informatics.

Public concerns about the use of human tissue

The use of human tissue in the complex endeavours of medical research and development has not been free of public concerns. First, there is the issue of public confidence and trust in the medical research. This precious public trust has been severely tested by wide coverage that has been given to the UK inquiries into hospitals in Bristol and Liverpool concerning the improper and non-consensual storage of human organs and tissue samples. Similar revelations of improper and non-consensual use of human tissue have occurred in other hospitals and forensic laboratories elsewhere in the world. It is critical that the research and medical community observe ethical and legal practices that command the confidence and respect of the public. It can no longer be taken for granted that research will always be assumed as serving the public good. Modern research codes of ethical research practice have been shaped by the recognition of human rights and the ethical principle of respect for persons. There are community expectations that research will be conducted ethically, professionally and equitably. No longer is it acceptable to conduct research without the knowledge and voluntary consent of participants. Research risks and benefits must be disclosed to research participants. Researchers are accountable and must justify their research to their peers and to ethics committees.

Secondly, there has been a shift in funding for research and the increasing commercialisation of research. Most developed nations have defined knowledge-based futures built around biotechnology and genetics. These nations have tried to marshal private interests to increase and support private funding of research. There has been a rapid change from substantially publicly funded activity to more privately funded activity and partnerships with industry. This transition has led to structural, institutional and individual researcher adjustments with respect to funding, contracts, intellectual property arrangements, declarations of interest, investment, benefit sharing and reporting. Within a decade there has been a dramatic shift in the discourse, funding and practices within research culture. The increasing commercialisation of research was exemplified by the joint statement by the publicly funded Human Genome Project consortium joining with the private

1 See Komesaroff P Troubled Bodies: Critical Perspectives on Postmodernism, Medical Ethics and the Body Melbourne UP 1995
2 For example, see Hyde A Bodies of Law Princeton UP 1997; Scott R The Body as Property Allen Lane 1981 and Meyers D The Human Body and the Law Edinburgh Press 1990
company Celera Genomics to announce the sequencing of the first draft of the human genome in early 2001.

Thirdly, behind the glittering science of genetic research, are other public concerns about the information that this research uncovers. Human tissue can be prospected to uncover unique genetic knowledge. Many countries are now grappling with concerns that individual genetic information may be used as a basis of discrimination, particularly in insurance applications or employment assessments.

In the context of these changes, the Nuffield Council on Bioethics Report on Human Tissue: Ethical and Legal Issues (Report on Human Tissue) is not only a template for the future ethical and legal uses of human tissue but also a seminal contribution in the engagement of public trust.

The Report

With prescience, the Report on Human Tissue predicted these complex trends and issues in human tissue and genomics in the discussions and recommendations in 1995. The recommendations were directed to the removal, acquisition and supply, uses, patenting and safety and quality of human tissue in the United Kingdom. Their recommendations, however addressed ethical issues that transcend national borders as well as professional boundaries. Together these recommendations proposed a template for the modernisation of dealings with human tissue. Some golden threads run through the recommendations. First, consistent with World Health Council resolutions, commercialisation of human tissue was not supported; the sale and use of human tissue was rejected expressly. The Report concluded that organising the removal and supply of human tissue along commercial lines was totally unacceptable. Payments to patients or donors, beyond reasonable expenses were not an acceptable direction. The Report went on to recommend that patients whose tissue was removed in the course of treatment or volunteer donors were to be informed about the treatment and range of intended uses for tissue and any risks involved. The role of professional bodies was a second clear theme. Professional bodies were exhorted to ensure that their guidelines reflected responsibilities on the acquisition of supply of human tissue. Tissue banks should be set up as non-profit making enterprises and not as commercial for-profit enterprises. Similarly, human tissue was only to be used in the development of therapeutic products where the sources of the tissue were governed by recognised codes of professional practice operating on a non-commercial basis. Importantly also, independent research ethics committees were to play a pivotal role in auditing the practices in relation to human tissue. Research ethics committees were expected to be consulted about the ethical acceptability of proposals involving research on human tissue bolstered by the UK Department of Health and Medical Royal Colleges giving consideration and additional guidance.

The themes of non-commercialisation, the continuing role of professional intermediaries and oversight by research ethics committees, were bolstered by some specific recommendations aimed at further blocking the emergence of any possible market in human tissue. The Report recommended that patients should have no property rights in any tissue taken and that their consent should be taken to include consent to disposal, storage and any other ethically acceptable use of the removed tissue. In so doing, the Council veered away from some of the implications of the United States decision in Moore v The Regents of the University of California\(^3\). The law on the human body as property is far from satisfactory.

\(^3\) 13 P2d 479 (1990)
Professor Kennedy has suggested that the current common law “looks to Victorian precedents on body stealing and such arcana”. The Nuffield Council’s view was not the first word on this difficult issue nor will it be the last. An individual’s claim to a share in the commercial profits from therapeutic compounds derived from their human tissue may be tenuous. Had Monet borrowed paint and paint brushes from his friend Renoir to create one of the series of paintings of waterlilies in his garden at Giverny, no one would claim that Renoir owned all or part of the painting. The creative industry is undeniable. But the American Genetic Privacy Act includes a property right not so much for commercial claims against products but to ensure an individual’s enforceable claim on the maintenance of the highest ethical standards in the use, storage, release and dealings of their tissue and genetic information. Sensibly, the Council’s recommendation about non-property must be read in conjunction with the recommendation that the National Health Service of the United Kingdom should establish a central register of tissue banks approved for supplying human tissue for medical treatment and research. This, in conjunction with other recommendations would allow the traceability in the storage and use of human tissue, thus avoiding foreclosing finalisation of the development of ethical and legal debate in this complex area.

The Nuffield Council on Bioethics

The Nuffield Council on Bioethics is a unique institution. It is not like the Australian Health Ethics Committee which has the sole statutory responsibility to initiate public consultation and make guidelines for the regulation of medical research. Nor is it like the US President’s Commission on Bioethics with its aims of providing “extensive, rigorous and sustained ethical, jurisprudential, sociological, religious and other argument, stemming from stated moral premises and taking into account strong counter-arguments”. No commission anywhere in the world is likely to be so richly resourced. Similarly, the Nuffield Council on Bioethics is constitutionally and compositionally different from the French Comité Consultatif National D’Éthique Pour Les Sciences De La Vie Et De La Santé, The Danish Council of Ethics, the Italian Commission, nor for that matter the Mexican Commission. The Nuffield Council of Bioethics was not a creature of government resolution. The Nuffield Council itself decided to establish a group, which amongst other terms of reference was:

“to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern.”

Where appropriate, this group was to make arrangements for examining and reporting on these questions with a view to promoting public understanding and discussion and the formulation of new guidelines by the appropriate regulatory or other body. That the United Kingdom has never established a formal government national ethics committee is probably a story about the influence of the Department of Health, the long gestation of the Human and Fertilisation and Embryology Authority and a lack of tradition of referring complex matters to specialist academics, although in recent years this latter trend has been reversed.

However, the National Council on Bioethics shares with the forty or fifty national ethics commissions7 a concern for what Professor Engelhardt described succinctly as the “disciplined puzzling” over birth, copulation, illness and death8. The Council’s first report on Genetic Screening: Ethical Issues9 was met with polite, if subdued approval. The Council’s Report on Human Tissue: Ethical and Legal Issues received sustained and pronounced approval. The practical and sage recommendations may not have led to a raft of new legislation but the indicators of the success of this report are pronounced in a move towards developing “international norms”.10 No serious national bioethics commission fails to derive wisdom by standing on the shoulders of those who have already considered the problem. This is not to suggest that there is outright copying of reasoning and results but rather a faithful examination of the reasoning behind particular recommendations may offer guidance to another commission. In this way the recent Australian National Statement on Ethical Conduct in Research Involving Humans included, for the first time guidelines in relation to the ethical conduct of research involving human tissue and human genetic material. These guidelines were developed with regard to the influential Nuffield Council’s Report on Human Tissue. Similarly, United States and United Kingdom Consensus Statements on pathology practice not only made reference to the Report but also clearly were influenced by its recommendations in the formulation of their advice.11 In Australia, the Royal Australasian College of Pathologists is undertaking a major review of pathology research and forensic practice and has similarly referred to this work. This is not surprising in view of the major focus of the Nuffield Council on Bioethics recommendations, which focus on the professional intermediary and professional standards rather than regulation by registration.

The Council’s contribution

Unlike the academic bioethicist that may line up between the banners of principlism - beneficence, nonmaleficence, autonomy and justice - the Report on Human Tissue adverts to moral premises but accepts that the approaches to moral philosophy in the shape of utilitarianism and rights-based ethics, virtue ethics and duty based ethics must be servants of sound defensible argument rather than the masters of conclusions.12 In any case, as any practitioner of medicine knows a patient’s autonomy is often in a tense struggle with a medical duty of beneficence and nonmaleficence.

Public ethics committees are accountable not to a closed academic community but to the public and the professions which serve that public interest. Bioethics committees must always strike a balance between the ethically sound and the practically achievable. The Consensus Statement of Recommended Policies for Uses of Human Tissue in Research Education and Quality Control produced by the UK Royal College of Pathologists stated that there is a need for “… balancing the needs of customary medial practice and research using human tissues with legitimate public concerns about protecting the rights and privacy of human subjects”(at 3). The Report on Human Tissue achieved this practical balance. In

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7 The informal world summit of bioethics commissions that was first convened by the National Bioethics Advisory Commission of the United States in San Francisco in 1996 was attended by some forty two commissions at its third meeting in London September 2000.
8 Engelhardt H T The Foundations of Bioethics Oxford U P 1985 at 9
12 See O’Neill O “Medical and scientific uses of human tissue” (1996) 22 Journal of Medical Ethics 5
ethics and law, as Professor Margaret Sommerville has reminded us, the revolution in science particularly in modern human genetics occur in a different timeframe to the reflective ethics, time with law time far behind and limping.

The Nuffield Council on Bioethics in its Report on *Human Tissue* followed that enduring quality of British scholarship, pragmatic common sense to produce an influential report, which not only responded to the new challenges of human tissue research and commercialism but also anticipated sensibly many of the forthcoming difficulties. The Council’s contribution is gratefully acknowledged, by those of us, in other parts of the world, that have found insight and guidance in its work on human tissue.