

### III. LAW & PRACTICE

#### 6. Current Law

- 6.1. There is currently little in the way of law (either common law or statutory law) governing some of the most fundamental questions in relationship to tissue banking in Singapore.
- 6.2. In respect of donations of cadaveric tissue, Parliament has provided a statutory mechanism for donation in the form of the Medical (Therapy, Education & Research) Act. This enables people to state in advance their intention to donate their bodies, organs or tissues for research or for transplantation after their death. It also enables the family of a deceased person to donate the body, organs or tissues for research or for transplantation.
- 6.3. In relation to gifts by *living* donors, there is currently very little guidance in the way of either statutory law or common law, outside of some provisions in the Human Organ Transplant Act.
- 6.4. Currently, the only express statutory provision for the governance and regulation of tissue banking is to be found in the Private Hospitals and Medical Clinics Regulations 1993. These Regulations provide that where a “private hospital” proposes to perform certain specified specialised procedures or services, prior approval of the Director of Medical Services must be obtained at least 30 days in advance. “Tissue banking” and “sperm banking” are included in the list of specialised procedures or services which require such approval.
- 6.5. Trade in human organs or blood is prohibited in Singapore. Under Part IV of the Human Organ Transplant Act 1987, it is a criminal offence, punishable with a fine or a term of imprisonment, or both, for persons to enter into a contract or arrangement for valuable consideration for the sale or supply of any human organ or blood. Likewise, the Act also makes clear that it is a criminal offence to issue any advertisement relating to the buying or selling in Singapore of any human organ or blood. The Act does provide exemptions for the *bona fide* reimbursement of expenses incurred by donors, Government-approved schemes for granting medical or other privileges to organ or blood donors and their families, and for production and sale of products derived from human organs or blood as may be specially sanctioned by the Minister under the provisions of the Act. But the general rule is clear, and we endorse and repeat the principle that all trade in human organs and blood is, and should continue to be, prohibited in Singapore. Our interpretation of the current provisions is accordingly

that the sale or the proposed sale for profit of human tissue samples is prohibited in Singapore by the Human Organ Transplant Act 1987.

- 6.6. At the present time, there does not appear to be any uniform approach to the governance and regulation of tissue banking internationally. The Draft Discussion Document entitled *Data Storage and DNA Banking for Biomedical Research: Informed Consent, Confidentiality, Quality Issues, Ownership, Return of Benefits: A Professional Perspective* issued by the Public and Professional Policy Committee of the European Society of Human Genetics as part of the EUROGAPP Project 1999-2000 offers an illuminating survey of the gamut of existing opinions, legislation, guidelines and other policy statements applied in or issued by EC institutions, 18 European countries, the United States, and international organisations. Except in the case of the United States, and possibly France, the majority of the jurisdictions surveyed are notable more for the absence of specific agreed national guidelines or legislation than for the presence of such guidelines or legislation in relation to storage of data derived from human tissue research and DNA banking.
- 6.7. For the present time, we must conclude that a full consensus has yet to emerge on many of the most critical issues in relation to human tissue banking. The most difficult problems in this regard are the issues of property, control and ownership rights to tissue samples.
- 6.8. We think, however, that it is desirable that a review be undertaken of the law governing this area, and a professional and public dialogue initiated to discuss the ethical and social considerations which should inform the shape of the law in this area.
- 6.9. Legal review has recently acquired a new urgency in light of moves by other countries to clarify their own laws on human tissue banking with the current interest worldwide in the new life sciences. Increasingly, the harmonisation of laws and rules in this field is likely to emerge as an important consideration in shaping the laws and rules in each jurisdiction.
- 6.10. In a world where large-scale collaborative research projects tend to transcend national borders, there is an increasing likelihood that many countries may demand proof of each other that there is approximate equivalence in the degree of ethical and legal protection or regulation before they will allow the cross-frontier transfer of research data, or allow cross-border research collaboration which involves access to their national tissue collections or data.
- 6.11. For example, Singapore researchers may be asked to demonstrate that their protocols for the safeguarding of the confidentiality of data meet the

standards of the jurisdictions in which their proposed collaborators are based. Failure to achieve such standards locally may well mean that Singapore researchers may be excluded from opportunities for collaboration with researchers in those jurisdictions (which include most developed countries).