EXECUTIVE SUMMARY

i. In December 2000, the Bioethics Advisory Committee (the **"BAC"**) was appointed by the Cabinet to examine the potential ethical, legal and social issues arising from research in the biomedical sciences in Singapore, and to recommend policies to the Life Sciences Ministerial Committee.

ii. Three Sub-Committees were constituted by the BAC: one of these Sub-Committees is the Human Genetics Sub-Committee (the **"HGS"**), which was constituted in February 2001 and given the task of examining ethical, legal and social issues arising specifically from human genetics research in Singapore.

iii. A Consultation Paper on Human Tissue Research was prepared by the HGS for the BAC after extensive research, careful deliberation and consultation with experts towards the end of February 2002. With a view to seeking a broad and representative spectrum of views, the Consultation Paper was used by the BAC as the focus of a consultation process in which views and input were sought from a total of 66 religious, civic, professional, scientific, medical and health care organisations, as well as from members of the public.

iv. This Report on Human Tissue Research (the **"Report"**) is the culmination of that process of research, consultation and deliberation on issues affecting the conduct and governance of human tissue research and human tissue banking in Singapore.

v. The Report is organised as follows:

- **Part I: Introduction**
  Part I covers Sections 1, 2 and 3 of the Report. **Section 1** describes the consultation process that culminated in this Report. **Section 2** sets out definitions: we use the term "human tissue" to refer to all

kinds of human biological materials derived from living or dead persons. Blood banking for therapeutic purposes is excluded from the purview of this Report, as this is already statutorily regulated in a comprehensive way. Likewise, cadaveric donations made under and governed by the Medical (Therapy, Research and Education) Act are also excluded. This Report and the recommendations which we make here are not intended to supplant the more specific recommendations which we made in relation to the treatment of human embryos, cord blood, gametes and stem cells in our earlier Report of June 2002 entitled "Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning" (the **"HSR Report"**), and therefore do not apply to such tissues. **Section 3** sets out the main objectives of this Report, and our general approach to the formulation of applicable principles.

- **Part II: Human Tissue Research**
  In Part II, we examine the role and promise of human tissue research in the advancement of genetic and medical knowledge (**Section 4**), and the current state of practice of human tissue banking in Singapore (**Section 5**). We suggest that all forms of tissue banking which permit research access be statutorily regulated through licensing by a statutory authority. We exclude collections of tissues taken for purely therapeutic or diagnostic purposes from the purview of this Report, so long as these tissues are retained only as part of the record of patients, and for which no research access is intended. The licensing authority could be the same statutory authority which we previously recommended to be set up for the regulation and supervision of human stem cell research in Singapore. We recommend that as a general rule, collections of tissues intended for research use should be held by institutions only, as opposed to private individuals.

- **Part III: Law & Practice**
  In Part III, we survey the state of the current law (**Section 6**), and identify some issues which we think need to be addressed for the future. We conclude that a full consensus has yet to emerge internationally 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. We suggest a continuing professional and public dialogue on the ethical and social considerations which should inform the shape of the law in this area. This dialogue should be undertaken with a view towards ensuring the harmonisation of our laws with accepted international best practice and consensus on relevant legal

doctrines and principles such as are being developed in the leading jurisdictions around the world.

- **Part IV: Specific Issues**
  In Part IV (comprising Sections 8 to 11), we address specific issues, and advance our recommendations:

  - **Section 8** deals with the issue of consent to donation. We take the view that research tissue bankers and those taking tissue for research have an obligation to ensure that valid and appropriate consent is obtained, and that such consent should be informed and free. Sufficient information should be given to prospective donors to enable them to exercise a real choice. Gifts of human tissue should be made as outright gifts, in the sense that the donor should renounce any property rights to the tissue. But donors should be entitled to choose between making a general gift (which may be used for any research purpose), or a restricted gift (which may be used only for research purposes specified by the donor). Where a primary purpose or objective of the taking of the tissue is research, the consent form for the donation of the sample for research should be separate from the consent form for the taking of the tissue for therapeutic or diagnostic purposes. In such cases, consent for therapy or diagnosis should be taken separately by the attending medical practitioners (for therapy or diagnosis) and by the researchers (for research).

  - **Section 9** covers the issue of consent in relation to legacy tissue collections. We take the view that it is consistent with good stewardship to allow reasonable and respectful research use of such legacy tissue collections for the greater public good.

  - **Section 10** deals with the obligation of researchers and tissue bankers alike to respect and protect the privacy of donors, and the confidentiality of personal information. The use of arrangements such as anonymised data arrangements which protect the confidentiality and privacy of the donors is an alternative in situations where consent or reconsent is impossible, difficult or socially unacceptable to obtain.

  - **Section 11** deals with approaches to governance. Given the current pace of developments in the genetic and genomic sciences, we recommend against hard-coding specific rules in legislative form for the regulation of research and commercial

activity, as overly-specific rules run a risk of rapid obsolescence. Instead, we recommend a more flexible and responsive legislative regime in which a statutory authority is constituted to supervise and regulate research tissue banking. The principal point of supervisory control could be through the licensing of accredited institutions, rather than through the direct regulation of individual researchers and tissue collections by the statutory authority. The emphasis should be on institutional responsibility and good internal self-governance, and on the promotion of adherence to the spirit rather than to the letter of the law. This proposed statutory authority could be the same statutory authority which we recommended be constituted for the regulation of human stem cell research.

- **Part V: Recommendations**

  In this Part, we set out our recommendations. The body of ethics and law in the field of human tissue and research is still in a state of flux and rapid evolution in leading jurisdictions around the world, as some of the most fundamental issues are just only now beginning to be grappled with and debated. Our recommendations represent our considered responses to some of these challenges, and are our contribution towards providing a foundation for the sound development of a body of ethical guidance and professional best practices in a field where global debate continues on many fundamental issues. We recommend that:

  - **Recommendation 1:**

    We recommend the adoption of the following ethical principles:

    - **1A. Primacy of the Welfare of the Donor.** That the health, welfare and safety of the donor shall be the paramount consideration in the taking of any tissue.
    - **1B. Informed Consent.** No tissue should be taken, or be accepted, unless the full, free and informed consent of the donor has been obtained. Patients should be informed when material left over following diagnosis or treatment might be used for research, and their consent sought and obtained. Special attention should be paid to the legal and ethical resolution of consent issues in relation to legacy tissue collections. In specific situations, it may be ethically acceptable to proceed in the absence of clear consent provided that sufficient precautions are taken for the protection of the privacy of the patient and the patient's family (for example, through appropriately

designed anonymisation procedures for legacy tissue collections).

- **1C. Respect for the Human Body.** The human body and its remains should be treated with respect. Researchers and tissue bankers need to be sensitive to religious and cultural perspectives and traditions, especially when whole cadavers or gross organ parts are concerned. Especially where these are concerned, donors or their families should be consulted in advance of the donation as to their wishes for the appropriate disposal or return of surplus tissues when these are no longer required.
- **1D. Donations to be Outright Gifts**. Gifts of tissues should be accepted only on the basis that the donor renounces any property rights or claims to the tissue that they choose to donate. Donors should be informed of this principle, and if they do not agree, then their donation should not be accepted.
- **1E. Ethical Review of Research Proposals and Access Requests.** All research using human tissue samples should be approved by appropriately constituted research ethics committees or institutional review boards.
- **1F. Confidentiality.** Researchers and all those involved in research tissue banking have an obligation to protect the confidentiality of the personal information and the privacy of donors. This obligation extends to the confidentiality of the personal information given by donors about individuals who are not themselves donors (such as information given about family members in providing details of the medical history of the donors' family members).

- **Recommendation 2:**
  Subject to our views as set out in Section 5, we recommend that research tissue banking should be conducted only by or through institutions such as may be approved by the appropriate authorities to do so, and not by private individuals.

- **Recommendation 3:**
  We recommend that there should be statutory regulation and supervision of research tissue banking, and that a statutory authority should be given supervisory and licensing jurisdiction for this purpose. We further recommend that all institutions that conduct research tissue banking should have in place

transparent and appropriate systems and standards for the proper ethical, legal and operational governance of research tissue banking. This proposed statutory authority could be the same statutory authority which we recommended be constituted for the regulation of human stem cell research.

- **Recommendation 4:**
  Given the background of a rapidly shifting and evolving consensus and opinion in the leading scientific jurisdictions, we recommend that a continuing professional and public dialogue be initiated towards:

  - Settling the principles which should guide the conduct of research tissue banking, against the background of evolving consensus on these principles in the leading scientific jurisdictions, and
  - Achieving an early resolution of the legal and ethical questions in relation to the ownership and custody rights to donated human tissue.