

V . R E C O M M E N D A T I O N S

12. In this Part, we set out our current recommendations arising out of the matters discussed above. We emphasise that these recommendations should be viewed as our considered responses to the challenge of the development of a sound body of ethical guidance and professional best practices in the current circumstances. Research tissue banking is a rapidly evolving field in Singapore, and we expect that over time, new issues and new questions in the social, ethical and legal spheres will arise and require resolution. On many issues, such as the issue of legal property in the body, there is still a lack of international consensus and an absence of clear law both locally, as well as internationally. We also emphasise that not all the issues raised in this Report can find an immediate solution in either ethics or the law, let alone both, and that some of them can only be resolved after further professional and public debate and dialogue, and with a better understanding of the issues involved, as well as the needs and concerns of the relevant participants.

13. WE RECOMMEND THAT:

Recommendation 1: Governing Ethical Principles

- 13.1. As a starting point for this dialogue, we recommend the adoption of the following principles in the conduct of research tissue banking¹:

1A. Primacy of the Welfare of the Donor

- 13.1.1. The health, welfare and safety of the donor shall be the paramount consideration in the taking of any tissue.

Where tissue is being taken primarily for a therapeutic or diagnostic purpose, research considerations should not be allowed to compromise or prejudice in any way the primary purpose of the taking. Where a tissue sample has been taken primarily for the purposes of diagnostic procedures, no further sub-sample should be taken from the main sample for the purposes of research until the diagnostic procedures are satisfied, or unless the diagnosing pathologist certifies that the taking of the sub-sample will not compromise the main diagnostic purpose of the taking of the main tissue sample. Where the taking of the tissue is primarily for the purpose of research, such taking and research should only be

¹ A number of these principles are adapted from the Report of the UK Medical Research Council entitled Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines (January 2001).

proceeded with if the potential benefits of the taking outweighs the potential risks to the patient. All living donations involve some degree of risk to the donor, although in the vast majority of cases, this risk will be negligible.

1B. Informed Consent

- 13.1.2. No tissue shall be taken, or shall be accepted, unless the full, free and informed consent of the donor has been obtained. Our remarks in the section on Consent above applies, as well as the exceptions noted thereto.
- 13.1.3. Clinicians and researchers should not assume that tissues left over following diagnosis or treatment (described as surplus to clinical requirements) may be used for research. Patients may be under the expectation that any waste tissue will be disposed of appropriately, and may object to the use of such tissue for research, or to their inclusion in a research tissue bank. The appropriate consent as outlined in the section on Consent above should be sought, and obtained.
- 13.1.4. Special attention should be paid to the legal and ethical resolution of consent issues in relation to legacy tissue collections. Where such resolution cannot be satisfactorily achieved, we recommend separate regimens of access for the legacy and non-legacy portions of a research tissue bank holding both kinds of tissue. 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, and recommend accordingly. We repeat our comments in relation to legacy tissue collections in the section on Consent and Legacy Tissue Collections above.
- 13.1.5. We recognise, however, that there are arguments that in specific situations it may be ethically acceptable to proceed without consent provided that sufficient precautions are taken for the protection of the privacy of the patient and the patient's family. For instance, this may be achieved through appropriately designed anonymisation procedures or data escrow arrangements as may be approved by the institution's ethics committee or review board. We also recognise that it may be impractical to apply the principle of informed consent in its full force to legacy tissue collections, or to research tissue banks in which the legacy tissue material cannot be reliably separated. In these cases, a national ethical policy may have to be worked out as suggested in paragraph 9.6 above.

- 13.1.6. Research tissue banks should develop and have in place electronic database systems that will enable the consent status and consent conditions (if any) of every human tissue sample to be tracked.

1C. Respect for the Human Body

- 13.1.7. Ethics, the law, and the cultural and religious traditions of our society are all in agreement with the principle that the human body and its remains are to be treated with respect. Researchers and tissue bankers need to be sensitive to religious and cultural perspectives and traditions, and should in particular be aware that whole cadavers, limbs or gross organ parts are viewed in very different light from small tissue samples by lay persons. Researchers and research tissue bankers should always ensure that donors and the families of donors fully understand the extent of the intended gift. For example, the term “tissue” should not be used without further elaboration and explanation if in fact it is intended that limbs, organs or substantial parts of organs or limbs are to be taken. Especially in the case of gross tissue samples, 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 Gifts

- 13.1.8. Donations of tissue samples for use in research should be accepted only if they are given as outright gifts. Gifts of tissues should be accepted only on the basis that the donors renounce any claim to property or rights in tissue that they choose to donate. Donors should be informed of this principle, and if they do not agree, their donation should not be accepted. As a corollary of this principle, it should be made clear to donors that they should not expect any personal or direct benefit from the donation of tissue, including information of any medical condition or predisposition or likelihood of such discovered in the course of research on the sample, unless this has been agreed upon in advance of the donation of the tissue. Likewise, researchers and research tissue bankers should not be under any obligation to disclose such information to the donors, unless they have agreed to do so in advance of the donation. If a donor is not prepared to make the donation on the basis of an outright gift, then we recommend that the donation be declined.

- 13.1.9. Although donations are to be in the nature of outright gifts, the use of such tissue (except legacy tissue) must remain governed by the terms of the consent to the donation: researchers should ensure that the proposed use of a given sample of human tissue is covered

by the terms of the consent. Donors should be free 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 the intention is for a general gift, it may be appropriate to ask for consent to be given for any and all research purposes as may be approved by a properly-constituted ethics committee or institutional review board in accordance with any rules, standards or codes as the relevant authority may lay down. To this end, effort must be made in good faith to give the donor or the donor's family a fair picture of the principal uses which the tissue is likely to be put to, with the caveat that new uses not within current contemplation or practice may and are indeed likely to arise in the future. In certain cases, it may be that re-contacting a donor (or the family of a deceased donor) for re-consent may itself be an impractical or insensitive exercise: in such cases, the ethical review board of the relevant institution should give guidance to researchers as to whether such recontact and re-consent may be dispensed with on a case-by-case basis.

- 13.1.10. Donors should not be paid any financial incentives for the donation, although they may be given reasonable reimbursement of any expenses incurred in the donation of the sample.

1E. Ethical Review of Research Proposals and Access Requests

- 13.1.11. All research using human tissue samples should be approved by an appropriately constituted research ethics committee or institutional review board. Especial attention must be paid to the independence and integrity of such committees or review boards, and any conflict of interest (whether real or potentially real, or even the semblance of a conflict of interest, even if such semblance is in fact unfounded) should be scrupulously avoided. The appointment, and constitution of such ethics committees or review boards should be as transparent as is practicable.

1F. Confidentiality

- 13.1.12. Researchers and all those involved in the conduct of research tissue banking have an obligation to protect the confidentiality of the personal information of donors, as well as the privacy of donors. Consent must be obtained from the donor (or from his or her family, if deceased) for the release of any personal information to researchers or to any third party.
- 13.1.13. Researchers and all those involved in the conduct of research tissue banking also have an obligation to protect the confidentiality of personal information given to them by donors about other

individuals who are not themselves donors, as well as the privacy of such individuals. Scientifically valuable information is often given by donors of tissue samples which may relate to individuals other than the donor himself or herself. Commonly, a donor may be asked to provide details of the medical history of family members. Researchers should recognise that such information and such individuals should be accorded the same respect and protection as accorded to the donor.

Recommendation 2: Institutional Research Tissue Banking

- 13.2. Subject to our views as set out in Section 5 above, we recommend that research tissue banking should be conducted only by institutions such as may be approved or licensed by the proposed statutory authority to do so, and not by private individuals or groups of private individuals.

Recommendation 3: Operational Aspects of Research Tissue Banking

- 13.3. We recommend that all research tissue banks should be licensed by a statutory authority, which should be conferred the appropriate supervisory jurisdiction. No research tissue banking should be carried out without the licence of the statutory authority. The statutory authority should be given sufficient powers of direction, enforcement and supervision, so as to enable it to effectively supervise and give ethical and legal direction for the conduct of research tissue banking in Singapore.
- 13.4. 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.
- 13.5. Such systems and standards might include, but need not necessarily be limited to:
- 13.5.1. The formulation of clear and transparent written ethical guidelines and policies for the operation of research tissue bank and the governance of their research tissue banking activities;
 - 13.5.2. The formulation of clear written Standard Operating Procedures for the day-to-day operations of the research tissue bank, with especial attention being paid to ensure the integrity and biological safety of the tissue holdings;
 - 13.5.3. The establishment of an appropriately constituted research ethics committee or institutional review board to oversee requests for

research access to or the use of human tissues, on clear, objective and transparent criteria;

- 13.5.4. The provision of a proper system for periodic and impartial census and audit, and a proper inventory system for their tissue holdings and for research accesses to the holdings;
- 13.5.5. The working out of simple and clear procedures and proper documentation of the required consent process in consultation with their legal advisors;
- 13.5.6. The establishment of clear and written policies for the sharing of research tissue bank resources with other tissue bankers and researchers;
- 13.5.7. The establishment of written procedures and policies for the culling and appropriate disposal of unneeded human tissue samples from the bank;
- 13.5.8. The establishment of legally and ethically adequate and acceptable systems to protect and safeguard the confidentiality of personal information of donors, and the privacy of such donors and of any other individuals (not being donors themselves) whose identity or personal particulars to which such information may relate; and
- 13.5.9. The establishment of a system for the periodic reporting of activities to those who have overall responsibility of the larger institution to which the research tissue bank belongs.

Recommendation 4: Initiating An Ethical Dialogue

- 13.6. Given the background of a rapidly shifting and evolving body of ethics, legal rules and opinion governing human tissue research and banking 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 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, custody and property rights to donated human tissue.

- 13.7. 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.
 - 13.8. While we expect that most of the input in the dialogue will come from professionals in the life sciences, we also recommend that the views of the public be sought. This Report is issued by us as part of that process.
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