

HUMAN TISSUE RESEARCH

A REPORT

I. INTRODUCTION

1. About this Report and the Consultation Process

- 1.1. At the end of February 2002, a Consultation Paper entitled “Consultation Paper on Human Tissue Research (the “**Consultation Paper**”) was prepared and submitted by the **Human Genetics Sub-Committee** of the **Bioethics Advisory Committee, Singapore** (the “**BAC**”) to the BAC. The members of the Human Genetics Sub-Committee are set out in **Appendix A**.
- 1.2. In its work on the Consultation Paper, the Human Genetics Sub-Committee (the “**HGS**”) had the benefit of valuable expert advice and background information presented by eminent experts and professional bodies in a series of Position Papers commissioned by the BAC. Copies of the commissioned Position Papers relevant to the Consultation Paper and this Report are set out in **Appendix B**. The BAC records its appreciation to the Chapter of Pathologists of the Academy of Medicine; Professor Edison Liu of the Genome Institute of Singapore; and Associate Professor Kon Oi Lian of the National Cancer Centre for these Position Papers.

- 1.3. With a view to seeking a broad and representative spectrum of opinion, the Consultation Paper was sent by us (the BAC) to a total of 66 religious, civic, professional, scientific, medical and health care organisations on 27 February 2002 with a request for feedback and suggestions. A copy of the Consultation Paper is set out in **Appendix C**. In addition, a press conference was held on 4 March 2002, and public participation was invited in the feedback process. The release of the Consultation Paper and our invitation to the public was widely reported upon in the media. This consultation exercise was carried out in an effort to inform, test and shape the recommendations which we propose for adoption in this Report.
- 1.4. A total of 37 parties to date have responded to our request for feedback on our Consultation Paper. Of these, 33 parties responded with comments and suggestions, while the remaining 4 parties replied to say that they had no comments. The full text of all the written responses received by us are set out in **Appendix D**.
- 1.5. In general, respondents were supportive of the principles proposed in our Consultation Paper. This Report is a revision of our Consultation Paper, after carefully considering and debating at length the responses that we have received to date.
- 1.6. As indicated in our Consultation Paper, our primary objective has been to recommend a basic framework for the ethical and legal regulation of human tissue research in Singapore. We believe that the recommendations set out at the end of this Report meet this objective, and provide a firm foundation for the proper and ethical governance of human tissue research in Singapore, both for the present and for the future. We are reinforced in our views by the comments expressed by the majority of our respondents, and by the fact that the core principles are consonant with those held to be applicable in the leading scientific jurisdictions.
- 1.7. Human tissue research is a broad field of inquiry. This Report is not intended as an exhaustive survey. Instead, we focus on a few specific issues arising out of the practice of human tissue banking which we think require resolution as a matter of priority. Other issues (some of which are also identified in this Report) may be addressed at a later time in separate working consultation papers and reports.
- 1.8. We have made recommendations on issues where we think such recommendations may be reasonably and confidently advanced. As to the other issues, we have simply identified some issues which we think merit further discussion and consideration. As in our Consultation Paper, we have not made any specific recommendation for those issues and we

continue to invite views, comments, suggestions and other feedback on these other issues.

2. Definitions

- 2.1. In this Report, we use the term “**human tissue**” to refer to all kinds of human biological materials derived from living or cadaveric donors, including solid body tissues, organs, foetuses, blood and other body fluids and their derivatives, cord blood, embryos, gametes (sperm or eggs) or any part or derivative thereof.
- 2.2. However, we exclude the following from this review:
 - a. Blood banking for therapeutic purposes, as this is already well-regulated in Singapore (but blood and blood derivatives collections which are used for research are covered by this review);
 - b. Donations of cadavers, organs and cadaveric tissue made under and governed by the Medical (Therapy, Education and Research) Act; and
 - c. Human stem cell research, reproductive and therapeutic cloning. These recommendations are not intended to supplant the more specific recommendations which we have made in relation to the treatment of human embryos, cord blood, gametes and stem cells in our separate Report of June 2002 entitled “Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning” (the “**HSR Report**”). Where common ground is covered in this Report and the HSR Report, it should be understood that the more particular and specific recommendations which we made in the HSR Report in relation to human embryonic stem cell research and on human cloning, should control: the particular recommendations made in the HSR Report are to be taken as being in addition to the general recommendations set out in this Report.
- 2.3. In practice, human tissue banking is carried out in the following main settings:
 - a. Human tissue which is taken for the purposes of clinical diagnosis or treatment, but which could be used subsequently for research. Blood, urine and other biological fluids are commonly taken for the purposes of clinical diagnosis or monitoring of patients’ medical conditions, or less frequently, for treatment. Upon completion of the clinical testing procedures, excess blood or urine are often kept in the clinical laboratory as part of the patients’ medical records. However, such collections of excess blood, urine or other biological fluids could also be used in research

studies. In the same way, tissue may be removed from a patient for pathological diagnosis in the form of a biopsy or surgical excision. Tissue may also be removed from a patient as part of his or her treatment, for example, when a cancer is resected from the big intestine. Such tissue is processed and examined histologically by the pathologist as part of the clinical care of the patient. Excess tissue which is stored as frozen tissue or in the form of paraffin blocks is retained by the institution as part of the patient's medical records in case the tissue needs to be reviewed in the future for patient care purposes (see also paragraphs 5.1 to 5.6 below). However, such collections of tissue can also be used in research studies;

- b. Small or limited collections of blood or tissue may be taken or stored with the patients' consent for specific research projects conducted by individual doctors or research teams. In such cases, the collection is only made for the limited purposes of specific research projects. On the completion or termination of the research projects, these collections may remain in the care of the individual researchers or teams of researchers, or they may be merged through accession to the larger research tissue banks of institutions as discussed in (c) below. We discuss these small or *ad hoc* collections for specific research projects in paragraphs 5.15, 5.16, 5.19 and 5.20 below, and make the recommendation that, where appropriate and where the prior patient consent allows the researcher to do so, they should be consolidated into larger institutional tissue banks upon the completion or termination of the research project (see paragraph 5.22 below); and
- c. Research tissue banks are collections of human tissue which are assembled specifically for the purpose of research. Such research tissue banks differ from that in (b) immediately above, in that the scale of collection is generally much larger, and in that donations may be sought for a much wider range of research applications. In many cases, the tissue donated to such research tissue banks are donated for research in general, without any restriction on the research uses to which they may be applied. Such research tissue banks need not be physically centralised (see paragraph 5.21 below). Tissue in such research tissue banks may also be made up at least in part of tissue originally collected as in (a) and (b) above, but which are subsequently consolidated into larger institutional research tissue banks upon exhaustion of their original purpose or use. We further elaborate on such research tissue banks in paragraphs 5.7 to 5.15 below.

3. The Objectives of this Report

- 3.1. In recent years, much public attention has been focused on developments in the new life sciences, and on genetic and genomic research in particular. These new life sciences offer enormous promise of potential benefits.

- 3.2. In many of the current thrusts of the new life sciences, researchers are entering completely new grounds which raise many novel legal, ethical and social issues. Consequently, the body of community ethics is being asked to offer ethical direction and guidance for the ethical conduct of research in entirely new situations for which there are no readily available precedents. In many areas too, the state of the law sometimes lags far behind the realities of the current and future state of technology, so that practitioners and researchers in the new life sciences are forced to act in the absence of clear legal guidance.
- 3.3. We believe that, in this respect, the development of sound ethical principles which are acceptable to and supported by the community at large will assist in the formulation of the law in areas and for situations where this is eventually felt to be necessary. Such a body of sound ethical principles will also serve as the common understanding on which ethical research work may be carried out.
- 3.4. The majority of scientists and researchers are responsible and are aware of potential ethical concerns in the work that they do, and in that which they may propose to carry out. Most wish to do what is ethically right. Indeed, some may be inhibited from participating in some areas of research (which may in fact be entirely acceptable to the community, and be in the public interest) by the lack of clear ethical direction or agreement on a given point, or by uncertainty generated by controversy in related areas.
- 3.5. Accordingly, **the principal objectives of this Report** are:
- a. To review current issues affecting the conduct of human tissue banking and human tissue research in Singapore;
 - b. To recommend a national framework for the proper governance of research tissue banking activities in Singapore; and
 - c. To recommend a body of appropriate ethical principles and guidelines for the ethical conduct of research tissue banking and human tissue research in Singapore.
- 3.6. Where there is broad agreement in leading jurisdictions on applicable principles, we have in general tended towards recommending the adoption of these principles. It is only recently that various developed jurisdictions have embarked upon the task of the formulation of guidelines and rules for the governance of the new life sciences, and to examine the ethical issues involved. In some areas, an international consensus is beginning to emerge. But in many other areas, the future shape of the body of ethics is still being debated. We hope that the recommendations advanced in this

Report will help fill some of the more obvious gaps. We also hope that the public and the professional debate generated by the release of the Consultation Paper and this Report will help advance that process.