

8<sup>th</sup> April 2002

Our Ref : BAC1-tk-020408



To : Assoc Professor Terry Kaan  
Chairman  
Human Genetics Subcommittee  
Bioethics Advisory Committee  
250, North Bridge Road,  
#15-01/02 Raffles City Tower,  
Singapore 179101

Dear A/Prof Kaan,

**RE: FEEDBACK ON THE CONSULTATION PAPER ON HUMAN TISSUE RESEARCH**

Thank you for inviting our views on the issues outlined in the consultation paper & the interim recommendations advanced by the Human Genetics Subcommittee.

We enclose the comments from the Chairman, National Cancer Centre Ethics Committee (see enclosed) for your perusal.

Thank you.

Yours Sincerely,

A handwritten signature in black ink, appearing to read "Audrey-Anne Oei".  
Ms Audrey-Anne Oei  
Research Manager,  
National Cancer Centre Singapore



cc: Prof Soo Khee Chee  
Dr Vijay Sethi

CEO, National Cancer Centre  
Chairman, NCC Ethics Committee

Encl.Comments from the Chairman, National Cancer Centre Ethics Committee

**COMMENTS FROM THE CHAIRMAN, NATIONAL CANCER CENTRE ETHICS COMMITTEE:**

**1. Section 3.3**

We agree that the ethics that are applied should reflect the ethical stand of the community at large. In this respect we think that some degree of "public education" on ethical issues should be recommended by the committee. Exactly which bodies should do it can be decided later. The reason for asking for this is that a large number of doctors in Singapore still hold very paternal views and feel that the man-in-the-street is unable to understand the issues involved.

**2. Section 3.4**

Our own impression (from attending local courses on medical ethics) is that many persons involved in medical research are not actively thinking "ethics" especially when the ethical problems that may arise can delay or prevent their study. Therefore, the statement 'that the vast majority of scientists and researchers ... are acutely aware of the potential ethical concerns' is not something that we agree with. As with point 1 above, we suggest that the committee recommend education on ethics for doctors as well.

**3. Section 5.7**

Databases should also concern themselves with the eventual or final outcome of the tissues to prevent unauthorised use of the tissue when it leaves the tissue banks. Many studies by drug firms tend to leave this aspect vague and this may allow use of the tissues, at a later date, for other unrelated studies for which they have not taken specific consent.

**4. Section 8**

Arising from our observations (see 2 above) we feel that as far as possible, in a study or research setting, consent should always be obtained. As for the question of "reconsent" this can be a difficult issue, especially in cancer research where a large number of donors may not live for long.

On the whole we think section 8 provides a good basis for consent, (especially 8.10) where an ethics committee has a final say.

**5. Section 11. 9 &10**

Most if not all members of such committees use their "common sense" and as they are usually experienced persons they bring a depth of understanding to the discussions that are not "common." Our own observation as members of an ethics committee is that some form of special training in ethics can be useful. In addition the ethics people often need to draw on other resources to make their decisions. In this respect such committees will benefit from having their own administrative support.

**National Cancer Centre**

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**Feedback on the Bioethics Advisory Committee's  
Consultation Paper on  
Human Tissue Research**

Presented by the National Council of Churches Singapore



**Introduction**

The National Council of Churches Singapore (NCCS) wishes to thank the Bioethics Advisory Committee (BAC) for presenting a consultation paper entitled 'Human Tissue Research' for discussion and feedback. The NCCS also wishes to acknowledge the industry and thoroughness with which the BAC has presented the issues and regulations pertaining to human tissue research, and its generally sensitive and sound recommendations. The issues surrounding human tissue research must be studied in the larger context of research involving humans. What follows is a Christian response to the consultation paper, especially in relation to some ethical issues pertaining to the use of foetal or embryonic tissues.

**Theological and Ethical Perspectives**

*A Theology of the Body*

We begin our response by presenting, albeit only in outline form, what might be called a *theology of the body*. This is not a new theology, although its import is sometimes obscured in the history of Christian theology by cultural factors. The Christian Tradition holds that a human being, created in the image of God, is a psychosomatic being, comprising *both* body and spirit. The dualism that prevailed in certain periods in the history of Christian theology is not reflective of the fundamental theological anthropology of the Church. Because a human being is a psychosomatic unity, the lived body cannot be seen simply as a material instrument, used to communicate what the 'real person' living within it thinks. This form of Cartesian dualism is inimical to the Christian Tradition. Put differently, a human person does not possess a body. Rather, from the moment of conception, a person is an embodied being, and therefore cannot express himself or herself in any other way except bodily. Against the Cartesian body-soul dualism, we must assert that our bodies are fundamental to our essential humanity and constitute our identity. The doctrine of the incarnation affirms the importance of the body, for in the mystery of the incarnation the Son of God became body in order to bring healing and restoration to our bodily nature. The doctrine of the resurrection of the dead, so integral to Christian eschatology, also affirms this unitary view of a human being.

*Human Dignity*

This theology of embodiment implies that transgressing against the body is a violation of human dignity. The NCCS therefore supports the BAC's emphasis on the

importance of the principle that the ‘human body and its remains are to be treated with respect’ and its insistence that ‘researchers and tissue bankers need to be sensitive to religious and cultural perspectives and traditions’ (13.1.1.7). Respect for human dignity will produce an ethic of research involving human subjects that embrace two important principles: (1) the selection and achievement of morally acceptable ends, and (2) a morally acceptable means to those ends. It is unacceptable to treat a person solely as a means (i.e., as a mere object) to an end, for by doing so, not only will the intrinsic dignity of the person concerned be violated, but all of humanity will be impoverished. The theology of embodiment here articulated, which sees a human being as a unitary being, cannot but produce an ethic which aims to respect human dignity by protecting the multiple and interdependent interests of the person – bodily, psychological, spiritual, cultural. It cannot allow medical research to violate this principle, regardless of the promise of such research.

**Areas of Concern: Research Involving Embryos, Foetuses and Human Gametes**

Human tissue research does present some ethical concerns to the Church. These concerns have to do with the definition of human tissue. According to the BAC document, *human tissue* refer to ‘all kinds of human biological materials derived from living or cadaveric donors, including solid tissues, organs foetuses, blood and other body fluids and their derivatives, cord blood, embryos, gametes or any part of derivative thereof’ (2.1).

The inclusion of foetuses and embryos in this definition must be challenged from the Christian perspective. The NCCS maintains that the foetus and embryo are human beings, and to describe them as human tissue is to mislead.

*Foetuses and Embryos*

Therefore concerning the use of tissue from human foetus or embryo for research, the NCCS reiterates its position that human life begins at conception, and that the embryo from its earliest life is a human being deserving of the protection and respect that is accorded to all human beings. On the basis of this, the following guidelines obtain.

- a. It is unethical to abort the embryo or foetus for the purpose of research. This remains true even for countries in which abortion is legal, e.g., Singapore.
- b. It is ethically unacceptable to create a human embryo for research purposes. The NCCS maintains its position that therapeutic cloning for the purpose of research cannot be countenanced by the Christian church.
- c. It is ethically unacceptable for embryos which are created for reproductive purposes, and which are no longer needed for such purposes, to be used for research. This refers to excess embryos created for IVF.
- d. However, it is ethically acceptable to use foetuses and embryos that have perished because of spontaneous miscarriages for research, so long as these miscarriages are not caused intentionally.

The foetus should not be subjected to dissection procedures if a heartbeat is still apparent, or when there are other obvious signs of life. In circumstances where tissue is obtained from a deceased foetus, the following guidelines should be followed.

- a. Research involving foetal tissue taken in such circumstances should nonetheless be guided by respect for the woman's dignity. The same guidelines for free and informed consent should apply here.
- b. Research procedures should not be conducted in the immediate area in which clinical procedures are being carried out.
- c. Those concerned with research should not be involved in the management of either the mother or the foetus.

*Human Gametes*

Not enough is said in the BAC document on obtaining human gametes for research, although it is assumed that the general principles outlined in the paper obtain in this case as well. Here are some more guidelines for consideration.

- a. It is ethically unacceptable to use gametes for reproduction, even between tissues.
- b. In addition to free and informed consent, one must add that full disclosure of the purpose of the proposed research must be made to the donor.
- c. It must also be said that it is unacceptable to obtain gametes from cadavers, and from those from foetuses or individuals unable to consent for themselves.
- d. It is not ethical to use gametes for research if they have been obtained through commercial transaction, including transaction for service. The commercialisation of human reproduction must be prohibited morally because it transgresses the basic principle of respect for human dignity.
- e. It is unethical to create hybrid individuals by means of mixing human and animal gametes, or by transferring somatic and germ cell nuclei between cells of humans and other species. This violates the basic norm of human dignity.

**Comments on the Recommendations Presented by the BAC**

*Primacy of the welfare of the donor (13.1.1.1)*

The NCCS applauds the BAC for emphasising the primacy of the welfare of the donor, and for insisting that the health of the donor is paramount (13.1.1.1). Perhaps a clause on the respect for persons who are vulnerable, that is, those who have a diminished capacity or competence for making decisions on their own should be added. This would include children and institutionalised persons who require special protection against abuse, exploitation and discrimination. Special regulations should be established to protect the interest of such persons.

*Informed Consent (13.1.2 – 13.1.1.6)*

The BAC's insistence that 'no tissue shall be taken, or shall be accepted, unless the full, free, and informed consent of the donor has been obtained' must be affirmed. The BAC document states that consent should be obtained 'when it is practical to do so' (8.2). The NCCS, however, recommends that that consent should be obtained 'at all times' unless it is impossible to do so. The issue of voluntariness is important here.

It must be stressed that free and informed consent must be given *voluntarily*, and not as the result of manipulation and undue influence or coercion. Undue influence may take the form of inducement or deprivation. It must also be stressed here that consent may be withdrawn at any time.

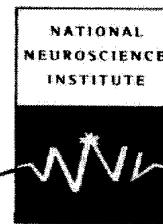
*Ethical Review of Research Proposals and Access Requests (13.1.1.9 – 13.1.1.11)*

While it is important that a national-level consultative committee be formed for providing ethical and other guidelines to govern human tissue research, such a committee must not only comprise professionals from relevant sectors but also representatives from the religions. This is to ensure that such committees will not be concerned only with scientific and pragmatic considerations, but will take into account the views of the various religious traditions. Input from the religious bodies will introduce important perspectives that is concerned with the good of society and that are not governed by scientific or economic ambition. The NCCS affirms the BAC's conviction that the community's views should guide the ethical framework for tissue banking and research (3.2, 3.3, 3.4). But the NCCS would like to add that the community should be adequately represented and should contribute in defining vague terms such as 'appropriate' (5.11) and 'reasonable and respectful research' (9.5).

*Confidentiality (13.1.1.12 – 13.1.1.13)*

The issue of privacy and confidentiality is also paramount, and the BAC document has delineated some strict guidelines to ensure that personal information of donors is protected. But in reality confidentiality is difficult to protect. There are several categories of human biological materials. The first is *unidentified specimens* for which identifiable personal information is not collected, and therefore not available in the repository. *Identified specimens* are linked to personal information in such a manner that the person from whom the material is obtained can be identified by name, patient number, etc. In research environments, samples can be similarly termed as 'unidentified' and 'identified'. Over and above these categories, there are also 'anonymised' samples, i.e., samples that lack identifiers or codes that can link a particular sample to a particular specimen or individual human being. But how anonymous are 'anonymised' samples? Merely stripping a sample of some of its identifying detail may not necessarily ensure anonymity. What circumstances would make it difficult to render a sample anonymous? And what policies can be created to ensure true anonymity? This is an issue that the BAC document must address more fully.

8<sup>th</sup> May, 2002.



A/Prof Terry Kaan,  
Chairman,  
Human Genetics Subcommittee,  
Bioethics Advisory Committee.

Dear A/Prof Kaan,

11 Jalan Tan Tock Seng  
Singapore 308433  
Tel : (65) 357 7153  
Fax : (65) 256 4755

Re : Feedback regarding Human Tissue Research in Singapore

I had earlier spoken to you in relation to the consultation paper on human tissue research in Singapore. I regret it has taken so long to put those opinions on paper.

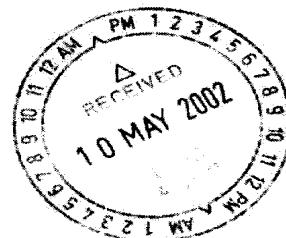
In general, I am in agreement with the proposals for the process of taking informed consent (IV-8, V-13). However, there is one comment on item 8.7. Contrary to the concerns expressed, there are renowned institutes in the US where the request for consent to donate tissue samples for research is on the same consent form for the surgical therapeutic or diagnostic procedure to remove the tissue (see enclosed example from Sloan Kettering Memorial). Although the use of the same consent form may predispose to an impression that "the best efforts made for his or her therapeutic or diagnostic benefit might depend on or be affected by the giving or refusal of consent to the donation" (sic 8.6), whether or not this impression results ultimately depends on the honesty, integrity and communication skills of the person taking the consent. Note that the use of a separate consent form does not necessarily prevent the risk of an inappropriate impression. Perhaps the Committee may wish to revisit this point.

My other concerns are with the use of legacy tissue collections (IV-9, V-13.1.1.5), specifically with recommendation to ensure confidentiality by using anonymisation arrangements or data-escrow arrangements. This is impractical, if not impossible, when the research requires the correlation of tissue findings with clinical information. I note that the Committee did recognise the impracticality of some of their recommendations for legacy tissue. I wish to reinforce this point.

Thank you,  
With kind regards,

Yours sincerely,

Yee Woon Chee,  
Deputy Director (Research)  
National Neuroscience Institute.



**APPENDIX D**

CB.FEB.2000 12:41 HCC DIRECTOR MED SC 3720161 NO. 589 P.3  
**CONFIDENTIAL PATIENT INFORMATION - HANDLE ACCORDING TO HOSPITAL POLICY**

Memorial Hospital for Cancer and Allied Diseases



Patient Consent Form For Diagnostic  
and Therapeutic Procedures



Patient Identification

I hereby give consent for the performance of the following procedure(s): \_\_\_\_\_

by or under the direction of \_\_\_\_\_ M.D.

The undersigned physician has fully explained to me why I need the proposed treatment, the risks involved, potential problems, the chances for success and the problems I may experience as I recover. We have also discussed alternatives to treatment and the risks and consequences of no treatment. If assistance of Anesthesia Service is required, I understand I will have an opportunity to discuss the anesthesia options, risks and possible complications with an anesthesiologist prior to my procedure.

If my doctor finds something he/she does not expect, I consent to have additional or different procedures the doctor thinks are in my best interest. I know the procedure has risks. I also know there is a chance that I might have a reaction or outcome that is not expected. I know that I will be given transfusions of blood or blood products if I need them and the risks associated with transfusions have been fully explained to me.

The hospital has my permission to use tissues and/or organs removed during the procedure for diagnosis and after that, in any way that advances medical science. I know the tissues and/or organs will be disposed of according to hospital practice.

As long as my identity is disguised, the hospital may publish or televise photographs and/or videotapes taken during the procedure if it is for the purpose of advancing medical education.

For females only: I do not think I am pregnant now, and if I am, I understand that there is a possible risk to the fetus (unborn child). I have had the chance to ask questions and I am satisfied that they have been answered. By my signature below, I confirm that I have read and understand the information in this form, and that all blank spaces have been completed prior to my signing. I acknowledge that no guarantees or assurances have been made to me concerning the results intended from this treatment.

\*Signature of Patient/Agent/Relative or Guardian \_\_\_\_\_

Witness (Optional) \_\_\_\_\_

(Print Name) \_\_\_\_\_

Date \_\_\_\_\_ Time \_\_\_\_\_

Relationship (if signed by person other than patient) \_\_\_\_\_

(Print Name of Interpreter (if consent discussion is translated on behalf of a patient)) \_\_\_\_\_

Signature of Interpreter attesting to having translated the full and complete content of the discussion to the best of his/her ability. \_\_\_\_\_

\*THE SIGNATURE OF THE PATIENT MUST BE OBTAINED UNLESS THE PATIENT IS AN UNEMANCIPATED MINOR UNDER THE AGE OF 18, OR OTHERWISE INCOMPETENT TO GIVE CONSENT.

**PHYSICIAN CERTIFICATION**

I hereby certify that the patient/agent/relative/or guardian has stated in my presence that he/she has received an explanation of the nature, purpose, benefits, reasonably foreseeable risks of, and alternatives to the use of intravascular contrast media, has had all of his/her questions answered, and has given his/her consent.

Date \_\_\_\_\_ Time \_\_\_\_\_

(Physician Signature) \_\_\_\_\_

(Print Name) \_\_\_\_\_

58-08484 A29 CMV Approval Date: 6/96

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NO. 422 P. 234 D01



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15 May 2002

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A/Prof Terry Kaan  
Chairman  
Human Genetics Subcommittee, BAC  
Bioethics Advisory Committee  
250 North Bridge Road  
#15-01/02 Raffles City Tower  
Singapore 179101

Dear A/Prof Kaan

**REQUEST FOR FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN  
SINGAPORE**

Please be informed that we do not have any comments to make regarding your consultation paper.

Thank you.

With kind regards,

Yours sincerely

Dr Goh Chee Leok  
Clinical Professor  
Director / Senior Consultant Dermatologist

DID: 3508401

Internet email: [nsc@pacific.net.sg](mailto:nsc@pacific.net.sg)



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17 April 2002

Professor Lim Pin  
Chairman, Bioethics Advisory Committee  
250 North Bridge Road  
#15-01/02  
Raffles City Tower  
SINGAPORE 179101

Dear Prof Lim

**HUMAN TISSUE CONSULTATION PAPER BY BIOETHICS ADVISORY COMMITTEE**

The members of the NUH Research & Ethics Committee (REC) met on 2 April 2002 and deliberated carefully on the abovementioned paper.

In summary:

1. The NUH REC gladly accepts all the points put forward as the paper conforms to the Singapore law and principals as well as existing regulations of overseas countries. The paper is clearer and well defined compared to those from many developed countries. This paper will be helpful in advancing the Singapore biomedical life sciences.
2. There is one main reservation with regards to "Item 2 : Definitions". The committee feels that foetuses, gametes (sperms or eggs) and embryos should be categorized separately rather than as a broad category such as "human tissue". Inclusion into this broad categorization may infringe on many religious, moral and social beliefs especially in this multi-racial, cross-cultural country such as Singapore. Our view is that fetuses, gametes and embryos should be treated as a separate category.
3. REC will also like to see a clearer definition of "tissue bank" and "blood bank". What quantity of tissue / blood samples have to be collected in order to be constituted as a "bank" and at what stage would the "banks" be considered as "licensed"?

Thank you.

Yours sincerely

*[Signature]*  
Assoc Professor K O Lee  
Chairman, Research and Ethics Committee  
National University Hospital  
C/o Medical Affairs Department

Cc: CEO, NUH  
CMB, NUH  
VCMB (Research), NUH  
NUH REC



Office of Life Sciences



28 April 2002

John E L Wong  
Professor of Clinical Oncology  
Director, Office of Life Sciences

Assoc Prof Terry Kaan / Dr Sylvia Lim  
Chairman  
Human Genetics Subcommittee, BAC  
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250 North Bridge Road  
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Singapore 179101



Dear Terry

**CONSULTATION PAPER ON HUMAN TISSUE RESEARCH**

Thank you for the opportunity to provide feedback on the consultation paper.

This is an excellent paper. My only comment pertains primarily to Item 8.7, under Section IV : Specific Issues. It would not be practical for 2 separate people to take consent.

Thank you.

With kindest regards

A handwritten signature in black ink, appearing to read "John Wong".

John Wong



**PARKWAY GROUP HEALTHCARE PTE LTD**

28 March 2002

A/Prof Terry Kaan  
 Chairman  
 Human Genetics Sub-committee  
 Bioethics Advisory Committee  
 250 North Bridge Road  
 #15-01/02 Raffles City Tower  
 Singapore 179101

Dear Sir

**CONSULTATION PAPER ON HUMAN TISSUE RESEARCH**

Thank you for sharing the paper on Human Tissue Research.

Overall we feel that the paper covers most areas of concern and that the interim recommendations proposed are sound and can form the basis for the legal and ethical framework to be built upon.

We will continue to discuss these issues at our hospital Medical Advisory and Independent Review Board levels and hope to be able to maintain a dialogue with your committee on these issues.

With kind regards

Yours sincerely

Dr S Thanasekaran  
 PGH Medical Affairs

DID : 64703 388

E-Mail : [tsinnath@glenagles.com.sg](mailto:tsinnath@glenagles.com.sg)

FAX: 64705 605

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SINGAPORE SCIENCE CENTRE

65 65659533 P.01

# Singapore Association for the Advancement of Science

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18 April 2002

A/Prof Terry Kaan  
Chairman  
Human Genetics Subcommittee  
Bioethics Advisory Committee  
250 North Bridge Road  
#15-01/02 Raffles City Tower  
Singapore 179101

By fax 68379190

Dear Prof Kaan

## **CONSULTATION PAPER ON HUMAN TISSUE RESEARCH IN SINGAPORE**

Thank you for your letter of 27 Feb, inviting our Association to provide feedback on the consultation paper prepared by your Subcommittee in relation to human tissue research in Singapore.

We recognize that it is a difficult issue and whilst the study appears balanced, some feedback have been received from our members. These are summarized hereunder :

### **Para 8.4 and 8.5**

It may not be fair to the donor if the gift is to be of an absolute one which requires the renouncing of entire rights so that all possible kinds of research procedures may be carried out on the donated human tissue sample. This also includes renouncing of all rights to possible future financial gains or benefits.

### **Para 13.1.1.1**

Details need to be given as to what criteria are used to decide whether the potential benefits of tissue-taking outweighs the potential risks to the patient. For instance, in major breakthroughs in research, the financial rewards and prestige from the researcher's viewpoint would obviously seem to outweigh the risks to the patient. However, from the latter's viewpoint, the risks incurred are of greater significance than the researcher's reward. Are we willing to sacrifice the life of a single person for the benefit of others.

### **Para 13.1.1.2**

The Committee should further define what they mean by 'informed consent' – for example, what is the nature of the information required and how much of it are they

APPENDIX D

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SINGAPORE SCIENCE CENTRE

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willing to disclose to the potential tissue donor. There should be a standardization of the quality and quantity of information given to the patient. Information should include not only the purpose of the tissue-taking but also the risks involved; the nature, location and quantity of tissue taken; how invasive the surgery would be, and so on.

General

The highly intellectual and well drafted consultation paper also exposes one thing. The subject, combining complex legal and scientific issues, is too "cheem" for the layman (Singapore word for esoteric).

The "fair picture" that is to be presented to the layperson donor could be elusive, if not impossible. The confidentiality promise will hard to enact, both in reality and in perception.

be

We need a campaign of public education, to take the meaningful dialogue beyond the legal and scientific experts. An exhibition, and a series of simple talks will go a long way to bring the subject into the consciousness of the general public. While their grasp of the technical issues will not be comprehensive, their collective moral views ought to really matter.

With best wishes.

Yours sincerely



Dr Chew Tuan Chiong  
Hon Secretary

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## SINGAPORE CANCER SOCIETY

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16<sup>th</sup> May 2002

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Assoc Prof Terry Kaan  
Chairman  
Human Genetics Subcommittee  
Bioethics Advisory Committee  
250 North Bridge Road  
# 15-01/02 Raffles City Tower  
Singapore 179101

Dear Assoc Prof Kaan,

### RE: Consultation Paper on Human Tissue Research

Thank you for your letter and the consultation paper on Human Tissue Research. We would like to inform you that we have no feedback on the consultation paper.

Thank you.

Sincerely

Dr Khin Khin Win  
Medical Administrator





Singapore General Hospital  
*A Tradition of Caring & Excellence*

11 March 2002

A/Prof Terry Kaan  
Chairman, Human Genetics Subcommittee  
Bioethics Advisory Committee  
250 North Bridge Road  
#15-01/02 Raffles City Tower  
Singapore 179101

Dear A/Prof Kaan,

**REQUEST FOR FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE**

Thank you for your letter dated 27 February 2002.

I am pleased to enclose SGH Ethics Committee's feedback on the HGS consultation paper for your attention.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Woo Keng Thye'.

Prof Woo Keng Thye  
Acting Chairman  
Medical Board

enc





## Singapore General Hospital

### MEMORANDUM

To : Ag CMB  
From : Dr Aw Swee Eng, Chairman, Ethics Committee  
Date : 8 March 2002

#### REQUEST FOR FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE

The members of the Ethics Committee are in general agreement with the well-crafted document. It is open-ended enough to accommodate any changes that will crop up when there is a better understanding of the issues.

I am not clear about the implications of 11.5. It is here suggested that "the jurisdiction of the DMS under the Private Hospitals and Medical Clinics Act be extended to all individuals and bodies (and not just healthcare establishments, hospitals, medical clinics and clinical laboratories) minded to engage in the conduct of tissue banking."

Although the reason is to place both non-medical researchers (who are not subject to the provisions of the Act) and medical researchers alike on a level playing field, the net is too wide. The difficulty will come in the direction, enforcement and supervision of such individuals or bodies in regard to the ethical and operational guidelines that the appropriate authorities may impose on them.

Moreover 11.5 contradicts the spirit of the guidelines laid down in 5.5 - 5.8 with reference to the subject of tissue banking. In particular, 5.8 states:

"Consolidation of smaller human tissues in larger institutional holdings confers many benefits. A larger institution has more resources for the proper maintenance and stewardship of human tissue samples under its charge."

The section on Informed Consent is acceptable. The details on anonymisation and data escrow arrangements need to be fleshed out.

There are some minor amendments:

- 13.1.1.6 The words "to be accessed" should be added to the end of the sentence.
- 13.1.1.8 "principle" should be "principal" and "practise" should be "practice".

Thank you.

A handwritten signature in black ink, appearing to read 'Aw Swee Eng'.

Dr Aw Swee Eng  
Chairman, Ethics Committee

Page 1 of 1

2 College Road Level 2  
Alumni Medical Centre  
Singapore 169850



Tel: 223 1264 Fax: 224 7827  
Email: sma@sma.org.sg  
Website: www.sma.org.sg

Our Ref: SMA/148HTR/2002

22 March 2002

Prof Lim Pin  
Chairman  
Bioethics Advisory Committee  
250 North Bridge Road  
#15-01/02 Raffles City Tower  
Singapore 179101



By Mail & Fax: 68379190

Dear Prof Lim

**REQUEST FOR FEEDBACK REGARDING  
HUMAN STEM CELL RESEARCH IN SINGAPORE**

Thank you for the letter of 27 February from Prof Terry Kaan inviting the SMA to provide feedback on the Consultation Paper on Human Tissue Research.

While we are considering your HGS Consultation Paper, we are already encountering the commercial overture of human tissue collection and banking. Some of our O&G colleagues have been approached by commercial enterprises with offers of compensation for collection of cord blood.

We would like to request the inclusion of the "ethics of compensation for collection of cord blood" in your HGS paper. We look forward to receive an interim statement from the BAC which we may circulate to our doctors and to commercial companies which are making such enquiries.

The SMA stand is that such transactions should be forbidden until the BAC has considered the matter and come up with a statement.

Yours sincerely

A handwritten signature in black ink, appearing to read "GOH LEE GAN".

**A/PROF GOH LEE GAN**  
Chairman  
SMA Ethics Committee

cc: A/Prof Terry Kaan, Chairman - Human Genetics SubCommittee, BAC  
Dr Lee Suan Yew, President, Singapore Medical Council  
Prof Tan Chorh Chuan, DMS, MOH

2 College Road Level 2  
Alumni Medical Centre  
Singapore 169850



Tel: 223 1264 Fax: 224 7827  
Email: sma@sma.org.sg  
Website: www.sma.org.sg

Our Ref: SMA/148HTR/2002

28 March 2002

A/Prof Terry Kaan  
Chairman, Human Genetics Subcommittee  
Bioethics Advisory Committee  
250 North Bridge Road  
#15-01/02 Raffles City Tower  
Singapore 179101

Dear Prof Kaan

**REQUEST FOR FEEDBACK REGARDING  
HUMAN TISSUE RESEARCH IN SINGAPORE**

Thank you for your letter of 27 February and the enclosure. We are grateful for the opportunity accorded to us to review the HGS Consultation Paper.

We have found the HGS Consultation Paper to be a well-thought-out paper which encompasses the various aspects that require consideration. We have no further suggestions to add with regard to the content of the paper.

As submitted by A/Prof Goh LG, Chairman - SMA Ethics Committee, on 22 March, we would however like to request for the inclusion of the BAC's stand on "ethics of compensation for collection of cord blood". We look forward to receiving the interim statement of BAC on this issue for circulation to the medical profession and commercial companies that make enquiries. Our view is that such transactions should be forbidden prior to the receipt of the BAC statement.

One of our members has taken the liberty to edit the layout of your recommendations, and the draft of this editing is attached as an annex for your consideration.

Yours sincerely

A handwritten signature in blue ink, appearing to read "Low Cheng Hock".

**PROF LOW CHENG HOCK**  
President  
for 42nd SMA Council

Enc:



## REQUEST FOR FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE

The following minor changes are tabled for consideration from syntax point of view.

1. para 2.1 (on page 3) - to delete the words "kinds of"

"2.1. In this Paper, we use the term "**human tissue**" to refer to all human biological materials derived from living or cadaveric donors, including solid body tissues, organs, foetuses, blood and other body fluids and their derivative thereof.

2. para 2.2. (on page 4) – to change the word "ones" to "uses"

"2.2 As blood banking is already well-regulated in Singapore, we exclude **bloodbanking for therapeutic purposes** from the ambit of this review, and do not include it in our definition of "**tissue banking**". However, we do include in our definition research involving studies of blood collections (whether the original samples were collected for therapeutic or research objectives, or a combination of both) or the use of such blood samples or their derivatives for purposes other than direct therapeutic uses such as transfusions.

3. **Para 8. (on page 10) - Consent Generally to amend to read "Informed Consent"**

8.1. Full, free and informed consent is the cornerstone of the legal and ethical legitimacy and validity of a gift of human tissue intended for research.

4. Para 13. (on page 17) we suggest to amend by deleting the words " and to replace with

"13. We recommend the Adoption of 8 Ethical Principles <sup>(2)</sup> as a starting point for this dialogue:

5. **Primacy of the Welfare of the Donor.** (page 18) - we suggest to amend as "13.1 Respect the Primacy of the Welfare of the Donor".

6. para "13.1.1.1" to be amended to read as "13.1.1"

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

7. **"Informed Consent" to number the para as "13.2"**

8. **"13.1.1.2" to renumber as "13.2.1"**

13.2.1 No tissue shall be taken, or shall be accepted, unless the full, free and informed consent of the donor has been obtained...

- "13.1.1.3" to renumber as "13.2.2"  
"13.1.1.4" to renumber as "13.2.3"  
"13.1.1.5" to renumber as "13.2.4"  
"13.1.1.6" to renumber as "13.2.5"
9. "**Respect for the Human Body**" to number as "para 13.3"
  10. **Paragraph 13.1.1.7** to renumber as "13.3.1"
  11. To start new paragraph and number as "13.3.2" at "Researchers and tissue bankers should always ensure that donors and the families of donors fully understand the extent of the intended gift. ...."
  12. "**Donations to be Gifts**" to be numbered as para "13.4"  
"13.1.1.8" to renumber as "13.4.1".
  13. Amendment to the paragraph as follows:  
*"13.4.1 Research tissue samples for use in research as outright gifts. Donors should not be paid any financial incentives for the donation, ....of such discovered in the course of research on the sample."*
  14. To start new paragraph and number as "13.4.2" at  
"Likewise, researchers and 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. ...."
  15. "**Ethical Review of Research Proposals and Access Requests**" to renumber and be amended to read as "**13.5 Set up Ethical Review Bodies**".
  16. **Paragraph "13.1.1.9"** to be renumbered as "13.5.1"
  17. To start new paragraph 13.5.2 at "The appointment, and constitution of such ethics committees or review boards should be as transparent as is practicable."  
"13.1.1.10" to renumber as "13.5.3"  
"13.1.1.11" to renumber as "13.5.4"
  18. "**Confidentiality**" to number as "13.6" and to amend as "**Respect Confidentiality of donors and relations**"
  19. "13.1.1.12" to renumber as "13.6.1"
  20. "13.1.1.13" to renumber as "13.6.2"

21. "Institutional Tissue Banking" to number as "13.7" and to amend as "Limit Tissue Banking to Institution"
22. "13.2" to number as "13.7.1"
23. "Ethical Governance of Operational Aspects of Tissue Banking" to number as "13.8" and to amend as "Set up Statutory Authority for Tissue Banking Governance"
24. "13.3" to renumber as "13.8.1"  
"13.4." to renumber as "13.8.2"  
"13.5" to renumber as "13.8.3".  
"13.5.1." to renumber as "13.8.3.1"  
"13.5.2." to renumber as "13.8.3.2"  
"13.5.3. " to renumber as "13.8.3.3"  
"13.5.4." to renumber as "13.8.3.4"  
"13.5.5." to renumber as "13.8.3.5"  
"13.5.6." to renumber as "13.8.3.6"  
"13.5.7." to renumber as "13.8.3.7"  
"13.5.8." to renumber as "13.8.3.8"  
"13.5.9." to renumber as "13.8.3.9"
25. "Initiating An Ethical Dialogue" to number as "14" and to amend as "Invitation of the Professions and the Public to an Ethical Dialogue"
26. To delete the numbering "13.6" but to keep the whole paragraph intact
27. "Resolution of Legal and Ethical Issues in Relation to Ownership and Custody" to number as "15" and to amend as "Resolution of Ownership and Custody Rights to Donated Human Tissues"
28. To delete the numbering "13.7" but to keep the whole paragraph intact.



## SINGAPORE MEDICAL COUNCIL

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Our Ref: SMC 14.2 Vol. 6  
Your Ref:

Tel: 6392 3070  
Fax: 6221 0558

9 April 2002

A/Prof Terry Kaan  
Chairman  
Human Genetics Subcommittee, BAC  
250 North Bridge Road  
#15-01/02 Raffles City Tower  
Singapore 179101



Dear A/Prof Kaan

### REQUEST FOR FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE

I refer to your letter dated 27 Feb 2002.

2. The Medical Council's comments on the issues outlined in the BAC's Consultation Paper are at Annex.
3. Please let me know should you require further clarification.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Lee Suan Yew".

DR LEE SUAN YEW  
PRESIDENT  
SINGAPORE MEDICAL COUNCIL

Annex

**SINGAPORE MEDICAL COUNCIL'S FEEDBACK ON BAC'S CONSULTATION PAPER ON HUMAN TISSUE RESEARCH**

Paragraph 5 – Human Tissue Banking in Singapore

- (a) Clear guidelines must be set as to what type(s) of "institutions" can have tissue banks. Preferably these should be not-for-profit institutions.
- (b) Centralisation of tissue banks is important for certain tissues that will benefit multiple groups doing research in the same area(s). However, smaller research groups with specific needs for certain tissues must not be prevented from collecting tissues if done in the proper manner. Where the storage of tissues is liberalised, it should be within the guidelines of legislature and professional ethics.
- (c) Confidentiality of the donor must be protected at all times - anonymisation of the tissues is important to protect the donor.
- (d) Legacy tissues collected in good faith at a time when there was a lack of any clear ethical, professional or legal guidelines governing the collection of such tissues should not be discarded as they are a valuable source of material. Anonymisation of the donors of the tissues should be done and the tissues can then be used for research purposes.
- (e) Agree that purpose-assembled research banks may be encouraged provided that all appropriate ethical and legal considerations and concerns are appropriately met and addressed.

Paragraph 8 – Consent Generally

- (f) When taking consent for tissues for research purposes, proper counselling must be done so that the patient knows that refusal to donate tissues for research will not affect his treatment in any way.
- (g) Consent for specimen collection for diagnostic or therapeutic purposes should be totally de-linked from consent for use of same specimen for research i.e., both consents should not be requested together. The consents should be so separated by time and place that a patient could not possibly feel any pressure to provide the latter consent, believing (albeit incorrectly) that diagnosis and therapy for an illness could somehow be linked to consent for research. For example, the latter consent could only be obtained after a patient has successfully completed treatment for an episode of illness. If the patient dies, then the family should be asked for a

second consent later. Careful and compassionate explanation/counseling would be in the best interest of both the patient and researcher.

- (h) The concept of 'absolute gift' is attractive, but it does not address the right of a donor to object to some uses of his tissue. For example, a donor may object to the use of his tissue for reproductive or therapeutic cloning or for transplantation into another person. While it is an easy option to ask for blanket consent, patients' concerns may not be satisfactorily addressed.
- (i) Concerning the issue of 're-consent', it may be helpful to have a concept of 'statute of limitations'. For example, after a certain reasonable time, no further consent should be required for further use of a tissue sample for new purposes that were unknown at the time of original consent.

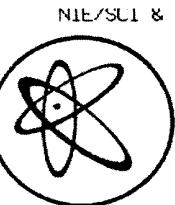
Paragraph 9 – Consent and Legacy Tissue Collections

- (j) A concept of 'statute of limitations' may also be helpful in the case of legacy tissue collections.
- (k) Good stewardship includes the presence of an institutional review board. Where there is such an arrangement, there need not be another layer of bureaucratic control.

Paragraph 13.1.1.8 – Donations to be Gifts

- (l) Where the origin of a specimen is known, it could be unethical to withhold from a patient the knowledge of any information gleaned from the specimen that revealed a medical condition or predisposition or likelihood of disease, especially if intervention could change the likelihood or course of that disease. This needs to be addressed.

**APPENDIX D**



NIE/SCI & TECH EDU

Fax: 65-68969450

Apr 6 2002 12:46 P.01

**SINGAPORE NATIONAL ACADEMY OF SCIENCE**

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**PATRON**

Dr Teh Chin Chye

**CONSTITUENT MEMBERS**

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Singapore (IPS)

Science Teachers  
Association of Singapore  
(STAS)

Singapore Association  
for the Advancement of  
Science (SAAS)

Singapore Institute of  
Biology (SI Biol)

Singapore Mathematical  
Society (SMS)

Singapore National  
Institute of Chemistry  
(SNIC)

Singapore Institute of  
Statistics (SIS)

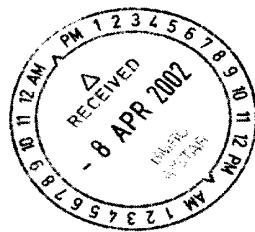
Singapore Society for  
Microbiology &  
Biotechnology (SSMB)

Singapore Society for  
Biochemistry &  
Molecular Biology  
(SSBMB)

4 April 2002

A/Prof Terry Kaan  
Chairman  
Human Genetics Subcommittee  
Bioethics Advisory Committee  
250 North Bridge Road  
#15-01/02 Raffles City Tower  
Singapore 179101

Fax: 68379190



Dear Prof Kaan

**CONSULTATION PAPER ON HUMAN TISSUE RESEARCH  
IN SINGAPORE**

Thank you for your letter of 27 Feb, inviting our Academy to provide feedback on the consultation paper prepared by your Subcommittee on human tissue research in Singapore.

Our Academy recognizes that it is a difficult issue to comment on. Whilst the study appears balanced to some members of our constituent societies, others have given some inputs, with a view towards contributing to the fine-tuning of certain aspects of the consultation paper. These are summarized below:

**Para 8.4 and 8.5**

It may not be fair to the donor if the gift is to be of an absolute one which requires the renouncing of entire rights so that all possible kinds of research procedures may be carried out on the donated human tissue sample. This also includes those relating to the renouncing of all rights to possible future financial gains or benefits.

**Para 13.1.1.1**

Details need to be provided as to what criteria are used to decide whether the potential benefits of tissue-taking outweigh the potential risks to the patient. For instance, in major breakthroughs in research, the financial rewards and prestige from the researcher's viewpoint

**APPENDIX D**

NIE/SCI & TECH EDU

Fax:65-68969430

Apr 6 2002 12:47 P.02

would obviously seem to outweigh the risks to the patient. However, from the latter's viewpoint, the risks incurred are of greater significance than the researcher's reward. Are we willing to sacrifice the life of a single person for the benefit of others?

**Para 13.1.1.2**

The Committee should further define what they mean by 'informed consent'-- for example, what is the nature of the information required and how much of it are they willing to disclose to the potential tissue donor. There should be a standardization of the quality and quantity of information given to the patient. Information should relate to not only the purpose of tissue-taking but also the risks involved; the nature, location and quantity of tissue taken; how invasive the surgery would be, and so on.

Generally speaking, the recommendations of the Committee should apply not only to tissues taken within Singapore but also to tissues taken from sources outside Singapore for use (research or diagnostic) within the republic.

With best wishes.

Yours sincerely



Professor Leo Tan Wee Hin  
President



**Singapore National Eye Centre**

11 Third Hospital Avenue Singapore 168751  
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3 April 2002

Assoc Prof Terry Kaan  
Chairman  
Human Genetics Subcommittee  
Bioethics Advisory Committee  
250 North Bridge Road  
#15-01/02 Raffles City Tower  
Singapore 179101

Total No. of Pages: 3  
(including this page)

Dear Terry,

**CONSULTATION PAPER ON HUMAN TISSUE RESEARCH  
EXTENSION OF DEADLINE FOR SUBMISSION OF FEEDBACK**

I refer to the abovementioned matter.

Please find attached the comments from our Ethics Committee for your attention.

Please do not hesitate to contact me at Tel: 6 3228323 should you require any classifications.

Thank you.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'DR ANG CHONG LYE'.

DR ANG CHONG LYE  
Director



FAXED & post  
DATE: 03/04/02

**Branches & Affiliated Centres**

- \* Changi General Hospital (Clinic G & Q)
- \* KK Women's and Children's Hospital (Clinic E)
- \* Mount Alvernia Hospital (Medical Centre Block E)
- \* National University Hospital (Eye Clinic)
- \* Singapore General Hospital (L Clinic)
- \* SNEC Eye Associates, Mount Elizabeth Hospital

A member of SingHealth

12/03/2002 11:13 EYE CLINIC SINGAPURA → 62277291

NO. 308

D02

**REQUEST FOR FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE**

As in all medical ethical issues, we are concerned for the patient --- his safety, and his rights.

**Item**

- 4.4 If the tissue collection is done primarily for research, then the risk (if any) of the collection or harvesting should be explained to the patient / subject, and informed consent taken. E.g. in the eye, removal of an early pterygium for research purposes, should be explained to the patient as risky, as it can cause a recurrence which is worse than the primary condition. See Items 5.9 and 13.1.1.1
- 2.2 A safety limit should be specified for Blood collection, which should not exceed, say, 50 ml. per subject at any one time. Otherwise the subject will need to have his Hb level checked.
- 2.1 We should separate human tissues derived from the living and those derived from the dead. In the case of cadaveric donors, safety is no more a concern ; they are governed by the Medical (Therapy, Education & Research) Act, and the Human Organ Transplant Act. See Items 6.2 & 6.3. We should also separate embryonic stem cell research and cloning, as stated in Item 2.3, which depend very much on whether you think an embryo is a person having all the rights of a person, but cannot give consent.
- 4.2 We should separate genetic (and genomic) research which is governed by the "Ethical Guidelines for Gene Technology" published in February 2001 by the National Medical Ethics Committee.
- 8.4 This is important, as in the case of cancer patients who die before the research is over. In order to avoid claims from heirs, it is best to anonymise the tissue. Anonymisation will also prevent breach of confidentiality, and use by health and insurance companies.
- 8.8 It is important that, as stated here, the research applications are approved by an Independent Ethics Review Committee, which ensures the scientific and ethical validity of the research work. See Item 13.1.1.9.

/2.

12/03 '02 TUE 11:13 [TX/RX NO 7445]

APPENDIX D

12/03/2002

11:13

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D03

- 2 -

This would also apply to taking of tissues (e.g. blood) for research work on Emergency Cases, where consent may be difficult to obtain.

Will researchers be allowed to distribute tissues to other centres in other countries when requested for ?

- 13.1.1.10      The social, religious and political issues, implications and reactions have not been dealt with, and must be sought for, especially with regard to embryonic tissues. Whether one believes the embryo is a person or not depends very much on religious belief. Also, the cultural belief that one must go to Heaven with an intact body has always been an obstacle in eye donation.
- 13.6

12/03 '02 TUE 11:13 [TX/RX NO 7445]

13/03 2002 10:58 FAX 65 3259211

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## SINGAPORE NURSING BOARD

13 Mar 2002

Assoc. Prof Terry Kaan  
Chairman  
Human Genetics Subcommittee, BAC  
250 North Bridge Road  
#15-01/02 Raffles City Tower  
Singapore 179101

Dear Prof Kaan

### REQUEST FOR FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE

Thank you for inviting the Singapore Nursing Board to provide feedback regarding human tissue research in Singapore.

We agree with the interim recommendations in para 13.

We would like to commend the Human Genetics Subcommittee for the comprehensive coverage of the potential ethical, legal and social issues related to human tissue research.

Yours sincerely

ANG BENG CHOO  
REGISTRAR



Level 4, Institute of Health, 3 Second Hospital Avenue, Singapore 168937 Tel: 2361996 Fax: 2361998

13/03 '02 WED 11:02 [TX/RX NO 9398] 001