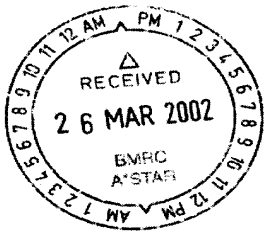
ACADEMY OF MEDICINE, SINGAPORE

PATRON: PRESIDENT OF REPUBLIC OF SINGAPORE

25 March 2002 (By fax : 65-8379190)



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

Dear Sir,

Re : Human Genetics Subcommittee Consultation Paper: Human Tissue Research

1. Thank you for asking the Chapter of Pathologists, Academy of Medicine Singapore to **comment** on the Consultation Paper on Human Tissue Research. We wish to state that we are in full support of the Bioethics Advisory Committee's (BAC) philosophy and principles as outlined in this paper and highly commend the suggestions framed within the Interim Guidelines. There are however a few areas that the Chapter would like to emphasize.

2. The Chapter strongly endorses the Bioethics Advisory Committee's stand on subsampling of tissue as outlined in paragraph 13.1.1.1. For this category where the sample of tissue is necessarily removed for the medical care of the patient, the duty of care is always, first and foremost to the patient. Hence the Chapter fully agrees that there should be no subsampling prior to analysis and examination of this tissue. This is especially so when fresh tissue is cryopreserved and banked for research. Without the reporting pathologist's input, tissue taken as 'non tumour ' tissue may contain small foci of primary tumours or may be marginal tissue required for prognostication.

3. The term '**human tissue banking**' is broad and fairly non specific in as much as it could be used to mean several very different entities. The Chapter is of the opinion that while there are issues in common, for instance of consent, confidentiality, governance and respect for the welfare of the donor, a distinction should be made between tissue banks assembled specifically for immediate patient therapy – as in skin grafts and bone grafts, versus research tissue banking, where tissue is assembled to facilitate medical education and medical research, both in the halls of academia as well as in the fields of industry. We believe that the comments regarding use of tissue archives in the BAC's paper refer to research tissue banking.

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4. The Chapter applauds the council's view on **good stewardship** of tissue, as stated in paragraph 9.5. The Chapter fully agrees and has stated in its own position paper on Ethical Laboratory Practice, that researchers should not be refused access to archival (stored) tissue. However, the Chapter would like to point out that pathology departments holding diagnostic tissue, that is samples on which diagnosis were based, have a duty to ensure that there is sufficient tissue remaining for possibility of satisfying diagnostic or medicolegal challenges and for future prognostic or therapeutic tests.

   Patients may seek treatment in other countries or institutions, and often this is accompanied by a request that diagnostic tissue be submitted for revaluation by their diagnostic team. Therapeutic agents may arise some years after the primary diagnosis of a tumour. Two examples of newly developed cancer therapies are Herceptin for Breast Carcinoma and Glivec (STI571/imatinib) with respect to Intestinal Stromal Tumours. The guidelines concerning effective use of these agents recommend that positive expression of specific tissue markers are sought prior to initiation of treatment. Had all tissue been released for research on completion or issuance of the report, there would have been no archival tissue left to submit for revaluation or on which to perform such tests. It is for these reasons that the Chapter, in line with other Colleges of Pathology advocate that where possible, the laboratory should keep sufficient diagnostic tissue to meet potential challenges.

5. The establishment of a research tissue bank using **'surplus'** tissue is important in the development of medical and biological research. The Chapter fully appreciates the fact that issues of conflict of interest are circumvented by the BAC's suggestion in paragraph 8.7, for separating the process of consent for donation of 'surplus' tissue (with respect to form and person obtaining consent) from that of the therapeutic or diagnostic procedure. The Chapter hopes that should these recommendations be upheld, that the agencies involved in tissue procurement will use professional trained (and accredited) personnel, as this is a time when the patient and family are most vulnerable. The Chapter suggests that information regarding the functions of research banking and the ultimate use of this donated 'surplus' tissue be made easily available to patients and members of the general public.

6. We would also like to draw attention to the fact that this **separation** of tissue for research versus tissue for medical diagnosis should and must extend to procedures pertaining to small biopsies where patients may be asked to donate tissue obtained by a second sampling, for medical research after the (taking of the) initial diagnostic sample. In this instance, this second sampling should not be regarded as 'surplus' to the first sample, as the primary purpose of this sample is research and not primarily for diagnosis. The purpose of this second pass or 'bite' should be clearly distinguished from the diagnostic sample.

7. In matters of **governance**, the Chapter supports the BAC in its recommendation for a national level committee comprising experts from relevant fields to oversee tissue banking in Singapore (Paragraph 11.8). The Chapter would like to underscore the importance of including medical research scientists and pathologists in institutional and national committees that involve research on human tissue. Tissue that is altruistically donated to the community should be put to optimum use, with the strictest of quality controls (inclusive of biohazard issues) and audit. Pathologists would have the training and expertise to advise on this.

We wish to state that the Chapter's views are made in line with **best professional practices** and with the welfare of the patient first and foremost. The duty of the doctor is firstly to his patient, and then to investigate and study disease. We as pathologists hold these values dearly. We hope our comments have been of use to your committee. Please feel free to contact us should you require any further clarification or information.

Thank you.

Yours sincerely

Dr Angela Chong
Chairperson
Chapter of Pathologists 2001 - 2002

ACADEMY OF MEDICINE, SINGAPORE

PATRON: PRESIDENT OF REPUBLIC OF SINGAPORE

2 April 2002

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

Dear Assoc Prof Kaan

Consultation Paper on Human Tissue Research

Your letter dated 27 February 2002 to the Master requesting for feedback regarding the consultation paper on Human Tissue Research is referred. The Academy of Medicine has no further comments to add.

Yours sincerely

Ms Monica Wong
Executive Director

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A/Prof. Rajasoorya
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18 March 2002

A/Professor Terry Kaan
Chairman
Human Genetics Subcommittee, BAC
Bioethics Advisory Committee
250 North Bridge Road
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Singapore 179101

Dear Prof Kaan

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

Thank you for your letter of 11 March 2002. I have circulated this paper to some senior clinicians in my hospital and attached is a summary of our comments.

Yours sincerely

Clinical A/Prof C Rajasoorya
Chairman Medical Board

A/Prof. Rajasooriya
MBBS, MMed, FAMS, FRCP (E),FACE
Chairman Medical Board
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SUMMARY OF COMMENTS ON HUMAN TISSUE RESEARCH

The Human Genetics Subcommittee should be commended for coming up with this Consultation Paper. It is an important initiative and I agree that we need to set up guidelines and processes for governance in this area.

A re-consent is advisable, preferably after the tissue diagnosis is made known to patient, specifically whether the tissue concerned is to be donated for research, or dispose of after a certain time frame. Since the diagnosis is already known and a treatment plan in place, it would not matter if the person who obtains this second consent is the same or different from the one who obtains consent for the procedure. This "re-consent" should be 'general' and not linked to a specific research project and 8.8 can follow.

Item 8.5
How are you going to settle the dispute if a donor later discovers that his tissues contain the genetic code that confers immunity to an incurable disease like AIDS and that code led to the manufacture of an antibody or vaccine that cures AIDS. The company can practically make millions or billions of dollars and this donor who is now in debt, wants some share of the fortune. May be better to decide on the quantum of compensation and make it into a law so that the company must pay whether the donor signs his tissue away for free or not. This will avoid costing disputes.

How are you going to police institutional staff from "selling" tissues to private companies for making a product that can be an economical success?

The genetic code on which the product is made must be traceable to the donor identity and this must be kept in the institution. Suppose the company refuses to reveal where the genetic code – how are you going to find out if it came from an institution and whether it was released to the company for R and D.

The current pace of development in genetic and genomic science is indeed very rapid. Hence the 'makers' of the rules and regulations must be nimble enough to not just respond to the changes but also have the foresight of impending change. It is difficult, but we do need "specific rules" (11.1) as the stakes are very high.

1 April 2002

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

Dear Assoc Pro Terry Kaan

CONSULTATION PAPER ON HUMAN TISSUE RESEARCH
EXTENTION OF DEADLINE FOR SUBMISSION OF FEEDBACK

I refer to your letter to Mr Bertie Cheng, Chairman Board of Directors, Ang Mo Kio Community Hospital dated 11 March 2002

There is no feedback from Ang Mo Kio Community Hospital. Human Tissue Research is not done in our Community Hospital.

Thank you.

DR LAU HONG CHOON
Hospital Administrator

Biomedical Engineering Society (Singapore)
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March 28, 2002

Assoc Prof Terry Kaan
Chairman, Human Genetics Sub-Committee
Bioethics Advisory Committee
250 North Bridge Road
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Dear Prof Kaan,

Request for feedback regarding human tissue research in Singapore

Thank you for sending the above-mentioned to our Society for our perusal and feedback.

Our Executive Committee met on the 27th March 2002 to review the document. We found the document to be balanced, on one hand ensuring that patients and donors' safety and rights are well protected, and on the other hand enabling human tissue research to progress without undue hindrance and having safe guards to minimize abuse. We found the Interim Recommendations to be adequate.

While the patients and donors' safety and rights are adequately address in the document, the committee felt that related issues such as the quality of staff and facilities involved in human tissue banking are just as important with regards to "Respect for the Human Body" and protection and safety of staff involved in such activities. It is not certain whether these related issues fall under the purview of BAC's, nevertheless they need to be addressed.

Thank you.

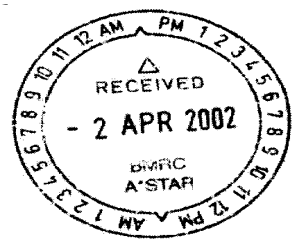
Yours sincerely,

Assoc Prof James Goh,
Vice-President

CHANGI GENERAL HOSPITAL

DEPARTMENT OF RADIOLOGY

Dr Khoo Teng Kew
MBBS, DMRD, FRCR
Senior Consultant & Chief



1 April 2002

Assoc. Prof Terry Kaan
Chairman
Human Genetics Subcommittee
Bioethics Advisory Committee
250 North Bridge Road
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Singapore 179101

Dear A/Prof Kaan

REQUEST FOR FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE

Thank you for the opportunity to give some feedback on the consultation paper on human tissue research.

I have taken the liberty to circulate to members of Medical Ethics Committee, Changi General Hospital, the consultant paper.

A/Prof Stella R Quah from the Department of Sociology, NUS brought up two relevant points:

Paragraph 8 – Item 8.2:

Tissue bankers have the obligation to obtain consent to the donation of the gift. This obligation should not be qualified "where it is practical to do so" because such a qualification invalidates this principle. In situations where the tissue bankers find it impossible to obtain consent, they should be required to present their case for discussion and approval by the respective appropriately constituted research ethics committee or institutional review board (described in item 13.1.1.9).

2 **Recommended Ethical Principles – Informed Consent – Item 13.1.1.5**

"in specific situations it may be ethically acceptable to proceed without consent ..."
This item should apply ONLY to the legacy tissue collection given the difficulty of tracing donors who donated tissue several decades ago.

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Page 2

Mr William Toh, another member of the MEC contributed the following comments:

1 **Consent**

The consent form should try to list down possible uses/research of the tissue donated, in case some intentions are objectionable(ie. cloning).

2 **Confidentiality**

Tissues should be coded and such codes is only breakable by legal authorities (eg. court of law) for reasons of such magnitude the court deem justifiable.

3 **Ownership**

There should be a clause that restricts sale or transfer of ownership.

How about safeguards against theft and sabotage?

Yours sincerely

DR KHOO TENG KEW
Chairman
Medical Ethics Committee

Cc: Chairman, Medical Board(CGH)
Hon. Secretary, Medical Ethics Committee(CGH)

Faculty of Medicine
Dean's Office

NUS National University of Singapore

13 May 2002

Assoc Prof Tery Kaan,
Chairman, Human Genetics Sub-Committee,
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 is Singapore

Thank you for sending the above-mentioned to our Faculty for feedback and perusal.

Attached are our comments on the BAC HGS Tissue Research Consultation Paper.

Thank you.

Yours sincerely

Prof Lee Eng Hin
Dean

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Comments to BAC HGS Tissue Research Consultation Paper

Para 5.7

In the first sentence, "...tissue banks should be held by institutions...", although some examples are given, there is otherwise no definition of "institution". Is there a need to define it? Does a biotech company that does research come under the definition of "institution"? Can an "institution" be purely profit-driven, or must it be solely non-profit or not-for-profit?

With regard to the Faculty of Medicine, NUS, it is important to note that most tissue samples are collected as part of investigator-initiated research projects approved by a Research and Ethics Committee. These samples are not housed in any centralized tissue bank but are located in the various research laboratories within the Faculty premises. There are no centralized facilities for tissue storage, and no funds to establish and maintain such a facility, within the Faculty. Also the majority of projects are non-overlapping, except for certain projects studying common diseases such as cancer, heart disease, and diabetes.

We thus support a position that there is no need and no benefit from centralizing the storage of research tissues used in the majority of research projects conducted in the Faculty of Medicine. We do however agree with the need for tissue banks for certain tissues involving disorders which may be of interest to multiple research groups, as this will simplify access to them. In fact, there already exists a tissue bank at the National University Hospital for the storage of tumors and other cancer tissues.

Para 8.7

We feel a clear distinction must be made between the use of tissue leftover from clinical testing for purposes of laboratory QC/QA and test development/validation, and use of tissues in research. Test QC/QA and development/validation are absolute necessities in all clinical diagnostic labs; unfortunately, without actual patient samples these cannot be accomplished satisfactorily and the validity of all tests become suspect. It is the standard practice of clinical laboratories worldwide to retain samples that have tested "positive" as "positive control" samples for subsequent testing of other patient samples (not all samples that are tested will be positive for the tested disease). So long as confidentiality of patient identity is maintained (which is not an issue in clinical laboratories), and all leftover samples are used within the laboratory, clinical laboratories must be allowed to utilize leftover patient samples for clinical purposes (as positive controls for test QC/QA, development, and validation).

With regard to research use of leftover material, many diagnostic laboratories in the United States provide consent forms which include a section on consent for use of leftover tissue for research. The question of whether patients are under the impression that they might or might not get the best care has never arisen, because the tissues are taken by referring physicians who use the forms provided by the referral laboratory. There is also no question as to different standards of care from the same laboratory, as all tests are fee-for-service. The physicians also do not have a vested interest in whether or not patients consent to use of samples for research.

We agree that the situation in Singapore hospitals may be different, with laboratories and physicians working under the same institution. However, simply separating the consent for tissue donation for research from the consent for testing, and requiring different people to take consent for testing and for research, will not allay patient fears. They only serve to give the impression to others that consent for research use of leftover tissue is freely given, but create more paperwork and manpower requirements, thus substantially raising the "cost" of

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research and medicine. This is because the "different" people taking consent for testing and research use will still be construed by patients as being part of the same team.

It is more important to ensure that when consent to use leftover tissue for research is requested, that patients are fully informed of their absolute right to refuse, and assured that their decision will not impact their disease management.

Central to the fears of patients in donating leftover tissues for research is the issue of confidentiality, as these samples will be studied in a research setting. We are in favor of following the practice in the United States of allowing samples leftover from testing to be used for research purposes after samples are completely anonymized, with no possibility of patient identification and recontact.

Paras 8.8 and 8.9

We strongly support the idea of delinking tissue donation from research purpose, but would like to see this option made available to all tissue donations, not only in the context of centralized tissue banks but also for investigator-initiated research projects.

The rationale is that delinking of tissues with research purpose will make tissue collections much more useful to other researchers, who may need the samples to look at other diseases. Re-consent is a major obstacle to the use of stored tissue that is hampering new research in the United States. Since all human research requires approval by Research and Ethics Committees under a standard set of guidelines, the question of improper use of tissues will not arise.

Para 9.6

With regard to legacy tissues from which no consents were originally sought, we suggest that the best strategy to ensure patient confidentiality while not "wasting" precious research resources is to anonymize these samples by removal of all patient identifiers to ensure that there is no possibility of patient identification and recontact.

Para 10.8

We wish to draw attention to another common situation, that of samples leftover from clinical tests for which either no research consent had been obtained, or consent was given only for a specific research project. Recontact of such patients for consent to perform a new research project may be difficult, especially for samples tested a long time ago and for referral laboratories which had no initial direct contact with patients. Such samples should be allowed to be used for research after proper and complete anonymization procedures.

Para 13.1.1.3

As we have stated in our comments to Para 8.7 above, our position is that a clear distinction must be made for samples leftover following diagnosis or treatment that are used within the clinical laboratory for QC/QA and test development and validation purposes. The confidentiality of patient identity is maintained as these samples are utilized within the clinical laboratory. It is critical that clinical and diagnostic laboratories continue to have access to test-positive patient samples for diagnostic or therapeutic purposes, and these samples should not be subject to the same informed consent requirements pertaining to research, if such laboratories are to function properly.

For the category of samples leftover following diagnosis or treatment that are used for research purposes, we recommend the continued use of clinical test consent forms which include a section on informed consent for research. The informed consent should clearly indicate the nature of research, or should clearly state that the samples are not linked to any specific research. The patients should be assured that their decision to decline donation will not impact their disease management in any way. We feel that in the Singapore context, proper counseling of patients is more important than mechanisms construed to give the impression of impartiality, such as separate consent forms for research and different people for taking clinical and research consents.

Finally, for clinical test samples for which no consents for research were obtained, such leftover samples should be allowed for research purposes provided proper anonymization of samples has been performed. Of course, proper informed consent is the preferred method for research uses, because it would allow re-contact of patients should the need arise, such as to obtain more epidemiological and/or family history information. However, sample anomymization provides a reasonable alternative to utilize rare and/or interesting samples for research purposes that do not require re-contact of patients, family history information, or any information that could identify the patients.

Paras 13.1.1.4 and 13.1.1.5

We similarly feel that with regards to legacy tissues and non-legacy portions of tissue banks, sample anonymization be provided as an option of last resort so that precious and rare samples can be used for research instead of being consigned for destruction.

Comments from Faculty of Medicine, NUS.

Assoc Professor Terry Kaan
Chairman, Human Genetics Subcommittee,
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250 North Bridge Road
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March 13, 2002

Re: Human Genetics Subcommittee Consultation Paper: Human Tissue Research

Dear Prof Kaan;

I want to congratulate your subcommittee on a remarkable draft of a new framework for human tissue research. I think, when implemented, it will propel Singapore to becoming a paradigm of ethical human research. My comments are more in terms of style, seeking clarification, and only occasionally addressing the substance of the document.

Specific Comments:

Section 8.7: The recommendation is for a decoupling of the consent for research on tissues and that for therapeutic consent. There is a growing movement for a tissue "consent" to be incorporated into standard admission or surgical consent forms. This is to obtain patient consent for the use of excess tissues procured during the conduct of standard-of-care procedures. The Subcommittee's comment in section 8.7 may be interpreted as a blanket prohibition against this. Is this your intent? If so, I would ask you to reconsider. I think that the incorporation of consent (with an opt out capacity) for use of excess material into the standard hospital surgical consent would not only validate the use of excess tissues for research, but can be used as a tool for educating/or engaging patients in the biomedical research enterprise.

Section 8.8/8.9: It is implied that delinking the consent for accession to that of a specific research process might solve the problem of reconsent. Though I am in agreement with this approach, but unless better described in this document and clearly structured, such an important operational concept might be rejected. I would urge an expansion of this section to provide a more extensive explanation.

Section 8.12: The comment "Consent given for the taking of tissue for a specific purpose does not necessarily authorize the use of the tissue for a different purpose..." appears contradictory to Section 8.8/8.9.

Section 10.8: The concept of data escrow has been raised, however, data escrow means many things to many people. I suggest that more space be devoted to define the concept better.

Section 13.1.1.3: This section states that patients should be informed when material left over following standard medical procedures are used for research. Here again, I would like to raise the possibility of a clause in the standard surgical or pathology consent forms for such a tissue accession procedures. Please refer to my comments on Section 8.7

General Comments/Overview:

I think the concepts that you have proposed are all correct and important. Several issues are of vital importance and would benefit from a presentation of clear models:

Legacy tissues: I recommend that in addition to the national forum/body that would decide on the management of these tissues, that you provide some models for how this problem can be resolved. For example one could recommend defining a clear set of guidelines (like the obtaining of a waver of consent through an IRB), the activation of the national IRB board to adjudicate these difficult legacy cases until a sufficient experience in "case law" has been achieved, and the activation of a data escrow system.

Data Escrow systems: It seems apparent that the establishment of a robust data escrow system is an essential solution to many of the ethical dilemmas we anticipate. For this reason, I recommend that the subcommittee be more forceful in describing the elements of a successful Data Escrow system. This can be used as a framework for development.

National IRB: I laud the strong recommendation in your document for the establishment of a national IRB. I would also recommend that the final subcommittee report include concrete models for how such a national body would look like.

Health care providers: Throughout the document, there were clear discussions of actions that would be deemed unethical and should be prohibited. However, there was no discussion as to the punishment that would follow some of these high level breaches of research ethics. I think there should be consideration of whether criminal penalties should be placed on the more egregious infractions. In addition, there should be a game plan in the final document on how the medical community will be educated in the details of the new regulations. This is key to the successful implementation of the new guidelines.

Prioritization of actions: I strongly suggest that the final report should include a prioritization of necessary actions for establishing the new regulatory framework

in Singapore. For example, establishing the national IRB/consensus body and the guidelines for a Data Escrow system should be considered first. These structures will be important in guiding the building of the other bodies.

Thanks for letting me participate in this important event. I would be happy to help in the implementation of the final recommendations.

With Best Regards,

Edison Liu, M.D.
Executive Director, Genome Institute of Singapore
Professor, National University of Singapore

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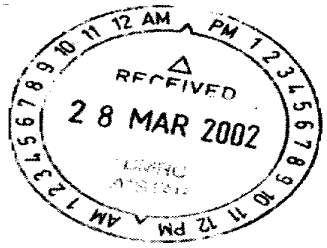
28 March 2002



Assoc Prof Terry Kaan
Chairman
Bioethics Advisory Committee
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Dear Prof Kaan

The Graduates' Christian Fellowship [GCF] would like to thank the bioethics advisory committee[BAC] for its consultation paper. We also acknowledge the sedulousness with which the BAC has presented the issues and regulations pertaining to the subject and its generally judicious and sensitive recommendations. Nevertheless we would like to provide the following brief feedback from a Christian point of view as represented by the GCF.

The Christian view of the human body:

In contradistinction to the secular, humanistic and naturalistic view that man is solely the result of a random, purposeless and evolutionary process taking millions of years, and thus is a highly sophisticated and complex molecular, computerized, biological robot imbued with an incredibly complex maze of neuronic circuits which in principle could be replicated in the future with the rapid advance in artificial intelligence research and advances in nanotechnology, Christians affirm that man is created in the 'image' of God. Thus a human being comprises both a physical body limited to the four dimensional spacetime continuum and a soul which is not constrained by this physical space time continuum and continues to exist after the physical death of the body. However, we also hold that a human being is a psychosomatic being who cannot express himself or herself in any other way except bodily as opposed to the traditional form of Cartesian dualism where the human body is perceived simply as a physical instrument to communicate what the 'soul' within it thinks. In the light of this, violation of human dignity occurs when the human body is not treated with due respect. The GCF 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 that researchers and tissue bankers need to be sensitive to religious and cultural perspectives and traditions'.

Areas of concern:

The GCF is of the view that human tissue research does present some ethical concerns with respect to the definition of human tissue. The BAC document states that human tissue refers to 'all kinds of human biological materials derived from living or cadaveric donors, including solid tissues, organs, fetuses, blood and other body fluids and their derivatives, cord blood, embryos, gametes or any part of derivative thereof.' From the Christian viewpoint, we view with concern the inclusion of fetuses and embryos in this definition. The GCF contends that the fetus and embryo constitute at the very least potential human beings and at a certain stage of development, become full human beings although the point of transition is unknown and has been and still is being debated and we are of the opinion that we will never know this with certainty.

In the light of the above, we are of the view that it is ethically acceptable to use fetuses and embryos that have perished because of spontaneous miscarriages for research. With regard to excess embryos created for IVF, we would not encourage the use of such embryos for research unless there are strong mitigating factors.

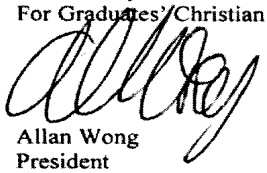
We are also of the view that it is unethical to abort the embryo and especially the fetus for research purposes. As for the creation of a human embryo in the laboratory for research, opinion is divided whether it is acceptable although the majority would probably be against it.

We agree that it is unethical to use gametes for research if they have been obtained through commercial transaction and to create hybrid individuals through the mixing of human and animal gametes.

As for the use of gametes for reproduction, we are unable to provide any firm recommendation at this stage.

We trust that our brief response maybe of assistance in your future deliberations.

Yours Truly
For Graduates' Christian Fellowship



Allan Wong
President

HP 24:03/31

11 April 2002

Health Promotion Board

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Chairman
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Dear Prof Kaan

CONSULTATION PAPER ON HUMAN TISSUE RESEARCH

Please refer to your letter of 27 Feb 2002.

2 The views of the Health Promotion Board's Ethics Committee were sought on the consultation paper "Human Tissue Research". The consolidated views of the members are stated below:

(a) Para 8.4

Members expressed concern about the right of donors to retract their consent should they object to any unstated purpose for tissue donated. Members are unanimous in that donors should still have a right over their tissues and should be free to withdraw their consent at any time rather than the tissues be considered as 'absolute gifts'.

(b) Para 8.10

Members are also concerned about cases where consent might be difficult to obtain eg incompetent or deceased. Members proposed that these tissues should either be considered as 'out of bounds' or clear guidelines must be given for these 'specific situations' as to the instances where consent can be referred to the designated Ethics Committee or institutional review board.

(c) Para 9.4

Some members were uncomfortable that it be assumed that legacy tissues were harvested in good faith and therefore can be utilised for research purposes without adequate consent. Another member is of the opinion that actions carried out prior to guidelines being set should not be penalised but wonders if future legislation would apply to legacy tissues as well and if so, at what length researchers would have to go to try and gain consent.

(d) Para 13.1.1.5

A member felt uncomfortable that the provision for proceeding without consent is not spelt out specifically. "In specific situations" can be opened to many interpretations. The scenarios should be specified (eg, deceased and next of kin not available).

(e) Para 13.1.1.8

Some members wondered whether free/discounted medical care/surgical fees/operation costs related to the removal of the tissue (either as a research or part of a diagnostic/therapeutic procedure) would be considered as the 'reimbursements' or would it be construed as 'payment' for the tissues obtained. Clear financial benefit/gain are objected.

(f) Section III

A member of the Committee commented that the revocation of an "irrevocable" donation is a major issue to be considered. The general thrust of the law, & attitude among the public, at present, is to protect the rights of individuals. To give researchers more teeth, statute must re-define rights of individuals & the needs of society. It will also be difficult for various ethics committees to bring about this shift in legal thinking, or to change attitudes.

It was opined that the paper must be discussed publicly and the public educated as to the facts before final decisions are made.

Yours sincerely

DR LAM SIAN LIAN
CHIEF EXECUTIVE OFFICER
HEALTH PROMOTION BOARD

Institute Of Mental Health
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9 Mar 2002

A/Prof Terry Kaan
Chairman
Human Genetics Subcommittee, BAC

HUMAN TISSUE RESEARCH IN SINGAPORE

I am responding on the behalf of Professor Kua Ee Heok, CEO of the Institute of Mental Health, to your request for feedback regarding your consultation paper which you and your subcommittee has prepared.
I am grateful for this opportunity to raise certain concerns on this very important topic.

A suggestion of "simplifying' the consent process involved in tissue banking is to delink it from research. It is also further suggested that it would be made clear to the donor that research applications are handled and approved by another independent body. Would the donor be told that although the tissue taken is primarily for diagnostic or therapeutic purpose(s), the leftover tissue could be used subsequently for research albeit after approval from a relevant body ? Does this mean that the informed consent of the donor (if still available) does not need to be obtained for subsequent research projects as ownership has now flowed to this body? If this is the case, then the individual is in effect being asked to sign a waiver of consent.
Your committee has rightly pointed out that consent process for tissue donation has two components. The first is the consent to obtain the tissue and the second is consent for the specific use(s) of this tissue. An individual may consent to have his or her tissue taken for a diagnostic purpose and may even give a broad

consent for the leftover tissue to be used for some future research. However, if one wants to be faithful to the spirit of informed consent where the emphasis is on *informed* , and if the donor does not know what sort of research is being done on his or her leftover tissue, it would therefore not be informed.

A tissue bank is a powerful and valuable resource for research material for present and future studies. It is the latter that is more problematic when it comes to obtaining consent because of the difficulties that your committee has highlighted. A solution is to ensure that data is "anonymised" and where the donor cannot be identified. In this case, a broad consent would have to be taken with the explicit understanding that the donor cannot be identified. In which case, new consent would then did not to be taken for research protocols that are not known at the time of tissue collection. While ethically this is acceptable, it would limit the utility of the tissue bank and precludes combinatorial analysis.

Another problem that may arise is when a research subject wants to withdraw from a project and exercise his or her right to have the donated tissue destroyed – would the delinking of data make this impossible or is the donation absolute in that the donor has no further right to it ? On the other hand, one could also argue that medical data of patients which are produced in the process of health care have been traditionally used for health care planning for the collective good of society. The cross-matching of medical records and tissue data (e.g. DNA) could potentially enable studies which may lead to significant advances in our knowledge of illnesses as well as economic gains – one of the driving force of Singapore's massive investment in the life sciences. At the micro level, there may also be benefits to the donors (provided there are measures to prevent discrimination) in that individuals at risk for a illness may be identified.

It is a difficult task that your subcommittee has undertaken and it is unlikely that all the subsequent recommendations would win universal approval. But there must be a commitment that whatever recommendations made and regulations

implemented, these would be reviewed and revised to make them relevant to advances in science and changes in our societal needs and values.

Yours sincerely

A/Prof Chong Siow Ann
Chairman
Research and Ethics Committee
Institute of Mental Health & Woodbridge Hospital

Copy to : Professor Kua Ee Heok

INSTITUTE OF MOLECULAR AND CELL BIOLOGY
An Institute Affiliated to
THE NATIONAL UNIVERSITY
of SINGAPORE

28 March 2002

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

Dear A/Prof Kann

REQUEST FOR FEEDBACK CONCERNING CONSULTATION PAPER ON HUMAN TISSUE RESEARCH IN SINAPORE

Thank you for your letter dated 27 February 2002 to Prof Hong Wanjin.

As per request, feedbacks from the Institute of Molecular and Cell Biology are as follows:

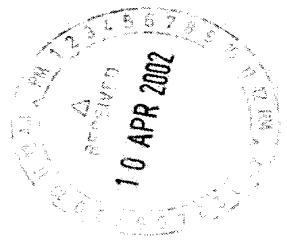
Feedbacks
1. Tissue banking: consider general access to all tissue banks for all Singapore researchers based on scientific merit of the proposed projects.
2. There should be only one "Human Tissue" Organization to cover everything from Genomic research, IVS, Blood, Pathological samples ... etc.
3. Points 8.5 and 8.7 are hard to define. With the advance in technology, any disease and non-disease human tissues are fundamental to development of diagnostics kits for commercialization.
4. It is best if a "law" could be passed for the government to own those legacy of tissue collection.

Thank you.

Yours sincerely

Tay-Png Hong-Lan (Mrs)
Chief Operating Officer
Institute of Molecular and Cell Biology

BioethicsAdvCommitteeFeedback.DOC/GEN CORR TPHL 3/ak



KK WOMEN'S
AND CHILDREN'S
HOSPITAL

18 March 2002

Assoc Prof Terry Kaan
Chairman, Human Genetics Subcommittee
Bioethics Advisory Committee
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Singapore 179101

FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE

With reference to your letter of 27 February, a committee was convened to review the Consultation Paper on Human Tissue Research. We are forwarding the comments of the said committee (please see enclosure), which also represents our stand on the matter.

A/PROF CHENG HENG KOCK
Chairman, Medical Board

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9 March 2002

FEEDBACK ON CONSULTATION PAPER "HUMAN TISSUE RESEARCH"

Preamble

Having been tasked by Chairman, Medical Board to prepare a feedback report on the Consultation Paper "Human Tissue Research" submitted by the Bioethics Advisory Committee, the following members met on 9 March 2002 to discuss the relevant issues:

Dr Carolyn Tan Eng Looi
Chairman, Division of Paediatric Surgery (designate)

A/Prof Yeo Seow Heong
Chairman, Division of Obstetrics & Gynaecology (designate)

Dr Ivy Ng Siew Lian
Head, Paediatric Medicine
Chairman, KKH Research Committee

Dr Chew Sung Hock
Senior Consultant, Histopathology

General Comments

All members felt that the Paper was very well deliberated and covered the relevant issues in today's context of biomedical research. It addresses the legitimate concerns of the donors and also shows a pragmatic approach to opportunities for the advancement of medical science.

Specific Issues Raised

Consent:

1. Format of the consent:
   A standard format for consent for obtaining tissues for research would be preferable.

2. The tissue sample as an outright donation, the donor renouncing all rights:
   This benefits the researchers, and the donor has no direct benefit. Therefore an advocate for the patient would be important and may be represented by the Institutional Review Board (IRB). Strong representation from the lay public within the IRB's would therefore be important. The issue of rights to the tissue should be handled cautiously and sensitively, and donors should be helped to understand that losing their rights to the tissue would be one result when the tissue is anonymised. Public feedback and discussion on this issue would be crucial.

3. IRB approval for collection and use of human tissue samples for research:

The consent form should state

- that the donated tissue will only be used for research vetted and approved by the IRB
- that the patient's treatment will not be affected in any way by his/her decision on the donation of the tissue
- the tissue will be treated with respect

4. Person to take the consent:
   It was felt that the principal clinician and the research team should not take the consent, as they have vested interests. The principal clinician could, however, bring the research project to the attention of the donor, and provide some explanation of its aims.
   An option to consider is to appoint a full-time staff member who is not directly participating in research projects and who is under the authority of the IRB to obtain the consent. It would be best if this individual had a nursing or paramedical background.

5. If consent is denied:
   When the tissue is obtained as part of the treatment, eg an operation, this tissue sample should be made part of a medical archive and not part of a tissue bank. The work processes must allow for clear distinction between tissues that are available for research purposes and tissues that are kept only as part of the patient records.

6. Donors changing their consent decisions:
   An issue to be considered is whether consent for donating one's tissue to research is binding indefinitely.

7. Education:
   Public education about the use of human tissues in research would be helpful to engage the lay public and to answer their concerns. The beneficiaries of such research will be our generations to come.

Legacy Tissue Collections:

1. Consent:
   It is reasonable not to retrospectively trace all donors for consent, as this will be very difficult and in some cases, impossible.

2. Database:
   It would be necessary for current legacy collections to be entered into databases in a nationally standardised format. If there is any doubt about the adequacy of the consent previously taken, based on the principles now set out by the Bioethics Advisory Committee, it would be better to regard that consent had not been obtained. The databases could be managed by those who currently hold responsibility for the tissue collections, but the data must at all times be available for audit and access by the IRB.

3. Pathology specimens:
   All current specimens stored by Pathology Departments, including Pathology Museums maintained for academic purposes, should be categorised as legacy tissue collections, and entered into databases. Subsequent to the formalisation and regulation of all tissue collections,

Pathology Departments will need a system for identifying which tissues are available for research and which are not.

Confidentiality:

1. Unexpected findings of genetic diseases:
   In the course of using tissue samples for research, the researchers may unexpectedly identify genetic diseases in the samples. The ethical dilemma presented to the research team as to whether the donors should be informed needs to be addressed.

2. Researchers blinded to donor identities:
   As far as is practical, researchers using human tissues should not have direct access to identities of the donors, and perhaps a section should be included in research protocols using human tissues as to the proposed anonymisation methodology to maintain donor confidentiality.

Governance:

1. Institutional Review Boards meeting international standards:
   As there are existing international guidelines regarding IRB's, it would be timely to ensure that all institutions participating in research involving human tissues set up IRB's meeting international standards. IRB's should have jurisdiction over all human tissue collections in the their respective institutions.

2. Private tissue collections:
   Private tissue banks should be subject to the same rules and regulations as public tissue banks, and be governed by IRB's either within the private institution or at the Ministry of Health.

3. National Regulatory Agency:
   Members agreed that such an agency would be necessary. The relationship between the IRB's and the proposed agency, and their respective levels of jurisdiction will need to be clearly worked out.

Interim Recommendations of the Bioethics Advisory Committee

All members opined that the recommendations are logical and reasonable. However, members hoped that the points raised in the previous section would be considered.

Dr Carolyn Tan Eng Looi

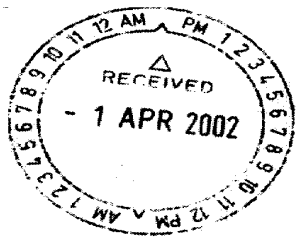
A/Prof Yeo Seow Heong

Dr Ivy Ng Swee Lian

Dr Chew Sung Hock

S I N G A P O R E A C A D E M Y O F L A W

April, 2002



ASSOC PROFESSOR TERRY KAAN
CHAIRMAN
HUMAN GENETICS SUBCOMMITTEE
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179 101

Dear Assoc Prof Kaan

Feedback Regarding Human Tissue Research in Singapore

Thank you for your letter dated 27 February 2002. We set out below our members' views on the interim recommendations advanced by the Human Genetics Subcommittee (HGS) in the consultation paper on "Human Tissue Research".

2 The Committee is of the view that there are two issues that must be treated discretely in any determination of policy regarding human tissue banking. First, the **tissue banking industry**. The role of regulators here would be to ensure oversight of tissue banking, guiding co-operation with other government or research agencies, tabling an established cycle of tissue bank inspections, mandating registration of tissue banks and developing assurances with regard to quality control (including bringing practices in line with international convention).

3 Next, there is **informed consent by the donor**. The role of a national-level body here would differ in the sense that it is not regulating a commercial industry. It would manage the process of obtaining consent and donations, including elements such as the timing of the request for donation, mode of request, staff training and supervision in handling such queries, the provision of written materials for the donor or donor's next-of-kin and the review of standards for obtaining consent. While the Committee was in agreement with the general principles raised by HGS, we did not immediately agree with the consolidation of these two discrete aspects of human tissue banking. As such, we would not encourage the establishment of one body that would manage both the industry and ensure informed consent of the donor.

4 **Establishing Distinctions at the start ~ pararaphs 2.1 & 2.3: Definitions**

4.1 Members were unequivocal in their insistence of separate treatment for (a) research materials relating to human embryonic stem cells and human cloning; and, (b) the other human biological materials generally described in paragraph 2.1. Perhaps this was appreciated by the BAC in its decision to establish two separate

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subcommittees for Human Stem Cell Research (HSR) and HGS respectively. Human biological materials described in (a) and (b) should be dealt with in separate frameworks. At the very least, the present sweeping caveat in paragraph 2.3 cannot stand without a clear and distinct explanation of areas where the BAC may have differing recommendations in relation to human stem cell research materials. The BAC should indicate where the caveat would apply.

4.2 Flowing from this distinction, our members would welcome separate statements by the BAC on stem cell research and other tissue research, regarding (1) existing ethical rules that apply (for example, from present medical professional practice); (2) possible scenarios where the researchers have exploited ethical rules – in those cases, what were the ethical rules; and, (3) what future rules would be needed to arrest these possible scenarios. It is these ethical issues which we hope will be raised in the continuing process of consultation.

5 Consent ~ paragraph 8 generally; paragraphs 13.1.1.1 to 13.1.1.6

5.1 Even though paragraph 13.1.1.2 spelt out the overriding principle of consent, paragraph 13.1.1.3 should nevertheless be clarified to state that full, free and informed consent of the patient must be obtained before a donor's tissue can be used for research. There is also an issue as to the scope of the consent required and the extent to which it must correlate to the exact type of research to be undertaken. Reasonable explanation of what the research entails should be given and the donor should be offered an opportunity to ask questions.

5.2 A distinction is made at paragraph 8.12 between consent to the taking and consent to the particular use of tissue. We seek the BAC's confirmation on the consent procedures required in the taking and use of tissue alluded to in paragraphs 8.7 and 8.8 and invite HGS to put in place a recommended procedure to reflect this position.

5.3 In respect of 'informed consent', our members would welcome a definition. They were of the view that the principles mentioned, for example, at paragraph 13.1.1.1 merely informed the doctor or governing body of relevant considerations in evaluating consent; however, further definition could be given to assist the donor in being assured he or she has sufficient information to give consent.

5.4 Following some discussion, members agreed that consent may be waived in the following instances:

(a) where it is required for purposes of police criminal investigation;
(b) where it is required for public health and safety reasons; and
(c) where there is an emergency that threatens the life and health of a person.

Naturally, the same 'national-level body' would be responsible for evaluating the reasons in each case that may arise in (b).

6 Legacy Tissue Collections ~ paragraphs 9.6; 13.1.1.5

6.1 While we agree that there should not be a blanket ban on access to these collections, this cannot mean a blanket referral to a 'national-level body'. The Committee considered that it would be appropriate for the framework of consent to tie in with existing regimes such as the Human Organ Transplant Act. Consistent with provisions in this statute, the question of consent should be referred to the donor's relatives. If the donor's next-of-kin refuses consent, there is no consent.

6.2 Where there is evidence that credible attempts to contact the donor's next-of-kin have been unsuccessful, perhaps the 'national-level body' can consent. However, it is recommended that the BAC explore existing 'national-level bodies' to determine whether there may be an overlap of functions and to employ existing resources in drawing up a framework.

6.3 Our Committee would recommend that this approach be legislated in respect of such collections as suggested at paragraph 9.6.

Persons with Mental Disorders

6.4 This approach may be extended to Singaporean donors who are not possessed of consistent complete decision-making capacity. We are aware that a somewhat different framework was recommended by the U.S. NBAC in its December 1998 report. Their recommendation identified several categories of consent – from 'assent' by a person incapable of independent decision making for whose donation will be applied to minimal risk research studies, to surrogate decision-making in three main forms. Applying this analysis locally, we would recommend the approach suggested above in relation to legacy collections. This corresponds to the U.S. NBAC's third category of consent described as 'Projection of personal relationships'. In this case, the donor appoints a proxy to make decisions regarding his or her biological materials in specific situations. We look forward to a separate analysis of informed consent for donors with mental disorders.

7 Donations to be Gifts

7.1 While in agreement with the underlying principle, members of the LRC felt strongly that the present phraseology used in paragraph 13.1.1.8 should be avoided. The discussion of financial incentives in the same breath as reasonable reimbursement of expenses incurred should be separated. They serve entirely different functions where 'financial incentives' possess a commercial character that cannot be ascribed to the act of reasonable reimbursement.

7.2 To this end, it is recommended that paragraph 13.1.1.8 should be rephrased to place emphasis on the principle that donors must not be induced by any financial incentives or benefit for the donation. BAC should also address the issue of whether trading in stem cells should be allowed. The Committee was of the view that the tissue bank should expressly be prohibited from sale or export of tissue for profit. To give flesh to its views, the BAC could give its recommendations should a situation such as the Moore case (USA) arise in Singapore. The BAC may also wish to comment on its position with reference to that of Iceland's Biobanks Act.

7.3 Finally we would welcome a detailed outline of the type of opportunities (cross-border collaborations alluded to in paragraph 6.8) which has hastened the BAC's production of this paper. The Committee would urge BAC to look into regulating potential markets that bloom from the tissue banking industry. For example, the E.U. Group on Ethics in Science and New Technologies met in November 2001 to discuss the ethical aspects of patenting inventions involving human stem cells.

8 Governance ~ paragraphs 11.6 and 11.7; 13.1.1.9 to 13.1.1.11

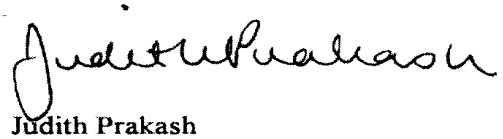
8.1 Paragraph 13.1.1.9 did not address the fundamental question of what type of research should be permitted. Furthermore, our members were concerned that the process of approval may not be transparent. There appears to be a lack of policy guidance regarding various scenarios. There is also no mention of how the research ethics committee or institutional review board would be constituted and what its composition would be. While our own research into the matter suggests the BAC may be considering adoption of the U.S. system of IRB review etc, we would ask the BAC to go further, for example, by identifying research protocols and the need for a mechanism to review these protocols.

8.2 Moving from the statutory agency to the board or committee, there is an absence of discussion on whose interests the respective body's members would represent. There is some reference in paragraph 13.1.1.10 to 'appropriate representation for the public' but no suggestion is given as to how this will be determined and achieved. In setting out the board's objectives, we hope the BAC will bear in mind our discrete treatment of banking and donor consent raised at our paragraphs 2 and 3 above.

Conclusion

We appreciate having been given the opportunity to comment on the consultation paper. Thank you.

Yours sincerely



Judith Prakash
Chairman
Law Reform Committee

LIFE INSURANCE ASSOCIATION

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BY POST ONLY

28 March 2002

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

CONSULTATION PAPER ON HUMAN TISSUE RESEARCH IN SINGAPORE

Our members, i.e. life insurance companies, generally have no comments to make, save for one.

The latter is enclosed.

Yours sincerely

PAULINE LIM
Executive Secretary

Copy: Tan Beng Lee, President

Request for feedback regarding human tissue research in Singapore

The current practice in the life insurance industry is that requests are usually made for medical reports from clinics and hospitals when potential policyholders declare a particular condition which they have when making a proposal to be insured. The authorization by the individual is usually recognized by the hospital or clinic.

The industry should have no problem with all of the interim recommendations except for 13.1.1.2 to 13.1.1.6 under Informed Consent and 13.1.1.12 to 13.1.1.13 under Confidentiality. As an insurance life company the concern is our ability to verify the risks involved in insuring a particular individual who have declared a particular condition.

Hence the industry would like explicit clauses to be included which allows an individual to authorize the use of information and reports to be made available to insurers based on his consent. This is not clear from the interim recommendations.

While one can understand the paranoia involved especially since the technology holds the promise of more accurate diagnosis of an individual's medical health, its value to the life insurance indusrty is its availability. While underwriting rules may have to be revised to accommodate this change, the information must be made available to the insurer once the individual has given his consent.

Date: 13 March 2002

مجلس اكام اسلام سيغافورا
Majlis Ugama Islam Singapura
(Islamic Religious Council of Singapore)

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MUI/OOM/31/2

10 Apr 2002

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Assoc Prof Terry Kaan
Chairman
Human Genetics Subcommittee
Bioethics Advisory Committee
250 North Bridge Road
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Singapore 179101

Dear Sir

REQUEST FOR FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE

I refer to your letter dated 26 Mar on the above matter.

2 Thank you for giving us the opportunity to provide our feedback on the consultation paper for the Human Tissue Research.

3 Our initial feedback is enclosed. Please take note that the feedback is not a Fatwa (Ruling) issued by the Legal (Fatwa) Committee.

4 Thank you.

Yours sincerely,

Syed Ahmad Syed Mohamed
Assistant Mufti
For Secretary
Majlis Ugama Islam Singapura

FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE

1. Definitions

1.1 There is no definition of "donor" in the paper.

2. Current Law

2.1 We agree to the proposal as stated in ***article 6.2*** that the donor should be given the opportunity to state in advance their intention to donate their bodies, organs or tissues for research or for transplantation after their death. We would like to suggest that the donor is also required to obtain the consent of two waris (next-of-kin). This is also in accordance with HOTA for kidney transplantation. The two next-of-kin are also regarded as witnesses to the donation of their bodies, organs or tissues for research or for transplantation after their death.

2.2 The witnesses and their relationship to the donor should be in accordance with the Muslim hierarchy of next-of-kin as indicated below:-

1. Father
2. Paternal grandfather
3. Son
4. Grandson
5. Full brother
6. Half brother (same father different mother)
7. Full brother's son
8. Half brother's son
9. Full paternal uncle
10. Half paternal uncle (same grandfather different grandmother)
11. Full paternal uncle's son
12. Half paternal uncle's son
13. MUIS (for those who do not have relatives as above).

3 Consent Generally

3.1 We agree that the tissue bankers have an obligation to obtain consent to the donation of the gift from the donor as stated in ***article 8.2***. They are also required to obtain consent from two waris (next-of-kin) of the donor as stated in **para 2.1**.

3.2 The next-of-kin must comply to the following conditions:-

1. Reach puberty
2. Sane
3. Able and capable to make decision
4. Willing

3.3 In the circumstances when a reconsent is required for specific research purposes not stated in the consent form, after the death of the donor, as stated in ***article 8.10***, the consent should be sought from the next-of-kins based on the Muslim hierarchy (refer to **para 2.2**).

When there is no clear person from whom valid consent can be obtained, and where the donor himself / herself is already deceased, or is legally incompetent to give the requisite consent, we recommend that the matter be referred to the religious authority for advice and consent.

In the case of Muslim deceased without any next-of-kins, Muis can act on behalf of the deceased in giving the consent for the tissue donation. This is due to the fact that Muis is the highest religious authority responsible for Muslim affairs in Singapore. The above should be stated clearly in the consent form.

3.4 We agree to the ***article 8.11*** which stated that the researchers and institutions having the responsibility for the custody, use and disposal of such tissues should at all times be sensitive to social, cultural and religious sentiments relating to the treatment, use and disposal of such tissues.

There should be proper guidelines with regard to the disposal of such tissue samples when they are no longer needed and deaccessed from the bank or collection.

For Muslims' gross human tissue samples that involve entire organs or blocks of organs, the organs should be buried appropriately. For any such samples, which involve parts of human body or of limbs, the parts should be cleansed and buried according to Islamic teachings. The limbs should be buried at a Muslim cemetery. It is also acceptable as stated in ***article 13.1.1.7*** that …. *"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."* This is also the current practice in hospitals when Muslim parents are consulted on the disposal of placenta after delivery.

Conclusion

The researchers and the institutions involved in the Human Tissue research should be clearly informed on the ethical conducts in handling the human tissue especially with regard to the consent and confidentiality procedures. They also should be sensitive during any occurrences that involve religious sentiments to seek the advice and consent of appointed / relevant religious authority upon agreement by the donor in the consent form. Any involved party in these research activities should sign a declaration form.