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Our Ref TTS/MED

27 March 2002

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

Dear A/Prof Kaan

CONSULTATION PAPER ON HUMAN TISSUE RESEARCH

I refer to your letters of 27 February 2002 and 11 March 2002.

I have sought the views of the relevant personnel and am attaching their comments / feedback for your consideration:

- Dr Angela Chong Pek Yoon
  Senior Consultant
  Dept of Pathology & Laboratory Medicine
- Dr Richard Bellamy
  Registrar
  Dept of Infectious Diseases
- Ms Cynthia Chan
  Manager, Legal Services

Thanks for seeking our views on your consultation paper. We hope our feedback is useful to your Committee.

Yours sincerely

Clin Prof Chee Yam Cheng
Chairman, Medical Board

Kfh : Y: bioethics

Feedback from Dr Angela Chong, Senior Consultant, Dept of Pathology & Laboratory Medicine, TTSH, on the Consultation Paper "Human Tissue Research" by The Bioethics Advisory Committee

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1. Agree with the Interim Guidelines.

2. Subsampling - No subsampling until diagnostic procedure has been completed or until therapeutic procedure has been confirmed that is after the pathologist has examined the tissue. Completion does not occur at the end of the surgical/ invasive procedure.

3. Tissue archives. Pthology archives currently store diagnostic tissue. This should NOT be given out to researchers without the consent of the hospital concerned - as these patients may still require their tissue for prognostic markers, therapeutic markers or for diagnostic or medicolegal challenge. As we have heard recently, we need to have some record. To have no record is not a valid excuse.

4. The border between 'legacy' tissue and current diagnostic tissue is not drawn. The hospital should retain the right to determine where to draw this line - with guidance from national oversight committees.

Z: Tissue-path

Feedback from Ms Cynthia Chan, Manager, Legal Services, TTSH on the Consultation Paper "Human Tissue Research" by The Bioethics Advisory Committee

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I agree that there is a dearth of legal precedents in this area of law, which is fast developing and has shot to prominence as a result of the surge of interest in the new life sciences such as human genetics and genomic research as well as recent events in Britain and New Zealand.

I have gone through the Consultation Paper on Human Tissue Research ("the Paper") prepared by the BioEthics Advisory Committee of Singapore ("BAC") in great detail and my comments are as follows:-

1) I agree that human tissue collections should be managed by a national databank and not by private individuals. All non-institutional legacy tissue collections build up over the years in hospitals, universities or research institutions should eventually be amalgamated with the larger collections of institutions.

2) I also agree that purpose-assembled research banks should be encouraged, provided that all appropriate ethical and legal considerations and concerns are appropriately met and addressed, in order to promote and enhance research for the benefit of mankind.

3) In view of the lack of any uniform approach to the governance of regulation of tissue banking internationally, the lack of any clear definition of "tissue banking" in the Private Hospitals & Medical Clinics Act ("the Act") or the Regulations under the Act or in any other statute and the dearth of any guidelines for the proper conduct of tissue banking, it would be prudent for us in Singapore to proceed cautiously on the various issues of property, control and ownership rights to tissue samples.

4) It is imperative that changes to the above be implemented as soon as possible to avoid blocking essential work. I wholeheartedly agree that a review has to be undertaken of the law governing this area by the Attorney-General's Chambers ("AGC") and that a professional and public dialogue should be initiated to discuss the ethical and social considerations which should shape the law in this area.

5) I fully agree that there is a need to procure the full, free and informed consent of the patients to the taking of their tissue samples, which should be separate from the normal Consent Form which the parties sign when they undergo an operation/procedure for therapeutic or diagnostic purposes. I am also in favour of the recommendation that wherever possible, the person responsible for explaining the nature of the donation and the taking of the consent for the donation should not be the person who receives the consent for the taking of the tissue for therapeutic or diagnostic purposes.

6) I am cognisant of the fact that there may be situations where consent may be given generally and not for a specific purpose, or where it would be impracticable or impossible to insist on consent being obtained. I agree that in the latter situations, an appropriately constituted Ethics Committee or institutional review board should be looking into the decision for the taking of human tissue from such persons within the limits permitted by law.

7) In view of the multi-racial society that we have in Singapore, we should be mindful of social, cultural and religious sentiments in relation to the custody, use and disposal of tissues and take extra care with the same.

8) I support the recommendation that steps should be taken to formulate a national ethical policy governing reasonable access to such legacy tissue collections, to be led by a national-level body. I feel that in this aspect, the National Medical Research Council ("NMRC") would be the most appropriate body to undertake this role (which would mean an expansion of its current role), rather than have a separate body constituted for this purpose.

9) I agree that in cases where it may be difficult or impossible to re-contact the donor or the donor's family for consent (or re-consent), for example, in the case of legacy tissue collections for the purposes of further research on the tissues or where it may be socially unacceptable to do so, for example, where there is a strong possibility that the donor is dead or otherwise uncontactable, it is permissible for researchers to consider the use of anonymised data arrangements or data-escrow arrangements as may be approved by appropriately-constituted Ethics Committees or institutional review boards.

10) The BAC has recommended legislative intervention only in situations where it is clear that effective professional self-regulation and a fair balance of rights and interests between individuals and the public in encouraging research cannot be achieved without legislative teeth. I agree that this should be the case and it would not be the first time that this approach has been taken. In the case of the Electronic Transactions Act, the intention of the government is to allow the individual organisations freedom to embrace and adopt Internet-advanced technology as long as it is done in a responsible manner, being mindful that overly-specific rules would run the risk of rapid obsolescence as stated in paragraph 11.1 of the Paper. It is submitted that the same applies to the rapidly developing field of life sciences.

11) I agree that the jurisdiction of the Director of Medical Services could be extended to all individuals or bodies inclined to engage in tissue banking activities, so as to subject both medical and non-medical researchers to the same set of operational and ethical guidelines as may be imposed by the appropriate authorities. I am of the view that it may not be necessary to establish a statutory agency for the regulation of stem cell as that would create an additional superfluous layer of bureaucracy and may possibly lead to greater confusion on the ground.

12) While it is desirable to have consistent and transparent rules and standards which ought to apply to all forms of tissue banking in Singapore, whether carried out by the private or public sector, whether carried out primarily or incidentally for the purposes of research and whether such research is for a commercial end or for a non-profit end, I am not agreeable to the recommendation that a national-level committee or consultative body be appointed. This national committee already exists in the form of the NMRC, whose role can be extended to formulate a national party relating to the regulation, conduct and governance of tissue banking in Singapore. If need be, the members of the NMRC can be expanded to include experts from the relevant industrial, academic, research and professional sectors of the life sciences.

13) NMRC already has some supervisory powers over the decisions of institutional review boards or institutional Ethics Committees. I am of the view that the applications by researchers for access to human tissues can be dealt with in a manner similar to current applications for all other types of research work. There may be a need to fine-tune the available procedures to suit the particular aspects of tissue banking.

14) I also agree that tissue banks should develop and have in place electronic data systems that will enable the consent status and consent conditions (if only) of every human tissue sample to be accurately recorded and to facilitate ease of access by researchers, for the greater good of mankind.

15) It is imperative that researchers and all those involved in the conduct of tissue banking understand and adhere to the obligation of confidentiality of the personal information of donors entrusted to them, as well as the privacy of the donors. Appropriate consent must be obtained before the release of any such personal information to researchers or to any third party.

16) I wholeheartedly agree that there should be statutory regulation and supervision of all forms of tissue banking and that it should not be carried out without licence. The governmental authority (whether it be the Director of Medical Services or a separately established statutory authority) should be given sufficient powers of direction, enforcement and supervision, so as to enable it to effectively give ethical and legal direction for the conduct of all forms of tissue banking carried out in Singapore. This authority should also be tasked with ensuring compliance with such direction and such other rules, standards and codes of conduct so as to establish and maintain proper operational governance and protect the interests and rights of patients, donors and their respective families.

17) It is of utmost importance that institutions which conduct tissue banking have in place transparent and appropriate systems and standards for the proper ethical, legal and operational governance of tissue banking as stated in paragraphs 13.4 and 13.5 of the Paper.

18) Finally, I agree that a professional and public dialogue should be initiated as soon as possible to settle the principles governing tissue banking, so as to achieve an early resolution of the legal and ethical questions in respect of the ownership and custody rights to donated human tissue.

Z: Tissue-legal

Feedback from Dr Richard Bellamy, Registrar, Dept of Infectious Diseases, TTSH, on the Consultation Paper "Human Tissue Research" by The Bioethics Advisory Committee

Generally I think that this document is well written and considers most of the important relevant ethical issues. The document has not paid much attention to the effect which ethical guidelines may place on the practical aspects of tissue banking and on the impact this may have on research. This may be deliberate and may also be because the UK MRC guidelines did not explore this issue fully. However I believe it is important to consider these issues because the culture of institutions and the rights of individual researchers are very different here. Institutions here may read this consultation paper and then institute directives to comply with them without considering all of the potential future practical implications. There are several specific issues which I feel should be addressed.

Individual or Institutional ownership?

The consultation paper disapproves of individual ownership of tissue banks and states that these should be held by institutions. This does not recognise that most research tissue samples held within institutions are informally regarded as the property of the individual who has collected them. An institution may decide to end all individual rights to ownership on the basis of this paper. What potential problems could this cause? If you were to spend several years collecting a large number of samples for your own research you may feel it is wrong for the institution to decide what can be done with them. You would probably be in the best position to determine their value and to what use they should be put. If another individual in the same institution wants to use them for a purpose which you feel is a waste of the sample, should the institution be empowered to allow this without your approval? What if the samples have a high commercial value? Should the institution be allowed to sell them for profit without your agreement? This may be the end of your research!

Do not take this to imply that I feel that individual ownership is right either. This is something I strongly disagree with. In the past it has meant that scientists have been able to collect samples for one purpose and then do anything they want with them without any ethical regulation. Clearly this is not right. Also it has meant that individuals moving between institutions have nearly always taken their research collections with them. Whether this is right or not is a matter of debate.

My own opinion is that joint ownership agreements are needed between individuals and institutions. The consultation paper should discuss the ethical issues arising from this but not specify the nature of such agreements. These details could be decided at institutional level.

Can samples be sent abroad?

Tissue samples may be sent abroad for research which cannot be done in Singapore. It is not clear who should have the authority to agree to this. I do not think that the individual should have. Perhaps it could be the institution or perhaps the National Ethics review board. This is an important issue as research may be carried out which would not be allowed in Singapore.

Should samples be sold to commercial interests?

In the consultation paper it states that the consent form should state that "the gift is an absolute one, the donor renouncing all rights". I do not think that it is acceptable to use such terms as patients should have some rights and these should be protected by the institutional regulations. More appropriate wording would be "the sample may be used for any research purpose which is felt to be appropriate by the institution and which is approved by its ethics committee". This then places responsibility on the institution to ensure that the samples are used appropriately and ethically. This is particularly relevant to the issue of commercial interests using the samples. I believe it is acceptable for such groups to use the tissue samples under the regulation of the host institution. Each project would then need individual ethical approval. However I do not believe it is acceptable for the host institution to give/ sell the samples to a commercial interest and give up its control on what the samples are used for. If this is a possibility then this should be expressly stated on the consent form as many patients could be unhappy with this.

A formal approach to medical ethics

The consultation paper does not formally discuss the four principles of medical ethics, beneficence, non-maleficence, respect for autonomy and justice (Beauchamps and Childress). As a result of this the document has largely ignored two of the principles, non-maleficence and justice. Regarding the first of these it must be recognised that research can have potentially negative effects on the individuals who have donated the samples. For example if I had a collection of blood samples from cancer patients and I looked for mutations which might be associated with familial cancer and found some positive samples what should I then do? If I contact the individuals concerned I may cause unnecessary anxiety or problems with insurance etc. The patient may be cured of the first cancer but may be at increased risk of other cancers. Alternatively other relatives may be at risk etc. If I do not contact the patient he may die from an undiagnosed and curable cancer. This is just one example and the consultation paper should include some discussion of these issues. With regard to justice the paper should consider the uses samples are put to and the potential for others to benefit in the future. This is particularly important for commercial interests but also applies to patents and institutions etc. For example if I use some samples and make a great scientific breakthrough which has some financial worth I may sell the patent rights and become rich without considering if the patent will obstruct future research, drug development, vaccine development etc. My benefit and/or my institution's interests may conflict with those of patients and/or the scientific community. These issues should be discussed as they are common problems.

On the whole I think that the discussion paper has struck a good balance between the rights of individuals and the needs of research. Attempts at clarifying the ethical and legal issues are to be welcomed.

Z : Tissue-ID

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30th March 2002

Dear Sirs

CONSULTATION PAPER ON HUMAN TISSUE RESEARCH

We write in response to the BAC's request for feedback on the consultation paper entitled "Human Tissue Research".

First of all, we would like to thank you for your interest in our views on a matter as important as this. We understand that members of the BAC have devoted significant time and effort in coming up with such a paper, guided by a voice of conscience which you hold so true and dear.

Before we proceed further, we would like to state a few principles on which our response is made:
1. We defend, promote and accord absolute respect to every human being from the moment of conception to the point of natural death, including his primary and fundamental right to life, and his dignity as a person.(1)

2. The evaluation of the morality of abortion is to be applied also to forms of intervention on human embryos which inevitably involve the killing of those embryos.
This moral condemnation also regards procedures that exploit living human embryos and fetuses, either to be used as "biological material" or as providers of organs or tissue for transplants in the treatment of certain diseases. The killing of innocent human creatures, even if carried out to help others, constitutes an absolutely unacceptable act. (2)
God alone is the Lord of life from its beginning to its end: No one can under any circumstance claim for himself the right directly to destroy an innocent human being." (3)

3. To use human embryos or fetuses as the object or instrumentation of experimentation constitutes a crime against their dignity as human beings having a right to the same respect that is due to the child already born and to every human person. (4)

4. No end believed to be good, such as the use of stem cells for the preparation of other differentiated cells to be used in what look to be promising therapeutic procedures, can justify an intervention that will harm or destroy the embryo. A good end does not make right an action which in itself is wrong.

Having read the consultation paper on human tissue research, we have come to the conclusion that we have no choice but to disagree with it for the following reasons:

1. The consultation paper skirts the issue concerning what sort of ethical guidelines or regulations will be imposed on embryonic stem cell research. Instead the consultation paper deals with so many general principles and leave the specifics to statutory bodies to be set up. Various interest groups will not have an idea what will be the final ethical guidelines and regulations until they are enacted and published. By which time, it would be very embarrassing to put those published guidelines and regulations into reverse gear if we should be able to point out to something debatable or unethical.

2. At para. 8, "Full free and informed consent is the cornerstone of the legal and ethical legitimacy" in the gift of human tissue. This is not correct since an embryo is a human being from the moment of conception and has an independent right to life. An embryo certainly cannot give consent. Further, it is doubted if researchers will ever be so full and frank when obtaining consent to ask "Ma'am, can we have your consent to kill your baby embryo and use his cells for the purpose of our scientific research?" A parent's consent is certainly needed in many cases, but when such consent involves the killing of an offspring, and not given for the promotion of his interests, it cannot be considered valid.

3. In 2.1, it was stated that the term "human tissue" refers to all kinds of human biological materials derived from living or cadaveric donors, including ...foetuses.....embryos, gametes or any part of derivative thereof. Since the rest of the paper refers to the above as well, we cannot but voice our unequivocal objection to it for the same reasons as stated in our earlier points.

We hope our feedback is of use to you. We thank you for your interest in our opinions, and trust that you will look into them with due consideration.

Yours faithfully

REV FR JAMES YEO
CO CHAIRMAN
ARCHDIOCESAN BIOETHICS COMMITTEE
ARCHDIOCESE OF SINGAPORE

DR JOHN HUI
MASTER
THE CATHOLIC MEDICAL GUILD OF SINGAPORE

References:

1. Donum Vitae
(Instruction on Respect for human life in its origin and on the dignity of procreation), Introduction
2. Evangelium Vitae (The Gospel of Life), 63
3. Donum Vitae Introduction, 5
4. Donum Vitae 1, 4

cc Msgr Nicholas Chia, Archbishop of the Catholic Archdiocese of Singapore

THE JEWISH WELFARE BOARD
SINGAPORE

15 March 2002

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

Dear Assoc. Prof. Kaan

REQUEST FOR FEEDBACK REGARDING HUMAN TISSUE RESEARCH IN SINGAPORE

We thank you for your letter of 27 February 2002.

Enclosed please find our feedback which we hope is of use to you.

Thank you.

Yours sincerely

Joseph Benjamin
Honorary Secretary

Enc: 3 pages

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Organ Donation

by Rabbi Shraga Simmons

The Jewish position on organ donation is as complex as the issue of life and death, because it derives directly from the Jewish perspective on the sanctity of life and the role that our physical existence plays in the advancement of our spiritual selves.

On the one hand, we have a sacred obligation to preserve human life (*pikuah nefesh*).This is an overriding principle in Jewish law -- so important that almost any other law can be broken for this reason.For example, we can break Shabbat to drive an injured person to the hospital.

On the other hand, Jewish law prohibits desecration of a dead body (*nivul hamet*). A dead person's body, since it once housed the holy soul, is to be treated with the utmost respect. Every part of the body must be buried -- which is why you see the heart-wrenching images of religious Jews dutifully going around after a terrorist bombing, scraping up pieces of flesh and blood for burial.

How do we resolve these two principles?

TO SAVE A LIFE

Organ donation is permitted in the case when an organ is needed for a specific, immediate transplant.

In such a case, it is a great mitzvah for a Jew to donate organs to save another person's life.

Organ donation is not necessarily limited to dead people: Someone who can afford to spare a kidney, for example, may donate one to someone in need.

Yet in consideration of the prohibition against desecrating the body, it is forbidden to simply donate to an "organ bank," where there is no specific, immediate recipient.

Furthermore, it is also forbidden to donate for general medical research or for students to dismember in medical school.

CAUTION NEEDED

Even when there is a specific, immediate transplant, there is need for caution, because oftentimes in order to obtain organs as fresh as possible, a doctor will remove the organ before the patient is actually "dead" according to Jewish law.

The doctor is therefore effectively killing the patient, which is, of course, forbidden.

The bottom line is that each case is different. A myriad of considerations in *halacha* must be reviewed. So before going ahead with any procedure, consult with a rabbi well-versed in Talmud and Jewish law. It is clearly not as simple as blankly signing an organ donation card.

Sources:

Rabbi Yechezkel Landau - Noda BeYehudah II, Yoreh Deah 210
Rabbi Moshe Feinstein - Igrot Moshe, Yoreh Deah II, 174
Dayan Weiss - Minchat Yitzchak V, 7
Rabbi Eliezer Waldenberg - Tzitz Eliezer X, 25

Further information:

Institute for Jewish Medical Ethics in San Francisco (800-258-4427)
"Judaism and Healing" by Rabbi J. David Bleich (Ktav Publishing 1981)

QUESTION : Organs from a Cadaver: the Status of the Deceased and of his Family
Is a person obliged, or even allowed, to consent during his lifetime to the donation of organs after his death?
Is a person obliged, or even allowed, to sign a form of consent and to carry a donor's card?

Reply
A person has possession and ownership of his body while he is still alive, but his rights are limited by certain bans determined by the Torah, namely, deliberate suicide, self-inflicted injury, endangering oneself , and the like. A person is not forbidden to donate an organ from his body to save someone else's life, or to donate blood to cure even a patient whose life is not at risk, as he is doing this for an important reason where the ban on self-injury does not apply. It appears that a person has the same right to give permission to donate from his body even after his death for the purpose of rescue. If he has clearly expressed his wish to do so, no member of the family has any right to object to it. If there is good reason to suppose that were he asked he would agree, that is sufficient. On the other hand, if he expressed his clear objection to it, his wish must be respected. One who asks advice on whether or not to grant permission for his organs to be used posthumously for saving life should be encouraged, in that it is a mitsva (a worthy deed) which, although he is not duty-bound to perform after death, will stand to his credit on the Day of Judgment. However, one who asks advice should not be advised to sign an authorization or to carry a donor's card since this is meaningless except in the case of sudden death such as in an accident. It is not desirable for a person to express the possibility of such an occurrence, which he prays and hopes will never happen to him. The rabbis have already warned against this in their dictum "A person should never open his mouth to Satan."

QUESTION 4: Consent of Donor's Family
What is the status of the family of a deceased person in respect to consenting or refusing to donate organs?

Reply
Whenever someone suffers shame, disgrace or humiliation, this affects his family who in turn suffer hurt, upset, and humiliation. In particular, they feel humiliated by the humiliation of the dead. At the same time it is the duty of close relatives to deal with his burial. Consequently, when it comes to taking organs or parts of the body from a corpse for a transplant to save a Jew's life, the family does have a status. They have status as interested parties and may prevent the use of the organs of the deceased if he had expressed clear opposition to this during his lifetime. However, where the deceased had agreed to donating an organ or where there is good reason to suppose that were he asked he would have agreed, their opposition may be disregarded since the saving of life is of such great importance. Likewise, if the wish of the deceased is unknown, the family is obliged to give their consent. This duty overrides the duty imposed on them to bury the dead, as far as the relevant organs are concerned, but they should bury the remainder of the body in a suitably dignified manner.

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28 March 2002

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

Dear Prof Kaan

Feedback Regarding Human Tissue Research in Singapore

I refer to your letter of 27 February 2002 enclosing a consultation paper entitled "Human Tissue Research".

On behalf of the President, Mr Palakrishnan, SC, I am pleased to enclose for your attention the Law Society's feedback on your consultation paper. Council had referred the matter to our Intellectual Property Committee and the enclosed feedback is confined to legal issues only.

Thank you for inviting us to give our views and feedback on the matter.

Yours sincerely

Philip Jeyaretnam

Philip Jeyaretnam
Vice-President
for President

c.c. Council

c.c. Intellectual Property Committee

THE LAW SOCIETY OF SINGAPORE

HUMAN TISSUE BANKING AND RESEARCH IN SINGAPORE

INTRODUCTION

We are invited to present our views and suggestions on the issues and interim recommendations outlined in the consultation paper prepared by the Human Genetics Subcommittee (HGS) in relation to the above topic ("the Consultation Paper").

In doing so, we *will proceed on the basis that human tissue research and banking will play an important role in the discovery of modern medical research and knowledge and to that extent the practice should be encouraged and continued.* The scope of this analysis will be to comment on specific guidelines as to the implementation as well as the use of information derived from such research, while balancing the interests of the individual and respect for the human body. In addition, we also offer some recommendations for the kind consideration of the Bioethics Advisory Committee.

COMMENTS

Consent Generally

Paragraphs 8.1. & 8.2.

Construing the taking of human tissue for research as the donation of a gift presupposes a right of ownership in the human tissue. As a matter of principle the obligation to obtain consent cannot thus be qualified. To allow human tissue to be taken without consent in certain circumstances such as for example that contemplated in 8.10.would be inconsistent with the principle of ownership unless permitted by legislation.

Taking without obtaining consent should be justified on the basis that there are no claimants rather than the impracticality of obtaining such consent.

Paragraphs 8.4.

Consent forms may state that the gift is an absolute one but a donor should not be denied the right or opportunity to qualify the use to which his gift should be put to if he so wishes. Moreover, a donor should also be given the right to withdraw at anytime from any potential research applications including the destruction of their sample. The unavailability of such options and leaving a donor with only the choice of giving all or nothing could discourage donations and deprive the research community of badly needed material.

Paragraphs 8.7.

It is important that there should be no perception of undue influence or coercion when consent is sought for a donation. To this end, there should be present a third party, if the person

responsible for explaining the nature of the donation and taking of the consent for the donation is the same person.

Paragraphs 8.12.

We suggest that there should be different consent forms for two separate purposes. The form and substance of the consent forms should be prescribed by legislation. This would allow consent to be given with more certainty.

Paragraphs 8.10.

Where a donor is deceased, the person who is legally entitled to the body of the deceased may provide the consent. However, there are situations where there may be differing claims for a deceased's body for example, siblings to the body of a deceased parent. It has yet to be established whose priority in terms of the personal relationship between a deceased and the claimants takes precedence. The general position is that a"consent" order of court will have to be sought by either claimants. Where there is no unanimity between claimants or order of court, it is suggested that the donation should not be taken.

Consent and Legacy Tissue Collections

Paragraph 9

Whilst we share the view that reasonable and respectful research of legacy tissue collections based on good faith and best professional practices of the day should be permitted, we do advocate that an ethics committee or similar body should be tasked to oversee the use thereof. Further, We recommend that the composition of the proposed research ethics committee or institutional review board be drawn from a wide section of society. Members of the committee should not comprise primarily members of the medical profession. There is concern that their motivations may not encompass the concerns of lay persons.

Confidentiality

Paragraph 10

It should be a condition for the use of anonymised data or other like arrangement that have been made to obtain consent or reconsent and such efforts have proven to be futile.

The concept of maintaining confidentiality in human tissue research should be closely protected by enactment of legislation to that effect. By way of example in New South Wales, Australia, there exists a statutory obligation to preserve confidentiality. This obligation is to safeguard against malpractices by overzealous medical researchers and similar members of the industry. Any breach of confidentiality should be made a breach of statutory duty. Protection of both tissue and donor would be the objective for imposing such an obligation.

Approaches to Governance

Paragraph 11

The enactment of legislation would be preferred in areas such as consent for use of existing tissues use of legacy tissues and where consent is difficult or impossible to obtain. Legislation could spell out the preconditions such as the need to make due inquires throughinteralia public advertisements and taking reasonable care where consent cannot be obtained from a donor or his next of kin. A legislative framework given structure to regulations and guidelines. If there is no legislation enacted, ministry guidelines will be subject to the commonlaw which as yet unsettled in this area.

That said, it is recognised that there are areas where guidelines, as opposed to legislation is desirable. Guidelines are more autonomous, allow greater flexibility and are easier to amend when the need arises.

It is feasible to have a system whereby broad legislation and ministry guidelines co-exist. The legislation would be complemented by the ministry guidelines thereby accomplishing the objectives of having both structure and flexibility.

RECOMMENDATIONS

Consent

Informed consent to the taking of all tissue is desirable, whether from the living or from relatives of the dead, and to the extent that there is lacunae in the existing law in relation to the same, steps should be taken to address them.

Recommendations

1. Where there are gaps identified in paragraph 6 of the Consultation Paper in relation to the requirement of consent, these should *be studied and considered whether there is any need for legislative measures*. *Not all consent needs to be regulated*.

2. If feasible, the recommendation is for an *omnibus code of conduct* for the securing of all kinds of consent in relation to the receipt of tissue samples, subject to exceptions where necessary for selected purposes.

Collection And Ownership Issues

Only approved tissue banks

Given the potential difficulties faced with monitoring the collection and granting of access to tissue samples, we agree with the recommendation that only tissue banks that are institutions (and not individuals) that have been approved by a central regulatory body be allowed to collect store and grant access to tissue samples.

If this central regulatory has a directory listing of tissue stored at each tissue bank, it would give an idea of the types of tissue stored, and facilitate the quick retrieval of tissue for purpose-based research.

Create Sui Generis Property Right

On the basis that tissue donated constitutes a gift, and that donors or their relatives retain no rights of ownership over such donated tissue donated, it is nonetheless worthwhile considering creating a sui generis property right in the donated tissue in favour of tissue banks not unlike creating the sui generis database right under European Community law[1].

There is existing law that provides some guidance on this topic[2] although it was implied in a case that in the interests of scientific progress there should not be property in human tissue in favour of the donor.[3]

The creation of such a property right would entitle the tissue bank to deal with the tissue sample in its own discretion. This would add certainty and legal standing to any terms and conditions they would impose on researchers seeking access to tissue samples. To counteract any instance of abuse of this right, provision might be made for compulsory licences to researchers. There is also the issue of commercial exploitation of any research, which is covered below. Two examples of tissue banks that we could possibly emulate in conjunction with this proposal are set out below:

The International Institute for the Advancement of Medicine in Pennsylvania ("IIAM") was established in 1986 as a non-profit research tissue bank. It facilitates the distribution of non-transplantable human organs and tissue for biomedical research, education and development.

It uses a legal agreement, the "Biological Materials Transfer Agreement" ("BMTA") that sets out the responsibilities of the IIAM and the applicant regarding the use of tissue for research. They recognise that the BMTA may be difficult to enforce, but is helpful in order to ensure compliance with legal and ethical requirements, and gives an element of control over the use of the tissue.

The UK Human Tissue Bank ("UK HTB") is a non-profit organisation based at DeMonfort University in Leicester, UK[4], and collects processes and distributes non-transplantable human tissue for research purposes to scientists. They claim to adhere to all UK laws governing the donation and use of human tissues for biomedical research purposes.

It is interesting to note that not all the jurisdictions have decided on the ownership point yet.

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[1] *Directive 96/9/EC on the legal protection of databases*
[2] *See for example R v. Kelly [1999] 2 WLR 384 CA, Williams v. Williams (1882) 20 Ch. D 659 and Dobson v. North Tyneside HA [1997] 1 WLR 596*
[3] *Moore v. Regents of the University of California 51 Cal 3d 120*
[4] *Please see www.ukhtb.org/welcome.html*

Right of Access and the Exclusive Right to Exploit

The crucial role of tissue banks would be grant access of tissue to researchers. There must be some consideration as to how these banks are funded, and whether to charge a fee for granting such access. There is also the consideration of whether to allow the researchers or the tissue bank the exclusive right to commercially exploit the results or findings of any research done on such tissue. A property right in such tissue may go some way towards resolving this issue.

Recommendations

3. Only *approved tissue banks* should be allowed to collect, store and grant access to tissue. The approval should come from a *central regulatory body* with a *central database listing* of all tissue samples held by each tissue bank.

4. Create a *sui generis property right in the donated tissue in favour of the tissue bank* that allows them to licence, grant rights or enforce if necessary.

5. Consider the *funding aspects* of each tissue bank, and whether it is feasible to allow tissue banks to charge for access to tissue.

6. Consider also whether, bearing in mind the funding aspects, and the basic principles behind the setting up of tissue banks, it is desirable to allow a *monopoly over the right to commercially exploit the results of any research done on such donated tissue*, and if so, whether the external researchers, the tissue bank or anyone else should hold that right.

CONFIDENTIALITY

The basic concept for the requirement of confidentiality is accepted. The issue would be to set out clearly what, if any, are the exceptional circumstances that would warrant a departure from the usual requirement of confidentiality.

Recommendation

7. The suggestion is to consider *whether as a matter of policy*, it is correct to provide for *exceptions to confidentiality in circumstances of competing interests*, and if so, such as the identification of a possible criminal, inheritance claims, or whether it would be in the public interest to do so.

CONCLUSION: A HARMONISED APPROACH

We agree it is preferable to develop and reform the current laws in consultation with comparable organisations in other jurisdictions. All our underlying concepts and procedural rules should operate under basic principles that are universally accepted and in line with international standards.

This not only facilitates cross-border research collaboration and mutual exchange of tissue, but also gives an element of certainty to our industry of tissue banking and research, giving others confidence in our system.

Furthermore, to avoid over-regulating the industry, which may have the adverse effect of stifling or inhibiting research activity, there should be a balance between self-regulation and legislation.

Recommendations

8. The operational procedures, rules and regulations governing tissue banking and research should be developed *in line with international standards* and *in consultation with relevant overseas bodies*.

9. A *co-regulation model* could be adopted under which the industry self-regulates in conjunction with enforcement measures by the authorities in selected areas such as enforcement agencies and approval bodies (please see below). The intention being that *guidelines would only be necessary to stop abuses* and not for the conduct of the research.

10. The law should establish *a basic framework* in *co-existence with code(s) of conduct*, thereafter refined by legal precedent and improvements.

Prepared by
Law Society IP Committee
27 March 2002

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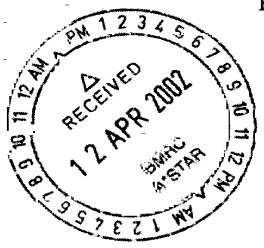
30 March 2002



Assoc. Prof. Terry Kaan
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Dear Assoc. Prof. Kaan,

FEEDBACK ON HUMAN TISSUE RESEARCH IN SINGAPORE

We refer to your letter of 27 February 2002. Below are the following comments from the Zoroastrian committee point of view:

1. The bioethics committee has indeed made a very good and comprehensive study of the problems of use and donation of organ or tissue for research purposes. They have dealt with all aspects like consent, legal issues, confidentiality etc. and there is nothing reallyto add to that.

2. As to its impact from the point of view of our Zoroastrian beliefs and teaching, there is nothing in the scriptures that could refer to organ or tissue donation for research. However, in our religion any part of the dead body or any tissue or organ removed from the body is considered as "NASO". However, Zoroastrian have donated their eyes, organs, and body parts after death for use for others and there has never been any objection raised from the point of view of subsequent funeral ceremonies and rituals by our priests.

   In fact, donating organs and tissues for the good of humanity has been considered noble from the point of view of Zoroastrian teachings.

3. Individuals may have objections about use of human tissues or organs for "cloning" of human beings or for example use of frozen sperms of a deceased husband for in vitro fertilization of the wife's ovum (egg). Such objections could be on personal level but not from religious point of view.

Hope these comments will be of some use to you.

Yours sincerely

R. M. GHADIALI