Written Responses to the Consultation Paper on "The Use of Personal Information in Biomedical Research"

1. College of Family Physicians Singapore
2. Department of Community, Occupational and Family Medicine, Yong Loo Lin School of Medicine, National University of Singapore
3. KK Women's and Children's Hospital
4. The Law Society of Singapore
5. Life Insurance Association of Singapore
6. Majlis Ugama Islam Singapura (Islamic Religious Council of Singapore)
7. Ministry of Information, Communications and the Arts (Private Communication)
8. National Cancer Centre
9. National Council of Churches of Singapore
10. National Dental Centre (Private Communication)
11. National Healthcare Group Research Ethics Committee (Private Communication)
12. National Medical Ethics Committee
13. National Skin Centre
14. NUH-NUS Tissue Repository
15. Office of Life Sciences, National University of Singapore
16. Parkway Hospitals Singapore Pte Ltd
17. Raffles Hospital
18. The Singapore Chinese Buddhist Association
19. Singapore Medical Association
20. Singapore Medical Council
21. Singapore Nursing Board
22. SingHealth IRBs
23. Society of Bioscience & Technology
24. StemCord Private Limited
25. Tan Tock Seng Hospital

College of Family Physicians Singapore

8 August 2006

Associate Professor Terry Kaan
Bioethics Advisory Committee
11 Biopolis Way
#10-12 Helios
Singapore 138667

Dear A/Prof Kaan

Feedback on Consultation Paper

Thank you for inviting the College of Family Physicians Singapore to comment on the consultation paper "The Use of Personal Information in Biomedical Research".

The College supports the recommendations suggested in the paper and acknowledges the great effort put forth by the Bioethics Advisory Committee in consolidating the research.

Thank you.

Yours sincerely,

A/Prof Goh Lee Gan
President
20th Council (2005 - 2007)

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Feedback to the Bioethics Advisory Committee (BAC), Singapore,

From the Department of Community, Occupational and Family Medicine, Yong Loo Lin School of Medicine, National University of Singapore
for the 14 June 2006 Consultation Paper entitled
"The Use of Personal Information in Biomedical Research"

	BAC's Recommendation	**COFM Response**
1.	*The Legal Protection of Personal Information* We recommend that the relevant authorities consider establishing a legal framework for the use of personal information in biomedical research.	Yes, we support this. It helps assure research participants that they are protected by a legal framework, on top of good practices and policies set out by Institutional Review Boards (IRBs) and the individual Principal Investigators (PIs). It also reinforces that biomedical research is for public good and not merely for scientific progress. Our concerns regarding this recommendation are: • The legal framework must not be too cumbersome and restrictive so as to balance protection versus research needs. • The legal framework should be broad and yet robust to remain relevant for the rapidly advancing field of biomedical science and the supporting or driving technology. It should take into consideration new technology e.g. Trusted Third Party (TTP) / Data Privacy Framework (DPF) mechanisms.
2.	*Consent and Proportionality* Specific consent should be obtained when research	Yes, we support this.

	BAC's Recommendation	**COFM Response**
	involves identifiable personal information or tissue samples. General consent may be obtained for subsequent research involving the use of de-identified information or remnant tissue. The information to be provided to the individual when taking consent should depend on the sensitivity of the information and the risk of harm.	We agree that the level of details in the consent form must be in proportion to the risk of harm to research participant. For example in a very low-risk procedure like taking blood pressure, it is not normal practice to explain beforehand to the participant about the slight discomfort that he will experience when the cuff is being inflated.. We also must have clear statements to cover legacy issues pertaining to studies, data, tissues, etc collected in earlier studies. While getting re-consent would be impractical, IRB review and approval would still be required.
3.	*Disease Registries* We recommend that the relevant authorities clarify the legal basis for the disclosure of medical information to disease registries by health care institutions and physicians; and establish mechanisms enabling the registries and healthcare institutions to increase the accessibility of personal information for research that can significantly advance public welfare, while safeguarding privacy concerns.	Yes, we support this. We would like to emphasize the need for legislation to allow access for research and suggest that legislation be restricted to research for policy and health planning. Our concerns regarding this recommendation are: Trying to get an omnibus Bill/Act to cover all possible disease registries would be too complicated and confusing. It may be preferable to go for disease-specific registries e.g. Cancer Registry, with all the proper justifications, procedures and safeguards. An alternative would be to have a very general Act, and leave the disease-specific details to the Regulations. We should try to expedite the enactment of such legislation as it is long overdue and urgently required to prevent the collapse of present registries. It would be extremely difficult to re-start a comprehensive population-based registry e.g. the Cancer Registry.

	BAC's Recommendation	COFM Response
4.	*Epidemiological Research and Public Health Research* We recommend that the relevant authorities consider establishing legal mechanisms to facilitate the use of personal information in registries, databases and medical records for epidemiological research and public health research. These mechanisms should also ensure that there is minimal risk to individual privacy and confidentiality.	Yes, we support this. Provisions for a TTP/DPF should be a key platform for privacy protection. We are concerned that as the legal mechanisms become formalised, extra costs will be incurred as a result of added administrative overheads and IT requirements. We foresee the need to adjust manpower funding (especially for small projects) for the overhead needed to comply with the legal mechanisms. We hope that funding agencies will provide for administrative support to the Principal Investigators to adhere to the legal mechanisms.
5.	*Clinical Audit and the Electronic Medical Record Exchange* We recommend that the relevant authorities consider legal provisions necessary to ensure that the potentially increased scope of clinical audit does not violate medical confidentiality and to assure the public that privacy and confidentiality interests in personal information will be safeguarded.	Yes, we support this. We understand that clinical audit is not considered research and the use of medical records in such activities is presently not subject to IRB review.
6.	*Vulnerable persons* We recommend that IRBs, when reviewing research, ensure that any concerns in regard to vulnerable persons	Yes, we support this. The Act must define "vulnerable persons".

	BAC's Recommendation	**COFM Response**
	are appropriately addressed.	
7.	*Withdrawal of Consent* Research participants should be allowed to withdraw their consent to participate in a research at any time without explanation and without prejudice. They should be assured that upon withdrawal their personal information and/or tissue samples will either be destroyed or irreversibly de-identified.	Yes, we support this. Participants must be given the choice either to have all data and tissues destroyed or irreversibly de-identified upon withdrawal. It should not be left open to the Principal Investigator's decision. At the same time, from our experience, we recognise that there can be several types of withdrawals e.g.: • Please don't contact me again. You can use all my data and samples that you have collected over the past 10 years. • Please don't contact me again. Please also destroy all my data and samples that you have collected so far. Provision should be made to cater for these different levels of withdrawal e.g. IRB to set guidelines for more complex cases of participant withdrawal.
8.	*Privacy and Confidentiality* Personal information should be de-identified as far and as early as possible and should be stored or transferred as de-identified information.	There are scientifically valid reasons for a research participant to be re-contacted or identified for the purpose of follow up or conducting longitudinal studies, such as in certain types of epidemiological research. In the current practice, the research participant would be asked for consent for follow up or re-contact after having been adequately informed of the implications. We strongly agree that the research participant's information/tissues need to be de-identified for privacy reasons, but irreversibly de-identifying these would disable research of the nature described.

	BAC's Recommendation	COFM Response
		At the same time, we recognize that there are some cases where irreversible de-identification would be appropriate and would not hamper the research process. For sensitive topics e.g. HIV/AIDs, this may be assuring for IRBs and for research participants. It would be better for Recommendation 8 to be suffixed with "The de-identification process should be made reversible or irreversible, depending on which best serves research participants' interests and research needs.
9.	Researchers should not attempt to identify an individual from de-identified information as it is a serious breach of ethics to do so.	For the same reasons stated earlier, we suggest that this recommendation be modified to "Researchers should not attempt to identify an individual from de-identified information unless there is proper justification to do so and the action is approved by the IRB".
10.	Irreversibly de-identified personal information generally need not be subject to privacy and confidentiality requirements.	Yes, we support this.
11.	When reversibly de-identified information is used for research, IRBs should consider the adequacy of the extent and means of the de-identification in proportion to the risk. Should a person be identified from de-identified information, the person should still enjoy confidentiality and privacy entitlements.	Yes, we support this.

	BAC's Recommendation	COFM Response
12.	The ethical principle of confidentiality should apply to the use of personal information from medical or public registries. Confidentiality safeguards should be commensurate with the potential risk of harm from inadvertent disclosure.	Yes, we support this.
13.	*Insurance* We recommend that the government consider implementing a moratorium on the use of predictive genetic information for insurance purposes and appoint an authority to consider long-term implications of the accessibility of predictive genetic test results by employers and the insurance industry and to monitor developments in this area.	Yes, we support this.
-	Other comments,	Information/tissue that potentially identifies an individual and will be sent to or received from overseas, must have approval from the relevant authorities. For research purposes, the IRB and Head of Institution must give their written approvals. The IRB, in its review, must also consider the mode of transmission of the information and ensure sufficient measures to ensure the safety of the information during transfer.
-	In conclusion: …	We are pleased to read the consultation paper that has been put together by the BAC on the

	BAC's Recommendation	COFM Response
		use of personal information in biomedical research. We are glad that many of the recommendations are already in place and implemented by us in the various population-based epidemiological studies that we have been conducting thus far in the department. This paper will help inform the public that researchers, in general, are aware and compliant with good practices in maintaining data confidentiality and privacy of personal information, and provide a vote of confidence in the high standard of research integrity maintained by researchers at large. While we applaud and support the detailed recommendations which have comprehensively covered many aspects in the use of personal information in biomedical research, we hope that the legal mechanisms can be streamlined to be both efficient and cost-effective for researchers. In particular, we are concerned that the need for a third party in providing the linkage of databases may necessitate a cost that needs to be provided for through grants. This may be problematic for small-scale studies that may not have the budget for the administrative cost incurred in this process. We are also concerned about the accessibility of identifiable information for the practicality of conducting long-term follow-up studies. Hence, we hope that while Principal Investigators adhere strictly to the use of escrow systems and data confidentiality, they will be allowed to have access to identifiable information when it is necessary for conducting the follow-up of individual research participants. Finally, while linkage is often done through the use of the NRIC, mistakes in data entry may lead to inaccuracies of linkage. Hence,

	BAC's Recommendation	**COFM Response**
		Principal Investigators should also be allowed to have sufficient information provided with the linkage, such as gender and birthdates in both databases, to verify the accuracy of the linkage.

This feedback is submitted through:

Professor David Koh
Head, Department of Community, Occupational and Family Medicine
By:
Professor Lee Hin Peng
Associate Professor Chia Sin Eng
Associate Professor Adeline Seow
Associate Professor Saw Seang Mei
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12 July 2006

Assoc Professor Terry Kaan
Chairman
Human Genetics Subcommittee
Bioethics Advisory Committee
11 Biopolis Way
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Dear Terry

REQUEST FOR FEEDBACK ON CONSULTATION PAPER

I refer to your letter dated 14 June 2006. We congratulate you for an excellent paper which was well written and comprehensive. We feel that this is a very timely paper covering all aspects of the use of personal information in biomedical research.

In principal, we agree with all the 13 recommendations and we would like to provide some feedback as appended overleaf.

Terry, we hope our feedback will be useful and please feel free to correspond with us if any clarification is required.

With warmest regards

Yours sincerely

A/Prof Tay Eng Hseon
Chairman Medical Board

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FEEDBACK ON CONSULTATION PAPER
"THE USE OF PERSONAL INFORMATION IN BIOMEDICAL RESEARCH"

We seek clarification as to what 'relevant authorities' refer to (1), (3), (4) & (5).

Is it members of hospitals. If hospitals, do we in KKH have the resource to establish a legal framework to carry out our ethical duties. Will there be many versions if each institutions establishes their own legal framework.

It is also not very clearly defined what made anonymised (i.e. to de-identify with the potential of re-identification later if necessary) and what made anonymous (i.e. to de-identify such that there can be no link ever of personal information to the person) is. Under what circumstances is fully anonymous data called for?

The protection of data is not sufficiently spelt out. Is it the PI's sole responsibilities? Where and under what securities should the data base be sited.

Part IV Para 10.

We feel that it is imperative what identity is "delinked"

Part IV Recommendation 2

For tissue samples, we are of the view that generally, de-identification should be irreversible, unless it address the treatment of disease and with consent from patients.

Our Ref: LS/85/06/CLT/dy Your Ref:

THE LAW SOCIETY OF SINGAPORE

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26 July 2006

Assoc. Professor Terry Kaan
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Dear Sir

REQUEST FOR FEEDBACK ON CONSULTATION PAPER

Further to our letter dated 22 June 2006, the Society appointed an ad hoc committee to review the consultation paper by BAC titled "The Use of Personal Information in Biomedical Research".

We are pleased to enclose our ad hoc committee's feedback on the matter for your consideration.

Thank you for giving the Society the opportunity to give our views on the matter.

Yours faithfully

Chua Lik Teng
Deputy Chief Executive Officer

enc./

26 JULY 2006

THE LAW SOCIETY OF SINGAPORE

AD HOC COMMITTEE'S FEEDBACK ON THE BIOETHICS ADVISORY COMMITTEE'S CONSULTATION PAPER ON THE USE OF PERSONAL INFORMATION IN BIOMEDICAL RESEARCH

THE LAW SOCIETY
OF SINGAPORE

THE LAW SOCIETY OF SINGAPORE

AD HOC COMMITTEE'S FEEDBACK ON THE BIOETHICS ADVISORY COMMITTEE'S CONSULTATION PAPER ON THE USE OF PERSONAL INFORMATION IN BIOMEDICAL RESEARCH

INTRODUCTION

The Law Society appointed an ad hoc committee (the "Committee") to conduct the review of the Consultation Paper by the Bioethics Advisory Committee ("BAC") on "The Use of Personal Information in Biomedical Research". This Committee comprises practitioners involved in advising and representing individuals and organisations in the health care industry as part of their legal work, who have also been involved in the review of an earlier consultation paper by BAC in April 2005.

In this review, the Committee's comments are limited to the legal aspects of the Consultation Paper based on the current law in Singapore.

The views of the Committee are set out as follows.

COMMENTS OF AD HOC COMMITTEE

1. The Committee agrees, in general, with the recommendations of the BAC, save for comments on the following points. We have addressed issues in the order in which they appear as recommendations in the Consultation Paper.

RECOMMENDATION 2

Specific consent should be obtained when research involves identifiable personal information or tissue samples. General consent may be obtained for subsequent research involving the use of de-identified information or remnant tissue. The information to be provided to the individual when taking consent should depend on the sensitivity of the information and the risk of harm.

2. Recommendation 2 recommends that specific consent should be obtained where research involves identifiable personal information or tissue samples. However, in respect of de-identified information or remnant tissue, the recommendation is that general consent may (as opposed to "should") be obtained.

3. Whilst we agree that general consent would be sufficient in the case of de-identified tissue and remnant tissue, the use of the word "may" suggests that the researcher has an option to obtain consent. We are of the view that the recommendation should be that general consent should (rather than "may") be obtained, as the participant's consent at the time would not have encompassed the subsequent use of the information or remnant tissue and it is conceivable that persons from whom the information or remnant tissue is obtained could have personal objections to the use of their tissue for research, notwithstanding the de-identification of such tissue and would not have participated in the research study if he had been informed of the possible subsequent use of the information or tissue samples.

4. We do, however, recognise that there may be situations where it would be appropriate for such consent to be waived. This should be the exception rather than the rule and should involve consideration and approval by the bodies involved in approving the research.

5. We agree generally with the statement that "(t)he information to be provided to the individual when taking consent should depend on the sensitivity of the information and the risk of harm", It is not clear what "harm" is envisaged and how this should be balanced against the sensitivity of the information.

RECOMMENDATION 3

We recommend that the relevant authorities clarify the legal basis for the disclosure of medical information to disease registries by health care institutions and physicians; and establish mechanisms enabling the registries and healthcare institutions to increase the accessibility of personal information for research that can significantly advance public welfare, while safeguarding privacy concerns.

RECOMMENDATION 4

We recommend that the relevant authorities consider establishing legal mechanisms to facilitate the use of personal information in registries, databases and medical records for epidemiological research and public health research. These mechanisms should also ensure that there is minimal risk to individual privacy and confidentiality.

6. The members of this Committee had previously commented that there are no decisions by the Singapore courts on the ambit and the applicability of public policy as a defence to the disclosure of confidential information and would agree that the legal position should be clarified by the relevant authorities.

RECOMMENDATION 6

We recommend that IRBs, when reviewing research, ensure that any concerns in regard to vulnerable persons are appropriately addressed.

7. We are of the view that guidelines or safeguards should be recommended and put in place to address the vulnerability of patients who are recruited by their treating physicians/ medical practitioners for research personally undertaken by their treating physicians/ medical practitioners.

RECOMMENDATION 7

Research participants should be allowed to withdraw their consent to participate in a research at any time without explanation and without prejudice. They should be assured that upon withdrawal their personal information and/or tissue samples will either be destroyed or irreversibly de-identified.

8. A distinction may need to be drawn between research participants who continue to be involved in research, for example, through the use of trial medication, and participants whose only involvement is to provide a tissue sample.

9. Clearly, if a research participant has a continuing involvement in the research, he is entitled to withdraw at any time and he should be informed of that right.

10. It is arguable that if the research participant only provided a tissue sample and has done so, the participant has surrendered "ownership" or rights to the sample. In that event, the participant may not be entitled to insist that the tissue sample should be destroyed and the researchers may not be obliged to destroy the sample, as long as the sample is used only for the purpose of the research for which it was provided.

11. However, there is a consensus that a research participant continues to have a right to confidentiality and should be assured that their personal information is destroyed or irreversibly de-identified and procedures must be put in place to ensure that this is actually carried out upon the withdrawal of the research participant.

12. The members of this Committee had previously addressed this point in the comments on the BAC's earlier Consultation Paper On Ethical, Legal And Social Issues In Genetic Testing And Genetics Research. For ease of reference, our previous comments are set out again below:-

2.1 Although the right of the individual to withdraw his consent in participating in the research study is recognised, it is not clear what the individual's rights are following the withdrawal of his participation in Genetic Testing in respect of:-

(a) the genetic material already taken from him; and

(b) the information/ results derived from such material.

2.2 We would suggest that there be a mechanism for the individual to withdraw from the test and at the time his consent is taken, information setting out how the individual can withdraw.

2.3 *Further, information should also be provided at the outset to the individual, stating whether the individual can insist on the destruction of all material and test or research results upon his withdrawal from the research, and if not, assurances as to anonymization of the information derived from the genetic material and whether the information can be traced to the individual.*

RECOMMENDATION 13

We recommend that the government consider implementing a moratorium on the use of predictive genetic information for insurance purposes and appoint an authority to consider long-term implications of the accessibility of predictive genetic test results by employers and the insurance industry and to monitor developments in this area.

13. It is unclear if the recommendation is intended to prevent disclosure or use of the information. We are of the view that the moratorium on the use of predictive genetic information should relate to its disclosure to employers and insurers for the purposes of this paper and the recommendation should include the consensus that no one should be compelled to undergo genetic testing as part of a pre-employment medical examination or in order to obtain insurance coverage.

Date: 26 July 2006

Life Insurance Association, Singapore

From:	Pauline Lim Executive Secretary Life Insurance Association, Singapore
Received by email:	28 July 2006

Comments received from three LIA member companies

We suggest that BAC make reference to other established research, such as the Australian policy on genetic testing.

Comments on the following two clauses:

6.14 Following the recommendations of the Select Committee, a moratorium was implemented by agreement between the UK Government and the Association of British Insurers from 2001. Under the moratorium, a person will not be required to disclose the result of a predictive genetic test unless approved by the GAIC (to date, only Huntington's Disease has been approved) and is for coverage of more than £500,000 of life insurance or £300,000 for critical illness insurance or income protection insurance with annual benefits of £30,000. The initial duration of the moratorium was 5 years and was later extended for another 5 years, to 2011.

6.15 We are of the view that a similar moratorium on the use of predictive genetic information could be considered in Singapore. This will allow both the insurance industry and relevant government authorities time to look into the substantive issues. Both parties should ensure that only relevant and reliable information is used in assessing insurance applications, and that the outcomes of the conditions considered are both serious and predictable, before considering lifting any such moratorium.

My view about the above practice and recommendation (6.14 and 6.15):
Predictive genetic testing has considerable potential for accurate risk assessment, although in the same time we should not deny that most predictive tests carry a degree of uncertainty about whether a condition will develop, when it will develop, and how severe it will be. (Note: Predictive genetic testing is the use of a genetic test in an asymptomatic person to predict future risk of disease.) So, to an Insurer, predictive genetic test result should be seen a material fact that could be deemed as a "NON DISCLOSURE" if an insurance's applicant fails to reveal such info upon application.

To give an idea about how big the risk could be, I illustrate with the following scenario for an example.

If two people who carry the defective gene of cystic fibrosis conceive a child, there's a 25 percent chance the child will have cystic fibrosis, a 50 percent chance the child will be a carrier of the cystic fibrosis gene, and a 25 percent chance the child will neither have the disease nor be a carrier.

(Note: cystic fibrosis is an inherited abnormality due to recessive defective genes. Manifestation of this condition could result in damage of lung, intestine, and other internal organs. The "recessive" nature of this condition means that this abnormality will only manifest/appear when a person inherits two abnormal cystic fibrosis genes, one from her father and another one from her mother. The condition becomes obvious when the child was 2-3 years old. If a person only has one defective gene and the other gene is normal, the abnormal condition does not manifest).

Positive predictive value of genetic test for this condition is 99.5% (meaning 99.5% of persons with positive genetic test result for cystic fibrosis are truly having cystic fibrosis gene). On the other hand, Negative predictive value of genetic test for this condition is 99.96% (meaning 99.96% of persons with negative genetic test result for cystic fibrosis are truly not having cystic fibrosis gene). These two values suggest considerably accurate predictive genetic test for cystic fibrosis.

So, if a positive result of predictive genetic test of a child from the above mentioned couple were not disclosed upon applying Insurance, then the insurer would be facing about 33% (see formula below) risk to cover the child with cystic fibrosis. Quite substantial risk, isn't it?

We would like to refer to comments made regarding NOT recommending a moratorium period as suggested in the consultation paper. The main reasons being:

1. it may be irrelevant as very few individuals go for a test
2. it can be mis-interpreted as the industry's willingness to waive its right for genetic discrimination

To emphasise point 1, I would like to share the comment made by Mary Francis, director general of the ABI, said in a statement:

"... because the existing moratorium works well, and the number of people currently taking relevant tests remains low, we felt confident about proposing to the government that it should be extended."

مجلس اكام اسلام سيغافورا
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7 August 2006

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Dear Sir,

RE: REQUEST FOR FEEDBACK ON CONSULTATION PAPER

We refer to your letter requesting our organisation's view on the Bioethics Advisory Committee's consultation paper entitled "The Use of Personal Information in Biomedical Research".

2 We append herewith our comments on the recommendations made in the paper.

3 We would also like to apologise for the delay in the response.

Thank you.

Yours sincerely

Nazirudin Mohd Nasir
Head,
Office of the Mufti
Islamic Religious Council of Singapore

Feedback from Majlis Ugama Islam Singapura (MUIS) on
BAC's Consultation Paper entitled
The Use of Personal Information in Biomedical Research

Introduction

The Majlis Ugama Islam Singapura (MUIS) has been invited to comment on the issues and recommendations contained within the Bioethics Advisory Committee's (BAC) consultation paper entitled "The Use of Personal Information in Biomedical Research". The comments are offered in the following three sections:

(i) Protection of Individual Rights

(ii) Pursuit of Public Interests

(iii) Balance between Individual Rights and Public Interests

(i) Protection of Individual Rights

2 All members of the human race are endowed with dignity, nobility and honour. Islam views dignity as one of the natural rights of every individual. The securing of one's dignity and honour is considered a principle of governance and an ethical code for interaction among people. It is not permissible to violate the personal dignity of anyone, regardless of religion, status or reputation.

3 The principle of securing the right of an individual to his/her dignity and honour entails the securing of the individual's right to his/her privacy. The right of an individual to his/her own privacy is considered as a divine right, given by Allah Al-Mighty as mentioned in the authentic sources of the religion. The Holy Qur'an has laid down the injunction: "Do not spy on one another" (49:12). The Islamic legal system adopts this principle in prohibiting unlawful entries and

searches, to the extent that incriminating evidence obtained by eavesdropping or other unlawful means cannot be used for prosecution. [1]

(ii) Pursuit of Public Interests

4 Concurrently, every member of the community has the duty to share public responsibility and promote public interest (*maslahah*). Islam places as much importance on public interest as it does on individual rights. In Islam, it is not only obligatory to do no harm toward others, but also to proffer benefit to the larger public welfare. Activities that lead to the securing of public interests are encouraged.

5 The Islamic legal philosopher, Abu Ishaq As-Syatibi (d. 790), identifies the enhancement of human life as one of the types of public interest that ought to be secured. This includes scientific research which leads to the prevention and treatment of diseases.

6 In any research work that benefits mankind, the protection of human dignity and all that such a principle entails, must be upheld. As such, strict guidelines must be institutionalised to protect confidentiality and human dignity for any research work.

(iii) Balance between Individual Rights and Public Interests

7 Exceptions from the requirement of safeguarding confidentiality are made in cases where doing so may cause greater harm, insofar as the safety of the society at large is at jeopardy, such as the case with an epidemic. This seemingly competing interest, between one's right to privacy and confidentiality, and the larger public welfare, calls for a delicate balancing act, where individual rights are protected, whilst beneficial scientific progress continues to be pursued.

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[1] Weeramantry, C.G. *Islamic Jurisprudence: An International Perspective*. Islamic Book Trust, The Other Press (Malaysia). 1996.

8 The recommendations by the BAC contained within the consultation paper, have largely taken into consideration the above principles, and have shown due care in balancing between the advancement of scientific research, on the one hand, and the protection of privacy and confidentiality, on the other. We find the recommendations agreeable and offer the following additional points:

i. We are fully supportive of the need to establish a legal framework for the use of personal information in biomedical research (Recommendation 1).

ii. All personal information should be irreversibly de-identified (Recommendation 8), unless doing the contrary is deemed necessary.

iii. In line with (Recommendation 7), the wishes of research participants should be respected at all times. As such, disclosure of information is possible if a participant has expressed, at the outset, explicit consent knowledgeably and willingly, that his/her information may be identified for future use, and that such information will be utilised to benefit the research work.

iv. In a situation where it is deemed necessary to identify personal information, whether before the initiation of, or at some point during, a research work, the case should be presented before the Institutional Review Board (IRB) for their assessment.

v. We recommend that the types of research which may require identification of the subjects or individuals be drawn up by the IRB to be used as guidelines by the research bodies.

vi. Appropriate and sufficient legal measures should be in place to address any attempts to identify an individual from de-identified information.

END

National Cancer Centre

Comments on the BAC consultation paper entitled 'The use of personal information in biomedical research' dated 14 June 2006

The intent and recommendations of this document echo trends and developments in other countries (mainly Western) in recent years. To this extent, the paper is timely and its recommendations are generally sound. A notable feature is the attempt to achieve a good balance between injurious disclosure of personal information (a well recognised hazard) and rigid and counterproductive overprotection of medical information that hinders and even prevents medical research, to the detriment of whole societies.

While the principles enunciated in the consultation paper are unexceptional and in line with current bioethical thinking, a few operational points could be made.

1. It is reasonable that data for certain disease registries (of public health importance) may be obtained without patients' explicit and prior consent (page 3, Part IV, para. 11; page 23, para. 4.25). It is also proper that the Singapore population be 'appropriately informed' of this practice. However, the BAC does not indicate what it considers to be appropriate measures of informing the public, whether members of the public will have the right to opt out of disease registries (page 31, section 5.4 suggests this may be allowed), and whether certain future types of disease registries (e.g. neuropsychiatric disorders) will be handled differently. It is also unclear if trawling for data for disease registries will be limited to patients who attend public hospitals and clinics or if private hospital data will be used also for disease registries (page 24, para. 4.28). If the former, the perception (not entirely unjustified) that money buys privacy will arise.

2. In discussing irreversibly de-identified information (page 18, para. 4.12), the consultation paper states that 'the individual should be able to opt out'. This does not appear possible if the information and/or biological sample of an individual has in fact been truly and permanently de-identified.

3. There can be no good substitute for children and adolescents as research subjects for certain objectives such as determining paediatric drug safety and optimal dosing. Thus it is inaccurate to state that children and adolescents should be research participants only when other participants (presumably adults) are unavailable or unsuitable (page 29 , para. 4.45).

4. The age of legal consent for medical decisions is currently ambiguous in Singapore. It would be helpful for the BAC or the relevant authorities to provide clearer guidelines on this fundamental point. Situations when parents and their adolescent children disagree will need to be dealt with.

5. While it is standard practice to enable research subjects to withdraw their participation (page 30, para. 4.52) and for such withdrawal to be accompanied by destruction of any residual biological samples, and complete and permanent erasure of personal information from the research database, it is unclear if research data already obtained from the patient's sample(s)/medical record before the decision to withdraw, may be retained by the investigators.

6. The consultation paper refers to close genetic relatives but omits to deal with how preserving the traditional confidentiality of the physician-patient relationship should be balanced against the need to provide relevant genetic information to the patient's close relatives, in the event that the index patient is unwilling to make the disclosure to his/her family (page 31, para. 5.3).

7. Much of the substance of the consultation paper is more reflective of Western societies than Singapore. While the principles of ethics are universal, the practice of bioethics must be culturally emplaced or it becomes a fig leaf. Much is made of obtaining 'informed consent', but little regards is paid to evaluating how much information patients and research subjects in Singapore wish to receive, the language that best conveys information and the extent of comprehension. There is a need for Singapore to conduct studies to develop and assess culturally appropriate consent practices in order to determine if the informed consent process, as practised in Singapore, is indeed achieving its true intended purpose.

Kon Oi Lian
22 June 2006

National Council of Churches of Singapore
新加坡基督教會協會
சிங்கப்பூர் திருச்சபைகளின் தேசிய மன்றம்

13 July 2006

Associate Professor Terry Kaan
Chairman
Human Genetics Subcommittee
Bioethics Advisory Committee
11 Biopolis Way, #10-12 Helios
Singapore 138667

Dear Prof Kaan

THE USE OF PERSONAL INFORMATION IN BIOMEDICAL RESEARCH

Thank you for seeking feedback from the National Council of Churches of Singapore on the above subject.

We hereby enclose our response to ***"The Use of Personal Information in Biomedical Research".***

We trust that this feedback will receive careful and serious consideration.

Thank you

Yours sincerely

BISHOP DR ROBERT SOLOMON
President
National Council of Churches of Singapore

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Comments on the Bioethics Advisory Committee's Consultation Paper on *The use of personal information in biomedical research*

Presented by the National Council of Churches of Singapore

The National Council of Churches of Singapore (NCCS) thanks the BAC for seeking feedback on the consultation paper, 'The use of personal information in biomedical research'. The NCCS notes that the intent and recommendations of the consultation paper echo trends and developments in other countries (mainly Western) in recent years. To this extent, the paper is timely and its recommendations are generally sound. A notable feature is the attempt to achieve a good balance between injurious disclosure of personal information (a well recognised hazard) and rigid and counterproductive overprotection of medical information that hinders and even prevents medical research, to the detriment of whole societies.

While the principles enunciated in the consultation paper are unexceptional and in line with current bioethical thinking, a few operational points could be made.

1. NCCS suggests that Recommendation 1 (page 2) be strengthened by adding two words (underlined) as follows:
   'We recommend that the relevant authorities consider establishing a legal framework for the use and protection of personal information in biomedical research.'
   The rationale is to guard against sliding into a purely utilitarian approach to the use of personal information driven only by expedience and economic motives. Emphasizing the twin responsibilities of researchers both to use and protect should help to defend vulnerable persons against disrespect, abuse and even exploitation.

2. It is reasonable that data for certain disease registries (of public health importance) may be obtained without patients' explicit and prior consent (page 3, Part IV, paragraph 11; page 23, paragraph 4.25). It is also proper that the Singapore population be 'appropriately informed' of this practice. However, the BAC does not indicate what it considers to be appropriate measures of informing the public, whether members of the public will have the right to opt out of disease registries (page 31, section 5.4 suggests this may be allowed), and whether certain future types of disease registries (e.g. neuropsychiatric disorders) will be handled differently. It is also unclear if trawling for data for disease registries will be limited to patients who attend public hospitals and clinics or if private hospital data will be used also for disease registries (page 24, paragraph 4.28). If the former, the perception (not entirely unjustified) that money buys privacy will arise.

3. In discussing irreversibly de-identified information (page 18, paragraph 4.12), the consultation paper states that 'the individual should be able to opt out'. This does not appear possible if the information and/or biological sample of an individual has in fact been truly and permanently de-identified.

4. While we agree with the principle of reciprocity (page 20, paragraph 4.20), it must not be used, for economic reasons, to pressurise or coerce anyone to forego their right to privacy and confidentiality.

5. There can be no good substitute for children and adolescents as research subjects for certain objectives such as determining paediatric drug safety and optimal dosing. Thus it is inaccurate to state that children and adolescents should be research participants only when other participants (presumably adults) are unavailable or unsuitable (page 29, paragraph 4.45).

6. The age of legal consent for medical decisions is currently ambiguous in Singapore. It would be helpful for the BAC or the relevant authorities to provide clearer guidelines on this fundamental point. Situations when parents and their adolescent children disagree will need to be dealt with.

7. While it is standard practice to enable research subjects to withdraw their participation (page 30, paragraph 4.52) and for such withdrawal to be accompanied by destruction of any residual biological samples, and complete and permanent erasure of personal information from the research database, it is unclear if research data already obtained from the patient's sample(s)/medical record before the decision to withdraw, may be retained by the investigators.

8. The consultation paper refers to close genetic relatives but omits to deal with how preserving the traditional confidentiality of the physician-patient relationship should be balanced against the need to provide relevant genetic information to the patient's close relatives, in the event that the index patient is unwilling to make the disclosure to his/her family (page 31, paragraph 5.3).

9. Much of the substance of the consultation paper is more reflective of Western societies than Singapore. While the principles of ethics are universal, the practice of bioethics must be culturally emplaced or it becomes a fig leaf. Much is made of obtaining 'informed consent', but little regards is paid to evaluating how much information patients and research subjects in Singapore wish to receive, the language that best conveys information and the extent of comprehension. There is a need for Singapore to conduct studies to develop and assess culturally appropriate consent practices in order to determine if the informed consent process, as practised in Singapore, is indeed achieving its true intended purpose.

COMMENTS FROM NATIONAL MEDICAL ETHICS COMMITTEE (NMEC) ON THE BAC CONSULTATION PAPER (THE USE OF PERSONAL INFORMATION IN BIOMEDICAL RESEARCH)

The BAC consultation paper on "The Use of Personal Information in Biomedical Research" is a good report. NMEC's comments on the BAC consultation paper would focus generally on the personal information that is recorded as part of clinical management within biomedical research.

	Section	**NMEC Comments**
Part II	Personal Information (p.2 and p.11)	Genetic information is particularly sensitive and therefore genetic studies require special precautions. For example, IRBs use a separate template for Informed Consent in genetic studies, which include statements such as "genetic information can affect a person's insurability, employability, reputation and private life." NMEC proposes a cross reference to BAC's Genetic Testing and Genetic Research Report wherever genetic studies are involved.
	Item 2.7(b) (p.13)	For genetic studies, IRBs usually require double coding, i.e. de-identification for the subject and another de-identification for the genetic sample.
	Item 2.6 (p.13)	NMEC recommends inserting a statement in this section regarding the recruitment of trial subjects. There could be opportunities when investigators might approach departments which keep medical records, such as the Medical Records Office, X-Ray Department, Pharmacy, and Laboratory, for names of patients who are potential trial subjects. If the investigator then contacts the patient (without asking the attending physician), it will be a breach of medical confidentiality. All the patient has to do is ask "How do you know I have Parkinson's Disease? (Or whatever the diagnosis)" as medical diagnosis is private information. Such breach of medical confidentiality happens easily in institutional practice, such as large national centres or re-structured hospitals where there is a general feeling that the patients' data belong to the centre or department concerned. The role of the attending physician is therefore important during the recruitment of trial subjects. There could potentially be an ethical problem of touting for patients under the disguise of "medical research" through such means.

	Section	NMEC Comments
Part III	The Legal Protection of Personal Information	With the increasing use of digitalization in healthcare data and information, there should be more transparency in the processes which ensure that digitalized information is adequately protected from unauthorized access or manipulation by the IT personnel. Moreover, in both healthcare clusters, the staff can access the medical information of any patients through their passwords. Therefore, it will be essential that healthcare institutions (both public and private) and disease registries should have policies and systems for tracking access to patients' electronic information. For example, in strengthening the security of the access to any kind of medical database, including disease registries, passwords given to authorized staff for such access should be "blinded" to the IT personnel. Healthcare institutions should have proper systems for safeguarding patients' personal and medical information from the auditors, including the information system managers.
	Data or samples that are sent abroad	There is no extraterritorial law with regards to data or tissue samples transferred abroad. Singapore laws can be applied only locally. There is no common law to govern the ownership of any tissue from a dead person. It is therefore recommended to clarify these issues clearly in the informed consent form, possibly in the nature of a contract, with a time frame, to ensure no dispute in the transfer of these tissue samples. IRB approval should be required for any movement of sensitive data or tissues' specimen across the country borders, for research purposes.
Part IV	Informed Consent	A living person can withdraw his or her consent, but this is not the case for a person who has passed away. However, the issue of confidentiality still applies even after the demise of the person. Although the IRB is the gatekeeper for this confidentiality, the question of liability and position of IRB would be raised if the next-of-kin should pursue legal action for breaches of confidentiality for the deceased. Even in common law, no one has ownership of the body parts for a deceased person, which cannot be claimed legally. To avoid breaching medical ethics and the legislation, NMEC proposes that researchers seek for informed consent to use tissue specimens for research purposes, consent to

	Section	NMEC Comments
		remove the tissue from the body, as well as the way it can be disposed of.
	Items 19 & 4.44 (p.5 and p.28)	(a) children and adolescents NMEC opines whether it is possible to make a statement regarding the Age of Consent. Very often, multi-centre trials (with foreign countries) involve subjects from the age of 18 years. So IRBs in Singapore are frequently faced with the dilemma of whether to amend the age to 21 years, which might not be right as this could alter the character of the trial cohort or stipulate that parental permission is required for subjects below 21. The "level of maturity" is mentioned in Item 4.47, line 6. NMEC proposes to substitute "Age of Maturity" which could be a better guide than the legal Age of Consent.
	Items 4.47, 4.48 (p.29)	Vulnerable subjects, such as adolescents or mentally impaired persons, may not want to disclose information to a third party or their guardian, in which case, it would be difficult to carry out the research study. If the study is essential, i.e. in their medical interests, we should be allowed to disclose relevant information to an appropriate person or authority (General Medical Council, UK ruling on Confidentiality, 2004)
	Items 19 and 4.44 (p.5 and p.28)	List of "Vulnerable persons" NMEC recommends that the list of "vulnerable persons" include "Pregnant Women and Foetuses", as they are "at heightened risk for adverse consequences of the research".
	Recommendation 3, 4 and 5	Recommendations 3, 4 and 5 would have significant impact on clinical practices. It is necessary to have a formal framework for accessibility of personal information by disease registries. In general, disclosure of information about a patient requires the patient's consent but there can be exceptions, such as information transferred to disease registries. In the USA, patients might not agree to such exceptions. There could also be a recommendation in the BAC report for the requirement in reporting side effects of Traditional Chinese Medicines (TCM), in the same way as there is for western medicines. NMEC opines whether the TCM Act could contain a statement allowing the traditional medical practitioners to disclose

	Section	NMEC Comments
		medical information in the public interest, e.g. adverse reactions from TCM practitioners.
Part V	Privacy and Confidentiality	The principle of primacy of ownership of health data should be recognized, unless there is the urgency of serious public health concerns (e.g. infectious diseases). Doctors treating patients have the rights to the data, but only for treating the patient. Similarly, HCIs own the medical records, but only to facilitate the treatment needs of the patient. The patient's data should not be used for any other purposes. Security of databases can be penetrated in some way by researchers, so there is a need for an internal security process to ensure appropriate anonymisation of data at the hospital and registry levels. (With digitalization of data, a person's health data can be disseminated very widely and rapidly. What if information in the records is false, for example, a person might be wrongly recorded as having tested positive for syphilis?)
	Recommendation 13	NMEC recommends a moratorium on the use of predictive genetic information for insurance purposes.

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18 July 2006

Assoc Prof Terry Kaan
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Bioethics Advisory Committee
11 Biopolis Way, #10-12 Helios
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Dear A/Prof Kaan

FEEDBACK ON CONSULTATION PAPER ON THE USE OF PERSONAL INFORMATION IN BIOMEDICAL RESEARCH

Thank you for the Consultation Paper.

Under para 2.2 of this paper, an "image" is considered information that identifies an individual. However often times pictures of patients are used in publication to illustrate the condition and discussions.

I feel it should be explicitly stated that images of patients may be used in publications for research and training if the patient cannot be identified from these images.

Yours sincerely.

Assoc Prof Roy Chan
Director

DID: 63508473

\Bioethics Advisory Committee – Consultation paper feedback\jw

Robert Hewitt, 31st July 2006
NUH-NUS Tissue Repository

Comments On Consultation Paper Entitled: The Use Of Personal Information In Biomedical Research

Many of the ethical issues that surround management of collections of personal data are identical to those relating to collections of tissue samples, since tissue samples contain personal genetic information. Patients require protection against misuse of personal information, whether their personal data or their tissue samples are being stored and used for research. This protection should include physical security, de-identification, access control by an ethics committee and legal protections.

Experience from tissue banking shows us that "informed consent" is interpreted in many different ways by different people. If conducted to a high standard, it is time-consuming, expensive and may be inconvenient to the patient. Typically, informed consent takes 15 to 20 minutes, and can only be taken when the patient is available and not being seen by medical or nursing staff. Consequently the difficulty in obtaining full "informed consent" is very easily underestimated. The question always remains as to whether patients who have been fully informed also fully understand the implications of consent, since the issues involved are complex. Consent forms are often hard to understand and at best, many of these forms are only understandable by people with a college education. If "informed consent" is to be required, then the practical implications and limitations should first be fully understood and the costs weighed up against the benefits.

For tissues, we have the concept of a legacy and non-legacy tissue collections, which is helpful in allowing ethics committees to take into account the difficulties in obtaining consent from patients who have left the hospital, moved away or perhaps even died. Ethics committees can relax the requirement for informed consent for legacy tissue collections, since obtaining it is often difficult/impossible. If informed consent is to be required for use of personal information, then perhaps the concept of legacy and non-legacy databases should be considered. Or perhaps a similar distinction could be made between retrospective and prospective data collection (where consent requirement is strongest for prospective collection of data).

The BACs recommendations for human tissue research state that research tissue banking should only be conducted by institutions and not by private individuals. This helps ensure that tissue samples are available to the most deserving researchers and not reserved by people whose circumstances allow them to collect the sample. Should the same apply to registries? Either way, the subject of researcher access to clinical information needs to be given careful attention. Should clinicians be allowed to control access to de-identified data from the patients they have treated, should "strings attached" be permitted, or should the information be freely available to approved researchers?

Comments on specific recommendations:

Recommendation 1: We recommend that the relevant authorities consider establishing a legal framework for the use of personal information in biomedical research.

Agreed, we need a legal measures to protect individuals against misuse of their personal information, because other protective measures are inadequate by themselves: *De-identification* alone does not provide sufficient protection, whether described as reversible or irreversible: Given that information on a given patient may be stored on many different databases, it may be possible to re-identify a patient by simply matching a combination of items in a patient's medical history. Similar difficulties apply for tissue samples which may be associated with the clinical data: The forensic scientist's ability to identify suspects from DNA samples, points to the fact that absolute irreversible de-identification of tissue samples is not possible, short of complete destruction of the contained genetic information. *Informed consent* is an important measure to show respect for patient autonomy, but it only offers protection against research-associated risks (eg. social or financial consequences) if the patient declines consent. If the patient agrees to participate, then their consent offers no protection at all against research risks. *Ethics committee approval* may help ensure that data is only used by appropriate researchers, but it cannot guarantee their good conduct.

Recommendation 2: Specific consent should be obtained when research involves identifiable personal information or tissue samples. General consent may be obtained for subsequent research involving the use of de-identified information or remnant tissue. ……

This recommendation may be difficult to apply in the context of Hospital-based Cancer Registries (HCR), since this kind of registry which contains very detailed clinical information, is used to help in the clinical management of patients. The information is regularly updated by a Cancer Registrar at each follow-up visit and may be used to ensure that patients attend all their follow-up appointments. For this reason, the information needs to remain identified. To require specific informed consent for data entry to an HCR would cause many problems. Firstly, if patient refused consent it would prejudice the quality of their own clinical care and this would be unacceptable. Secondly, it would diminish the value of the registry for clinical audit and other forms of research.

Perhaps the term "disease registry" needs to be defined. Is it simply a database of clinical information or does it carry some other more specific meaning? Also, would an HCR fit into the definition of registry as used in these recommendations?

One small note: If specific informed consent is obtained for identifiable material, it may be advisable to request general informed consent at the same time. This would allow subsequent de-identification and unspecified use of the information without the need for re-consent.

Recommendation 4: We recommend that the relevant authorities consider establishing legal mechanisms to facilitate the use of personal information in registries, databases and medical records for epidemiological research and public health research. These mechanisms should also ensure that there is minimal risk to individual privacy and confidentiality.

The importance of facilitating use of personal information for epidemiological and public health research is singled out in this recommendation. However there are other types of research requiring clinical information, which are also very important in terms of improving patient care. For example, clinical trials and biomarker studies. Is there some reason why it is considered less important to facilitate use of personal information for such studies? Agreed, the benefits are less immediate, but obviously they are important all the same.

Recommendation 7: Research participants should be allowed to withdraw their consent to participate in a research (study) at any time without explanation and without prejudice. They should be assured that upon withdrawal their personal information and/or tissue samples will be either destroyed or irreversibly de-identified.

Recommendation 10: Irreversibly de-identified personal information generally need not be subject to privacy and confidentiality requirements.

As argued above, absolute irreversible de-identification is not possible. Following along on this line of argument, withdrawal should mean both removal and destruction (*in contrast to recommendation 7*) and privacy and confidentiality requirements should still be required for information described as irreversibly de-identified (*in contrast to recommendation 10*).

Recommendation 9: Researchers should not attempt to identify an individual from de-identified information as it is a serious breach of ethics to do so.

Agreed, researchers should not attempt to re-identify cases themselves. However, researchers often need to obtain additional information for cases on which they have studied previously (this often applies for tissue samples) and to provide such information, re-identification is necessary.

For this reason there needs to be an approved third party (eg. a tissue repository), which can re-identify cases, link additional information, de-identify and then return required information to the researcher. This is labour intensive work and requires dedicated individuals to carry it out reliably. The process of re-identification should not be made too slow or difficult, otherwise it will create a bottleneck for research.

All other recommendations (3, 5, 6, 8, 11, 12 and 13): Agreed and no further comment.

Faculty of Science
Department of Biological Sciences

NUS National University of Singapore

Associate Professor Terry Kaan
Chairman
Human Genetics Subcommittee
Bioethics Advisory Committee
11 Biopolis Way, #10-12 Helios
Singapore 138677

July 31st 2006

Dear Terry,

Thank you for asking the Office of Life Sciences, NUS for feedback on consultation paper on the use of personal information in biomedical research.

1. The paper is well written, timely and it covers many of the important aspects of patient's right and confidentiality and the needs for biomedical research. It is a balanced document.
2. We understand that Professor Lee Hing Ping, Chair, IRB of NUS has also provided his feedback directly to the committee.

With best regards

Hew Choy Leong
Professor and Director
Office of Life Sciences
NUS.

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East Shore Hospital, Gleneagles Hospital, Mount Elizabeth Hospital

29 June 2006

Associate Professor Terry Kaan
Chairman Human Genetics Subcommittee
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BY FAX AND MAIL
FAX NO: 64789956

Dear Professor Kaan

CONSULTATION PAPER ON THE USE OF PERSONAL INFORMATION IN BIOMEDICAL RESEARCH

Guidelines on the use of personal information in biomedical research are timely and will be much appreciated by all involved in such research.

The BAC has obviously given these issues much thought and the consultation paper is indeed well balanced and comprehensive.

One area of concern is the definition of the age of consent. The legal age of consent in Singapore is twenty-one. There is confusion as to whether there are exceptions to this. Should someone less then the age of 21 but over the age of 18 and is financially independent; or is married; or is a member of the Singapore Armed Forces be treated as an exception and deemed able to give informed consent independent of the legal guardian?

It may be useful for Section IV of the guidelines which deals with informed consent to address and clarify this issue.

With kind regards

Yours sincerely

Dr S Thanasekaran
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Feedback on Consultation Paper of
The Use Of Personal Information in Biomedical Research
From The Singapore Chinese Buddhist Association

From Buddhist point of view, we do not object the research carried out for medical purposes of benefiting mankind as long as no killing is involved. As we can see this is the case of your Biomedical Research. However, there are other concerns that we have relating to the privacy and protection of individual rights-how can we protect them and the way to do it? We would like to raise the following concerns:

1. **The Legal Protection of Personal Information**

   a). When a person's information is required and is vital to be used for research but is not contactable, will the research still be carried out without the notification and the consent of the person involved.

   b). As the research may involve researchers from other countries, what measures will there be to ensure that information is not being transferred out secretly or without the consent of the person? How do we ensure that the information is firmly protected and not used by the researcher in future once he leaves our local center?

2. **Informed Consent**

   How we can ensure that the explanation is correctly and precisely explained to the person who may be an illiterates or not conversant in English? Where translation is involved we need to make sure the translator can relate to the person?

3. **Epidemiological and Public Health Research**

   If large numbers of public do not give their consents to the Board for the research, will the research still be carried out without obtaining the agreement form them?

4. **Privacy and Confidentiality**

   The concern is that the information may be used by foreign researcher who may use the same information in other countries or takes it with him when he leaves our laboratory?

5. **Access to Medical Information by Employers and Insurers**

   We should stress to the employers and insurance company that the normal health screening should not involve genetic test which is strictly for research

purposes only and should not be part of health screening of the employees or the insured.

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2 August 2006

Associate Professor Terry Kaan
Chairman
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Bioethics Advisory Committee
11 Biopolis Way, #10-12 Helios
Singapore 138667

Dear Associate Professor Kaan

REQUEST FOR FEEDBACK ON CONSULTATION PAPER "THE USE OF PERSONAL INFORMATION IN BIOMEDICAL RESEARCH"

1. Thank you for your letter dated 14 June 2006 in which you requested feedback from the Singapore Medical Association regarding the consultation paper, "The Use of Personal Information in Biomedical Research", put up by the Bioethics Advisory Committee.

2. The paper is well-written, and we agree with most of the recommendations in the paper, which should serve to accelerate the adoption of best practices in the management of personal information in biomedical research, although we note it also attempts to provide coverage for clinical audit.

3. We would, however, like to highlight the challenges posed by Page 17, Para 4.8 on consent taking by the researcher who is also the attending physician, which was mentioned in previous BAC report on human tissue research and guidelines for IRB:

   "...particular caution is necessary when the attending physician is also the researcher...patients may feel under obligation to their physicians...we recommend that the consent for research participation in such a situation be obtained by a competent third party."

   We recognise that this recommendation echoes the attempt by the Declaration of Helsinki to address the issue of coercion by dependent relationships and therapeutic misconception, where it is stated in clause 23 that:

   "When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship."

4. These are admirable research ethics standards. However, when taking into account local factors such as culture and belief system of patients, and limited resources available, the application of these ethical ideals are expected to pose certain practical challenges at the ground.

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5. Locally, most of our patients agree to take part in clinical research projects due to their trust and confidence in their physicians. Having a 'stranger' take the consent will most likely result in many patients declining participation. Ironically, this very relationship that the doctor has with the patient that can potentially generate conflict of interests and coercion, is also the very force that will enhance trust and communication between researcher and subject.

6. Enforcing the ethical standard as a legal requirement would mean that the budgeting of a clinical study will have to take into account the resources available to engage or involve a "well-informed physician" who is not involved in the investigation and who is completely independent of this relationship. Not only must such a well-informed physician (i.e. one who is able to answer all the requirements outlined by these very guidelines and declarations) be available in the institution, he or she must practically and physically be available to take the consent on behalf of the PI. In these days when every minute of the time consumed by a "well-informed physician" to obtain this consent has to be accounted for, the cost of research will rise significantly, and this may retard the development of clinical research.

7. If this other "well-informed physician" is not available, and the only available physician is not "well informed", i.e. unable to do a competent job in the consent process, failing to provide adequate information or clarification, makes unreasonable and unrealistic claims, it would lead to another ethical problem of poorly obtained informed consent of questionable quality, which can be a far more serious problem. Furthermore, informed consent is a continuous process, with an ongoing communication between researcher and subjects as the study proceeds. It is questionable if this other "well-informed physician-consent taker" will always be available.

8. One other point we would like to raise is the lack of clarity as to whether the recommendation on clinical audit include quality improvement initiatives. Many of such projects hover around the areas between clinical research and health services research, can sometimes pose significant risks to the privacy and confidentiality of participants. Perhaps the BAC could consider recommending the establishment of IRB-like review bodies to handle the ethical aspects for such projects.

9. Lastly, as mentioned in your letter, we are agreeable to having these comments published in your final recommendations to the Steering Committee on Life Sciences.

I hope the above will be of help to you and your committee.

Thank you.

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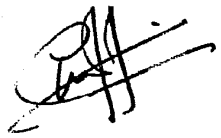
Yours sincerely



Dr Chin Jing Jih
Executive Director,
Centre for Medical Ethics and Professionalism
On behalf of 47th Council, Singapore Medical Association

SINGAPORE MEDICAL COUNCIL'S FEEDBACK ON BAC'S CONSULTATION PAPER ON "THE USE OF PERSONAL INFORMATION IN BIOMEDICAL RESEARCH"

Recommendation 2: Specific consent should be obtained when research involves identifiable personal information or tissue samples. General consent may be obtained for subsequent research involving the use of de-identified information or remnant tissue. The information to be provided to the individual when taking consent should depend on the sensitivity of the information and the risk of harm.

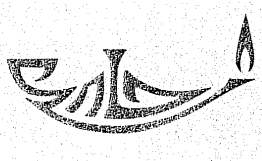
Comments: It will sometimes be difficult to determine what the risk of harm might be in research of this nature – so the last sentence of this recommendation is hard in enforce and rather vague.

Recommendation 7: Research participants should be allowed to withdraw their consent to participate in a research at any time without explanation and without prejudice. They should be assured that upon withdrawal their personal information and/or tissue samples will either be destroyed or irreversibly de-identified.

Comments: If tissue/data already de-identified, how can it be destroyed or further dealt with?

Recommendation 13: We recommend that the government consider implementing a moratorium on the use of predictive genetic information for insurance purposes and appoint an authority to consider long-term implications of the accessibility of predictive genetic test results by employers and the insurance industry and to monitor developments in this area.

Comments: There is some concern that an employer or insurer seems to have some rights to personal information. Although various angles were discussed it appears that in the end they do some rights to it implicitly or explicitly!



SINGAPORE NURSING BOARD

26 July 2006

Associate Professor Terry Kaan
Chairman
Human Genetics Subcommittee
Bioethics Advisory Committee
11 Biopolis Way, #10-12 Helios
Singapore 138667

Dear Terry

REQUEST FOR FEEDBACK ON CONSULTATION PAPER
THE USE OF PERSONAL INFORMATION IN BIOMEDICAL RESEARCH

Thank you for inviting the Singapore Nursing Board to give its views on the paper.

We would like to congratulate the Human Genetics Subcommittee for drafting such a comprehensive paper on this important matter. The paper has covered all the important issues regarding the use of personal information in biomedical research.

Yours sincerely

Ms Ang Beng Choo
Registrar
Singapore Nursing Board

16, College Road, #01-01 College of Medicine Building, Singapore 169854 Tel: 6372 3082/3 Fax: 6221 1160

Feedback from SingHealth IRBs

24 July 2006

The SingHealth IRBs have read and discussed the 13 recommendations proposed by the BAC in their consultation paper entitled, "The Use of Personal Information in Biomedical Research". We present our feedback on the paper here.

Firstly, we would like to express our deep appreciation to the BAC for addressing very valid and vital issues in human subject research in Singapore. Establishing a legal framework to address these issues would greatly facilitate the IRBs in their review of research proposals and provide standardized practices throughout the Republic.

Recommendation 1: We recommend that the relevant authorities consider establishing a legal framework for the use of personal information in biomedical research.

Our Comments: The healthcare institutions in Singapore have been conducting research involving human subjects for a considerable number of years and are cognizant of the need to maintain the privacy and confidentiality of personal identifiable information collected in the course of research. The IRBs are currently drawing guidance from overseas legal frameworks, particularly the US CFR in addition to ICH and SGGCP guidelines. A legal framework which is relevant and customized for the Singapore research environment will be most appropriate and a step in the right direction to propel Singapore onto the world stage for human biomedical research.

Recommendation 2: Specific consent should be obtained when research involves identifiable personal information or tissue samples. General consent may be obtained for subsequent research involving the use of de-identified information or remnant tissue. The information to be provided to the individual when taking consent should depend on the sensitivity of the information and the risk of harm.

Our Comments: Irreversibly de-identified tissue and/or personal information obtained with a general consent will be of little value in some kinds of clinical research as further prospective data cannot be gathered. However, the majority of clinical research projects do not require identifiable information. Researchers can work with de-identified tissue or personal information and draw appropriate conclusions from aggregate samples. Under special circumstances, where the research findings would impact on the specific subject's health or well-being, the IRB would recommend the storing of reversibly de-identified tissue and/or personal information. The investigator, with the approval of the IRB, should have the option of making the tissue and/or personal information identifiable and obtain further individual consent to gather data and/or enroll the subjects in a prospective study, many of which are long-term follow up studies. However, there is a need for the identity part of the information to be kept by a separate body and released on a case-by-case basis upon investigator's request, duly approved by the IRB. We agree that, unless the IRB grants waiver of consent (where there is overriding public health benefit versus the risk of individual privacy), the investigator should obtain informed consent for the specific research study from

each of the patients and all arrangements should be made to allow the subject to refuse participation or withdraw from the study, and for destruction of all collected tissue or information for the particular subject.

Recommendation 3: We recommend that the relevant authorities clarify the legal basis for the disclosure of medical information to disease registries by health care institutions and physicians; and establish mechanisms enabling the registries and healthcare institutions to increase the accessibility of personal information for research that can significantly advance public welfare, while safeguarding privacy concerns.

Our Comments: Disease databases are a valuable source of information for conducting research of public health importance. Clinical research can benefit tremendously from long-term follow up of a cohort of patients. De-identified information stored in such a longitudinal disease database, should have provisions for re-identification, especially when there is chance that research outcome or projects can benefit existing patients in prospective studies.

Recommendation 4: We recommend that the relevant authorities consider establishing legal mechanisms to facilitate the use of personal information in registries, databases and medical records for epidemiological research and public health research. These mechanisms should also ensure that there is minimal risk to individual privacy and confidentiality.

Our Comments:
Legal mechanisms are needed to prevent abuses of privacy and confidentiality. Penalties must be swift, sure and severe to inspire public confidence in such data repositories. It is also the responsibility of PIs, IRBs and research institutions to safeguard the privilege and legacy of tissue and clinical material entrusted to us for betterment of mankind.

Recommendation 5: We recommend that the relevant authorities consider legal provisions necessary to ensure that the potentially increased scope of clinical audit does not violate medical confidentiality and to assure the public that privacy and confidentiality interests in personal information will be safeguarded.

Our Comments:
The Ministry of Health will need to advise on the specific areas within which it would like to conduct clinical audit. Since audit is for the improvement of healthcare system delivery and assessment of provider compliance and quality assurance, the law must provide for this function, and the scope and coverage of such audit clearly delineated. IRBs should focus on safeguarding research subject's interest. Clinical audit must be separately enforced through administrative and management mechanisms.

Recommendation 6: We recommend that IRBs, when reviewing research, ensure that any concerns in regard to vulnerable persons are appropriately addressed.

Our Comments:
IRBs currently use the vulnerable persons definitions adopted by the USA. However, the different cultural context makes the operationalization of concepts such as assent, challenging. We would like the BAC to bring in foreign IRB expertise to help local IRBs work towards developing relevant and implementable approaches to safeguard these groups of subjects.

Recommendation 7: Research participants should be allowed to withdraw their consent to participate in a research at any time without explanation and without prejudice. They should be assured that upon withdrawal their personal information and/or tissue samples will either be destroyed or irreversibly de-identified.

Our Comments:
We Agree. This is already practiced by local IRBs. The challenge is in the policing and surveillance to ensure compliance by PIs, especially those where there is pharmaceutical sponsorship and the tissue and information reside with these companies.

Recommendation 8: Personal information should be de-identified as far and as early as possible and should be stored or transferred as de-identified information.

Our Comments: We agree in principle. IRBs need sufficient resources and national level frameworks to allow reversible de-identification of clinical databases and tissue repositories. The identity and research information bits should be held by different discrete agencies to safeguard privacy.

Item 2.6 - mentions that confidentiality and privacy in research are "usually achieved by de-identification of the information". We would like to emphasize here, that the golden standards for clinical research are prospective studies and randomized controlled trials, and it would not be possible to use de-identified subject information in these situations.

Recommendation 9: Researchers should not attempt to identify an individual from de-identified information as it is a serious breach of ethics to do so.

Our Comments: We agree. Punishment must be swift, sure and severe to discourage abuse.

Recommendation 10: Irreversibly de-identified personal information generally need not be subject to privacy and confidentiality requirements.

Our Comments:
We Agree. Once the infrastructure for de-identification is set-up with separate data repositories, key coding agencies this can be implemented. The difficulty lies in rare clinical conditions within sub-specialties where small numbers of unique conditions lend the de-identified information to significant potential identification risk.

Recommendation 11: When reversibly de-identified information is used for research, IRBs should consider the adequacy of the extent and means of the de-identification in proportion to the risk. Should a person be identified from de-identified information, the person should still enjoy confidentiality and privacy entitlements.

Our Comments:
We agree in principle. The legal framework, resources and guidance must exist to help IRBs operationalize such entitlements.

Recommendation 12: The ethical principle of confidentiality should apply to the use of personal information from medical or public registries. Confidentiality safeguards should be commensurate with the potential risk of harm from inadvertent disclosure.

Our Comments:
IRBs need to be adequately resourced to help ensure compliance in the post-approval period. Resources for monitoring and external audit by CROs need to be put in place.

Feedback Pertaining to the Use of Personal Information in Biomedical Research

Feedback Pertaining to the Use of Personal Information in Biomedical Research

Recommendation 1:

Our Society is in agreement with the proposal that the relevant authorities consider the establishment of a legal framework regarding the access and application of personal information in biomedical research. Such a legal framework is not only appropriate but also highly necessary as extensive research is currently undertaken to advance the life sciences to alleviate human suffering by ameliorating disease treatment outcomes. This legal framework when accepted, will subject bioscience practitioners to undertake a professional responsibility to adhere to strict guidelines when accessing, managing and using personal information for their research without compromising the integrity and confidentiality of an individual. It also serves to legally protect the researcher and an individual.

Recommendation 2:

We agree that consent should first be obtained when biomedical research involves the use of identifiable personal information or tissue samples. In accordance to the definition of General consent in Para 4.2, our Society feels that an additional step should be provided to enable an individual to reaffirm his earlier General consent after a period of time lapse. This serves to better and more precisely inform the individual on the intended research currently at hand that requires an affirmation of the earlier General consent. Additionally, we are of the view that, regardless of the sensitivity of the information and the risk of harm, information should be provided unreservedly to the individual when seeking his consent since personal information is rightly his ownership.

Our Society also proposes that while there is good intention and reason to provide assurance in the proper use of personal information by empowering Institutional Review Board (IRBs) to approve the appropriate use of personal information to secure privacy and confidentiality of such information, we should incorporate an additional step to ensure non-biased jurisdiction over the use of the information by ensuring the implementation of a tripartite panel. This panel should comprise of foreign bioethics experts (with good professional track record and of international repute), Bioscience Non-Governmental Organisations (NGOs) and representatives from the relevant Government agencies. The role of such a tripartite panel is to ensure and provide a comparable and professional benchmark that is familiar to foreign collaborating bioscientists who may be engaged in joint bioscience research projects with our researchers. Additionally, this will also provide a further assurance of non-biased or abuse to personal information provided by individuals.

Finally, in Para 4.8, the use of a third party to obtain informed consent should be mandatory.

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Recommendation 3

We recommend that the relevant authorities clarify the legal basis for the disclosure of medical information to disease registries by health care institutions and physicians; and establish mechanisms enabling the registries and healthcare institutions to increase the accessibility of personal information for research that can significantly advance public welfare, while safeguarding privacy concerns.

We have serious concerns with this recommendation as it is vague. By definition, disease registries deal with identifiable personal information. Making such information available to unspecified government entities raises serious consent and privacy issues. Would this mean for instance, that law enforcement agencies that we would not normally associate with medical research could obtain such confidential information?

Also, the BAC could go further towards the definition of the conditions under which privacy should be waived. Ideally, this should be achieved by a central body in Singapore and not for instance the individual IRBs.

We agree that seeking consent for the numbers of patients in a given disease registry may be difficult. However, we are of the opinion that they should be provided the choice to opt out of the research. That is, an explanative letter could be sent to them to inform them of their registration for the research in question and allowing them to opt out. This appears to have worked well for the purpose of organ donation and we are certain it can be successful in this particular instance.

Recommendation 6

On the point of proper protection of personal information for vulnerable persons, we are of the view that as we have earlier mentioned in our views for Recommendation 2, the formation of a tripartite panel will similarly extend the proper and more efficient safeguards to provide a non-biased jurisdiction of such personal information.

Recommendation 7

“Irreversibly de-identified” tissue can still be employed for research and/or commercial purposes. We are of the opinion that the patient should be allowed to dictate whether the tissue in question should be destroyed or irreversibly de-identified. Additionally, as in Recommendation 2, the affirmation step for an earlier provided General consent should be made available to enable the individual to re-consider his intentions based on a further knowledge concerning the more precise nature and objective of the research at hand compared to when he had first given a General consent at which time no specific research was then at hand.

Recommendation 8:

We corroborate that personal information should be de-identified as far and as early as possible and should be stored or transferred as de-identified information. In addition, we are also of the opinion that an independent agency or NGO is to be appointed to oversee the acquisition and de-identification process of acquired personal information whereby a benchmark audit should be implemented to determine and classify the level of security of personal information. Security auditors should similarly comprise of a tripartite panel to finalize and verify the adequacy of security for each stage of information acquisition and de-identification protocols that are implemented as well as to validate the competency of the security system in place. Manpower involved in the handling and the

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acquisition and de-identification protocols should be security vetted and subjected to legally bound confidentiality and secrets act to prevent possible leakage of invaluable personal information to commercial enterprises such as insurance companies.

Recommendation 10:

We do not agree with this recommendation as privacy or confidentiality should always be maintained regardless of it being irreversibly de-identified or not. Additionally, where enough information is amassed from a sufficient pool of statistical data, it could be exploited or abused. Thus, if this is not given similar treatment with all other personal information, there can be a loophole in a security system in place. As previously mentioned in our views for Recommendation 2, this jurisdiction should be managed by a tripartite panel similar to the treatment of all personal information.

Recommendation 13

Our Society perceives that it is important that the privacy and confidentiality of personal information be securely protected regardless of the pressures exerted by the insurance industry who has long lobbied for the disclosure of personal information by employing genetic advances to pursue selective discrimination. This issue however, would not be questioned some decades ago where current genetic advances are not even available for an industry to exploit in order to achieve self-interests and maximum benefits by indulging in selective discrimination.

It must be noted that should this be allowed in a particular industry, it would very soon proliferate and become a precedent for other industries to follow suit. Hence it will also become increasingly harder and extremely challenging to enforce or differentiate the need to maintain personal information as private and confidential; which would be better used if individuals do not suffer a stigma arising for exploitation or distrust but instead agree to the use of their personal information to benefit useful and meaningful biomedical research – which is the original intention.

Additionally, all the resources in terms of efforts and time that are employed to ensure a reliable system to assure individuals their privacy and confidentiality would soon be wasted when the general public develops a deep mistrust towards the system in place. Hence, our Society disagrees that the authorities be in any way supportive of commercial enterprises such as the insurance industry to use personal information (even if de-identified) via predictive genetic testing in association with commercial interests.

We urge the authorities to be focussed with regards to the objective in the use of personal information as rightfully themed in this feedback – for biomedical research.

- THE END -

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27 July 2006

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Chairman
Human Genetics Subcommittee
Bioethics Advisory Committee
11 Biopolis Way, #10-12 Helios
Singapore 138667

Dear A/Prof Kaan

REQUEST FOR FEEDBACK ON CONSULTATION PAPER

Thank you for your letter dated 14 June 2006 in which you requested feedback from Tan Tock Seng Hospital regarding the consultation paper, "The Use of Personal Information in Biomedical Research", put up by the Bioethics Advisory Committee.

We gathered feedback from various groups in the hospital and found the paper to be well-written and a step in the right direction. We agree with many of the terms of patient privacy and confidentiality and also, the absence of these terms in irreversibly de-identified personal information. The paper also provides clearer guidelines and will give legal muscle to an organization as it releases information and/or asks for consent.

There are, however, a few specific points which we would like to highlight.

Pg 16 Para 4.3: *"...Even if information is de-identified, the individual concerned must at some point have consented to the use of his or her information in research unless such research falls within the limited exceptions discussed below."*

For research involving only casenotes review, there is doubt whether patients had given prior general consent for use of their information for such purposes. Would we thus be in breach if the information was released, even if it had been approved by the IRB and CMB/HOD?

Pg 19 Rec 2: *"... for subsequent research involving the use of de-identified information or **remnant tissue.**"*

This may give room for misinterpretation and may lead to unlimited use of these specimens for research use.

Pg 23 Para 4.25: *"...We consider it to be ethically acceptable for medical information to be disclosed by physicians to disease registries provided that ... patients are appropriately informed."*

There could be a problem with implementation if this was actually insisted upon. Whose responsibility would it be to inform the patient, meaning would it be the custodian or the requestor/disease registry?

Pg 25 Rec 3: *"...We recommend that the relevant authorities clarify the legal basis for the disclosure of medical information to disease registries by healthcare institutions and physicians; and establish mechanisms... to increase accessibility of personal information for research... while safeguarding privacy concerns."*

If that is all that is required, that privacy concerns are safeguarded, there should be no issue.

Pg 27 Para 4.39: *"...The Ministry of Health does not currently permit research access to information in the EMRX."*

The paper mentions that it may be a future possibility and that *"...ethical principles of informed consent and patient confidentiality would apply..."* This would be another implementation issue. Currently the system allows one to either see everybody or nobody. The IT audits must be more regular and stringent to pick up potential violators.

To add further, we would like to ask for suggestions on practical ways for compliance including the de-identification of personal biodata in databases. We would also appreciate guidelines for which information like this could be secured.

Another point to note, although "Biomedical Research" is stated in the title of the paper, the BAC also seeks to protect the confidentiality of information derived from audits.

Clinical Ethics

From the clinical ethics point of view, we would like to highlight some reservations.

Firstly, would such legislation actually be necessary? The matter of confidentiality has traditionally been a matter of ethics. Now the door would be open for laws to protect such information.

Secondly, the paper allows for the transfer of de-identified information without any need for an ethics review.

Thirdly, we would like to highlight the challenges that will be posed by the following paragraph regarding consent taking by the researcher who is also the attending physician. This was was mentioned in a previous BAC report on human tissue research and guidelines for IRB:

Pg 17, Para 4.8: *"...particular caution is necessary when the attending physician is also the researcher...patients may feel under obligation to their physicians...we recommend that the consent for research participation in such a situation be obtained by a competent third party."*

We recognize that this recommendation echoes the attempt by the Declaration of Helsinki to address the issue of coercion by dependent relationships and therapeutic misconception, where it is stated in clause 23 that:

Clause 23: *"....When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship."*

These are admirable research ethics standards. However, local factors such as culture and belief system of patients, and limited resources in investigator-initiated clinical studies would likely pose certain practical challenges if these ethical ideals were to be enforced as a legal standard.

Locally, most of our patients consent to participate in clinical studies due to their trust and confidence in their physicians. Having a 'stranger' take the consent will most likely result in many patients declining participation. Ironically, this very relationship that the doctor has with the patient, which causes ethical problems, is also a critical factor in enhancing trust and communication between the researcher and the subject.

Enforcing this ethical standard rigidly would mean that the budgeting of a clinical study will have to take into account the resources available to engage a "well-informed physician" who is not involved in the investigation and who is completely independent of this relationship. Not only must such a well-informed physician (i.e. one who is able to answer all the requirements outlined by these very guidelines and declarations) be available in the institution, he or she must practically and physically be available to take the consent on behalf of the PI. In these days when every minute of the time consumed by a "well-informed physician" to obtain this consent has to be accounted for, the cost of research will rise significantly, and this may retard the development of clinical research.

If this other "well-informed physician" is not available, and the only available physician is not "well informed", meaning he is unable to do a competent job in the consent process, fails to provide adequate information or clarification or makes unreasonable and unrealistic claims, it would lead to another ethical problem. This would be that of poorly obtained informed consent of questionable quality, which can be a far more serious problem. Furthermore, informed consent is a continuous process, with an ongoing communication between researcher and subjects as the study proceeds. It is questionable if this other "well-informed physician-consent taker" be always available.

Finally, one other point we would like to raise is the lack of clarity as to whether the recommendation on clinical audits include quality improvement initiatives. Many of such projects hover around the areas between clinical and health services research which can sometimes pose significant risks to the privacy and confidentiality of participants. Perhaps the BAC could consider recommending the establishment of IRB-like review bodies to handle the ethical aspects of such projects.

Lastly, as mentioned in your letter, the hospital is agreeable to having these comments published in your final recommendations to the Steering Committee on Life Sciences.

I hope we have been of help to your committee.

Warm regards,

A/Prof Philip Choo
Chairman, Medical Board
Tan Tock Seng Hospital