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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

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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