Press Release

12 July 2012

BIOETHICS ADVISORY COMMITTEE SINGAPORE

Public Consultation on the BAC's Draft Ethics Guidelines for Human Biomedical Research

1. The Bioethics Advisory Committee (BAC) is currently seeking comments on its draft *Ethics Guidelines for Human Biomedical Research.* A **public dialogue session**, to be chaired by BAC Chairman, Senior Judge (Ret.) Richard Magnus, will be held on **26 July 2012 (Thursday) from 4.00 to 6.00 pm** at Room 01-01A, Block MD 6, Centre for Translational Medicine, National University of Singapore (14 Medical Drive, Singapore 117599).

2. The main purpose of these *Guidelines* is to present an accessible and consolidated ethics resource for biomedical researchers and members of ethics committees or institutional review boards (IRBs).The *Guidelines* are based on a review of the BAC's past recommendations, which aim to safeguard against unethical practices and to ensure the protection and assurance of the safety, health, dignity, welfare and privacy of research participants. The recommendations were issued in seven reports, published between 2002 and 2010.

3. While preparing these *Guidelines*, the BAC has taken the opportunity to update its recommendations, and some new material has been added, to ensure that the *Guidelines* are relevant to the current state of biomedical research in Singapore. The *Guidelines* also seek to reconcile any apparent discrepancies and clarify any uncertainties emerging since the original reports were published. (A summary of the main revisions is provided below.)

4. The *Guidelines* include a summary of the legislative and regulatory framework for human biomedical research in Singapore, together with the relevant current guidelines from the Ministry of Health, and other authorities. The supervening Mental Capacity Act, which was enacted in 2008 and revised in 2010, is explained in relation to obtaining consent for research involving persons lacking capacity to make decisions for themselves.

5. A copy of the draft *Guidelines* is available on BAC website at http://www.bioethics-singapore.org/. Individuals interested in participating in the dialogue session should register their attendance with the Secretariat at **contactus@bioethics-singapore.org** by 19 July 2012.

6. Members of the public are also invited to send their comments and queries by **15 August 2012** to the Secretariat at the above email address.

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About the Bioethics Advisory Committee

The Bioethics Advisory Committee was established by the Government in December 2000 to examine the ethical, legal and social issues arising from human biomedical research; and to recommend policies on these issues, with the aim of protecting the rights and welfare of individuals, while allowing the biomedical sciences to develop and realise their full potential for the benefit of humankind.

The BAC has published the following seven reports:

a. Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning (2002);
b. Human Tissue Research (2002);
c. Research Involving Human Subjects: Guidelines for IRBs (2004);
d. Genetic Testing and Genetic Research (2005);
e. Personal Information in Biomedical Research (2007);
f. Donation of Human Eggs for Research (2008); and
g. Human-Animal Combinations in Stem Cell Research (2010).

Summary of Main Revisions

The main revisions to the original recommendations are as follows:

i. **Definition of Human Biomedical Research.** "Human biomedical research refers to any research done for the ultimate purpose of studying, diagnosing, treating or preventing, any disease, injury or disorder of the human mind or body, and which entails the involvement of humans, human tissues or information derived from humans or human tissues." It covers "economic, sociological and other research in the humanities and social sciences whenever this research fits the above definition of human biomedical research."

ii. A **principle of "solidarity"** is included as one of BAC's general ethical principles. It was previously described as "reciprocity", but the term "solidarity" better reflects the importance of general altruism as a basis for participation in biomedical research.

iii. **Research Integrity.** The integrity of the research process is of increasing importance given the competitiveness in research. The BAC recognises this importance and is of the view that research institutions have a responsibility to ensure that the requirements of research integrity are observed.

iv. In view of the investment of time and effort entailed in planning research, the BAC has recommended that there be an **appeal mechanism**, to allow the Principal Investigator to make an appeal for reconsideration of their proposals if they are not approved by an IRB. Institutions would be responsible for ensuring that such a mechanism is in place.

v. **Compensation / payment to research participants.** It has always been a fundamental principle that participation in research should be voluntary. There should be no coercion or undue influence on a prospective volunteer. In this connection, it is important to avoid financial inducement to participate in research. Participants may be

reimbursed for legitimate expenses, such as the cost of transport and child care services, and actual loss of earnings. Reimbursement and any additional payment to be given, whether monetary or in kind, should not amount to an inducement. Donation of tissue for research, however, is considered an altruistic gift and there should be no payment of any kind, except in the case of donation of human eggs for research by healthy volunteers, as the process required to obtain the eggs is invasive and carries a health risk.

vi. **Specific and General Consent.** Specific consent has been redefined as "consent for a particular research project . .. It refers to the case where a participant is recruited for participation in a specified research project, or where his or her tissue or information is sought for such a project." General consent "may be taken for the storage and future use of tissue or personal information". The BAC has proposed that "IRBs should have the discretion to decide, when considering a research proposal, whether specific consent is required or general consent is sufficient, if previously given."

vii. It is to be expected that with rapid advances in science and improvements in technology, the number of incidental findings discovered in research will rise. Such findings may or may not be clinically significant, where a **clinically significant incidental finding** means one that has a clear implication on an individual's health. Such findings, though they are incidental to the purpose of the research, have to be managed responsibly so that any serious consequences can be prevented. This means that the affected individual is advised of the need for a fuller medical consultation and advice, with a referral if and when appropriate. The BAC is of the view that where there is a possibility that the research may yield clinically significant incidental findings, it should be explained to participants in advance, and they should decide whether or not they will want to be informed of any such incidental findings.

viii. **Consent from minors on turning 21.** An increase in biobanking, as well as large-scale longitudinal studies involving storage of biological materials and long-term follow-up of individuals, has led to some re-consideration of consent policies. If the research is still on-going, respect for an individual's autonomy would require that personal consent be obtained for the continued use of any biological material from a minor, previously collected and stored with parental or guardian consent, when that minor reaches 21 years. The individuals concerned will then also be in a position to make their own decisions regarding whether or not to be contacted in the event that clinically significant incidental findings are uncovered.