



8th Global Summit of National Bioethics Advisory Bodies

26 to 27 July 2010

Newsletter 4 · June 2010



MINISTRY OF HEALTH
SINGAPORE



Updates on the 8th Global Summit

Since the last newsletter in March 2010, the local organising committee has been working closely with the Ethics and Health Team at the World Health Organization (WHO) and the European Commission (EC) on finalising details for the programme, as follows:

- The focus of the first day (26 July) will be on research ethics committees, and ethical issues in organ, tissue and cell transplantation and in tuberculosis (TB) control. The WHO's three new guidance documents on organ and tissue transplantation, research ethics committees and TB control will be discussed at the meeting. Also to be included on the first day is an update on the developments in some international and national bioethics bodies.
- The second day (27 July) will comprise combined and break-out sessions. There will be two EC-initiated sessions, on:
 - a. synthetic biology, where there will be an opportunity for national bioethics advisory bodies to exchange information and experiences; and
 - b. biobanking, where several national experiences and policies regarding the challenges of biobanks will be discussed.
- Other topics to be discussed include:
 1. Ethics of medical profiling and online medicine;
 2. Healthcare organisation and ethics;
 3. Stem cell research and therapy;
 4. Research involving human-animal hybrids and chimeras;
 5. Ethical considerations in end of life issues; and
 6. Research ethics.
- A statement that seeks to enhance co-operation among national bioethics advisory bodies will also be discussed at the Summit. In addition to the finalised programme, draft documents to be discussed will be sent to all participants for consideration ahead of the meeting.
- A welcome dinner on the evening of 26 July will be held at the Arts House, which is Singapore's oldest surviving government building. Built as a residential house, it served as Singapore's Court House, the Assembly House and subsequently as the Parliament House until 1999. As Singapore's newest arts and heritage venue, Summit participants will have the opportunity to tour the Arts House and view its exhibits, including the old parliamentary debating chamber, before dinner.

Registration

All National Bioethics Advisory Bodies are invited to participate in the 8th Global Summit in Singapore. Each body may send one or two representatives. There is no registration fee. Registration forms have been sent to all national bioethics advisory bodies. If you are interested in participating in the Summit and have not received the registration form, please contact the Secretariat at: gsnbab2010@bioethics-singapore.org. Information on accommodation is available at: www.bioethics-singapore.org/gsnbab2010/Accommodation.

Key Information

Date:
26 to 27 July 2010

Venue:
Suntec Singapore International Convention
and Exhibition Centre

8th GSNBAB Website:

www.bioethics-singapore.org/gsnbab2010

8th GSNBAB Secretariat

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WHO Guidance Documents on Research Ethics Committees, Human Organ, Tissue and Cell Transplantation, and Tuberculosis (TB) Control

Based on the input of global stakeholders, bioethics experts, and national bioethics committees, the WHO is coordinating the drafting of proposed standards for **research ethics committees** (REC). Since several important international ethical guidelines exist for researchers, such as the CIOMS guidelines and the Declaration of Helsinki, and since REC review has become an expectation for research in much of the world, there may be a need for an international document that outlines standards for how RECs should function, operate, and be governed. WHO has coordinated the drafting of such standards, and they will be presented for the first time to representatives of national bioethics committees for feedback and modification. The purpose of a standards document is to outline aspects of REC operations, functioning, and governance that global stakeholders agree to be non-negotiable for such committees in general. The ten standards in the draft document therefore include, for example, a requirement that committees must be independent and a requirement that ethical considerations must form the basis for committee decisions. The final document will also include guidelines for RECs (modified from another WHO publication for RECs from 2000) intended to provide concrete guidance on how committees can establish procedures to meet these ten standards.

The session on **organ, tissue and cell transplantation** will be an opportunity for national bioethics bodies to discuss the implementation of the guiding principles set out in the WHO's resolution on the subject, which was adopted by the 63rd World Health Assembly in May 2010. In addition, national bioethics bodies will also discuss the *Declaration of Istanbul*

on Organ Trafficking and Transplant Tourism that was prepared by the Transplantation Society and International Society of Nephrology, and adopted by participants at the International Summit on Transplant Tourism and Organ Trafficking in May 2008. Those interested may refer to a 2008 editorial in the journal *Nephrology Dialysis Transplantation* for background information: <http://www.sld.cu/galerias/pdf/sitios/trasplante/declaracion-estambul.pdf>.

Following the recommendation of the WHO Task Force on Extensively Drug-Resistant-TB (XDR-TB) at their second meeting (April 2008), a Task Force on Addressing **Ethical Issues in TB Care and Control Programmes** was established in August 2008. It undertook a comprehensive analysis of ethical issues in order to lay the groundwork for the formulation of WHO guidance to governments and other stakeholders in implementing TB care and control programmes in an ethical manner. Discussion papers were commissioned on (1) Access to diagnosis and treatment; (2) Obligations and rights of health care workers and patients; (3) Public health measures; and (4) Research. The Task Force met in Dec 2008 (Toronto) and August 2009 (Geneva) and the resulting draft guidance document was presented in outline at the Stop TB department's Strategic and Technical Advisory Group for Tuberculosis (STAG-TB) in November 2009. Further input was provided at the 40th Union World Conference on Lung Health in December 2009. The revised guidance document will now be discussed at the 8th Global Summit.

EC Sessions on Synthetic Biology and Biobanking

Broadly understood, **synthetic biology** is the engineering of biological components and systems that do not exist in nature and the re-engineering of existing biological elements. It is a field that is developing rapidly as is demonstrated by the announcement of the first 'synthetic cell' was reported in an article in *Science* on 20 May 2010.

Synthetic biology holds great potential and may have an impact on a number of applications, including biofuels, antipollutants, textiles, cosmetics, diagnostic and therapeutic tools, vaccines, drugs, food and feed ingredients. However, synthetic biology also raises a number of concerns, for example about bio-safety, bio-security, benefit sharing and human dignity. Several ethics advisory bodies have evaluated, or are evaluating synthetic biology. The European Group on Ethics of science and new technologies (EGE) adopted an Opinion on the ethical, legal and social implications raised by synthetic biology last year. At the request of President Obama, the US Presidential Bioethics Commission will deliver a report by the end of 2010 on the implications of synthetic biology. The 8th Global Summit will be the first occasion where the field will be discussed on a

global level by ethics advisory bodies. It will be an opportunity for national bioethics advisory bodies to exchange information and experience.

Biobanks, containing stored biological samples, are an important tool in biomedical research. They help researchers identify the genetic basis of diseases, as well as environmental factors that influence the risk of developing diseases. For these biobanks to live up to their full potential, international collaboration and exchange of samples and information is essential. This research needs to be governed by adequate data protection and a review of the nature of provisions for informed consent may be required. There are numerous challenges in implementing data protection and other ethical guidelines relating to international biobank research. One particular challenge is whether or not a more general form of informed consent can be acceptable, given the fact that new research interest may emerge over time for which consent has not specifically been given by sample donors. In this session, several national experiences and policies regarding the challenges of biobanks will be discussed.

Draft Programme for the 8th GSNBAB:

Day 1 – 26 July 2010 (Monday)

Time	Programme
8.00 – 9.00 am	Registration
9.00 – 9.05 am	Welcome by Mr Richard Magnus, Chairman of the 8 th Global Summit Organising Committee
9.05 – 9.20 am	Address by Prof K Satkunantham, Director of Medical Services, Ministry of Health (Singapore)
9.20 – 9.50 am	WHO Strategy on Ethics - Collaboration with National Bioethics Bodies by Dr Ruediger Krech, WHO-ETH Director
9.50 – 10.05 am	Report on 7 th Global Summit by the French National Consultative Ethics Committee (CCNE)
10.05 – 10.35 am	Tea
10.35 am – 12.00 pm	Ethical Issues in Organ, Tissue and Cell Transplantation <ul style="list-style-type: none"> • Ethical Principles • International Guidelines • Organ Trafficking and Transplant Tourism
12.00 – 1.30 pm	Lunch
1.30 – 3.00 pm	Research Ethics Committees <ul style="list-style-type: none"> • Ethical Standards • International Guidelines • Accreditation
3.00 – 3.30 pm	Tea
3.30 – 5.00 pm	Ethical Issues in TB Control <ul style="list-style-type: none"> • Groundwork formulation to help governments and other stakeholders implement TB care and control programmes in an ethical manner.
5.00 – 6.00 pm	Bioethical Developments (International and National Bioethics Bodies)
7.00 – 10.00 pm	Welcome Dinner at the Arts House

Draft Programme for the 8th GSNBAB:

Day 2 – 27 July 2010 (Tuesday)

Time	Programme	
8.30 – 10.00 am	<p>Ethical Issues in Synthetic Biology</p> <ul style="list-style-type: none"> • Impact of the technology • Ethical and other implications • Possible ethical responses • Exchange of information and experiences <p>(Representatives from the EGE, Germany's Ethikrat and the US Presidential Commission on the Study of Bioethical Issues will be sharing some thoughts and experiences)</p>	
10.00 – 10.30 am	Tea	
10.30 am – 12.00 pm	<p>Biobanking</p> <ul style="list-style-type: none"> • Discussion of ethical challenges • Sharing national experiences and policies <p>(Representatives from the Hellenic National Bioethics Commission, the French National Consultative Ethics Committee for Health and Life Sciences and the Austrian Bioethics Commission will be sharing their national policies and experiences)</p>	
12.00 – 1.00 pm	Lunch	
1.00 – 2.30 pm	<p>Ethical Issues in Stem Cell Research and Therapy</p> <ul style="list-style-type: none"> • Policy updates • Chimeras and hybrids <p>(Representatives from the Ethics Committee of China's Ministry of Health, Japan's Expert Panel on Bioethics of the Council for Science and Technology Policy, and the Danish Council of Ethics will provide updates from their respective countries)</p>	
2.30 – 4.00 pm	<p>Breakout Session 1</p> <ul style="list-style-type: none"> • Profiling and online medicine • End of life ethics 	<p>Breakout Session 2</p> <ul style="list-style-type: none"> • Research ethics • Healthcare organisation and ethics
4.00 – 4.30 pm	Tea	
4.30 – 5.15 pm	Planning for follow up activities and 9th Global Summit	
5.15 – 5.30 pm	Closing Remarks	
5.30 – 6.30 pm	Press Conference	