Follow-up to the recommendations of the fifth session of the Intergovernmental Bioethics Committee (IGBC): comments of IGBC on the report of the International Bioethics Committee (IBC) on consent

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FOLLOW-UP TO THE RECOMMENDATIONS OF THE FIFTH SESSION OF THE INTERGOVERNMENTAL BIOETHICS COMMITTEE (IGBC): COMMENTS OF IGBC ON THE REPORT OF THE INTERNATIONAL BIOETHICS COMMITTEE (IBC) ON CONSENT

I. INTRODUCTION

At its fifth session (UNESCO Headquarters, Paris, 19-20 July 2007), the Intergovernmental Bioethics Committee (IGBC) invited the Director-General to provide the International Bioethics Committee (IBC) with a detailed list of all comments formulated by IGBC on the Report of IBC on Consent (Ref. SHS/EST/CIB-13/06/CONF.505/2 Rev.2 of 19 May 2007).

In application of the recommendations of the fifth Session of IGBC, the Director-General therefore invited Member States of IGBC to submit their comments in writing (letters ref. SHS/EST/07/473 of 16 October 2007 and ref. SHS/EST/08/100 of 15 May 2008).

This document presents the relevant recommendations of the fifth session of IGBC, a compilation of the comments received in writing from IGBC Member States as of 23 June 2008 (in their respective original languages) and a summary of specific comments made orally during the discussion at the fifth session of IGBC.

II. RELEVANT RECOMMENDATIONS OF THE FIFTH SESSION OF IGBC

"At its fifth session, the Intergovernmental Bioethics Committee (IGBC),

(…)

In relation to the Report of IBC on Consent,

9. *Acknowledges* and *values* the work carried out by IBC on the principle of consent and *thanks* the Committee for the efforts made in preparing its Report on this issue.

10. *Recalls* that the Report of IBC on consent, drawn up by an advisory body composed of independent experts, is not prescriptive and does not necessarily represent the views of UNESCO and all Member States, but *considers* that, as such, it constitutes an important contribution to the intense ongoing debate on the issue of consent at both international and local levels as well as a useful resource for Member States, organizations and individuals dealing with this issue.

11. *Considers nevertheless* that some important aspects of the Report need to be considered further, in particular : the philosophical and legal basis of the principle of consent ; the relation between the principle of consent and the principle of autonomy and freedom; advance directives; withdrawal of consent and its modalities; between clinical practices and the research context; research on children; exceptions in the context of public health; the coherency of the document and its consistency with the language used in the Declaration.

12. *Invites* the Director-General to provide IBC with a detailed compilation of all the substantive comments made by IGBC during its fifth session and, to this end, *calls upon* all its members to communicate to the Secretariat their comments.

13. *Deems appropriate* therefore that IBC examines this compilation and, on that basis, considers the possibility to revise its report. (…)."

III. COMMENTS RECEIVED IN WRITING FROM MEMBER STATES OF IGBC (AS OF 23 JUNE 2008)

GENERAL COMMENTS

CANADA	Canada is of the view that the Report by the Director-General on the work of IBC and IGBC (Ref. 34 C/REP/12 of 21 August 2007) adequately identifies the issues that Canada would like to see raised with the International Bioethics Committee with respect to the IBC's Report on Consent. Canada has no additional comment.
JAPAN	Japan appreciates recent progress of bioethical activities in UNESCO including examination of two reports by IBC which were launched at its 12th Session held in Tokyo in 2005. Japan considers that recent IBC works are important to raise awareness and deepen analysis of principles of the Universal Declaration on Bioethics and Human Rights, and at the same time it is also important to lead worldwide discussions and to develop common understanding of scientific issues of bioethics.
MEXICO	The first aim would be to identify the real goal of the document; there are many guidelines on informed consent as well as journal publications and the present document is not a critical reflection nor a complete clear and coherent guideline; taken alone as a reference by a Member State, it could be misleading and incomplete; policies derived from such a document would not be adequate. Hence, the need to review the whole document in order to make it conceptually coherent and consistent in content. To have a clearer definition of autonomy and freedom, giving a clear message of the real goal of consent and move form the idea of a piece of paper. To differentiate between clinical practice and research context.
SLOVAKIA	The Slovak Bioethics Committee fully supports the recommendations of the Fifth Session of IGBC which took place in Paris, 19-20 July 2007 in relation to the Report of IBC on Consent.
UNITED STATES OF AMERICA	We applaud the Chair and her Working Group for their effort. They have grappled with difficult issues and made thoughtful judgments on complex issues. They have walked into a hornet's nest of issues, as the previous interventions about various judgments made by the Report have indicated. We would like to suggest a different approach by the IBC. We believe the IBC should set out the issues and discuss them. And, It should explain the philosophical basis of the issues, and this includes as a fundamental matter freedom. In making specific judgments on issues arising out of the Article on consent in the Universal Declaration on Bioethics and Human Rights however, the Report goes beyond this. The essential point, we believe, is that it should not make judgments on specific issues under the Declaration. The Report sounds like a manual for consent. By providing specific conclusions, the Report makes the IBC appear to be a supranational ethics committee. It is not, and cannot be. The IBC report now exists. It may be that our best course would be to recommend to the Director-General that he ask IBC to prepare a philosophical and analytical report, as more suitably fitted to its appropriate role.

PARAGRAPH 12

UNITED STATES OF AMERICA	Paragraph 12 implies that information must be provided about the provider's financial benefit as part of the consensus process. We do not believe this is necessary or appropriate, and this position would open up a number of irrelevant issues, unnecessarily complicating the consent process.

PARAGRAPH 15 (AND 30)

JAPAN	In paragraph 15 and also 30, we can see the description that consent may be withdrawn at any time and for any reason. On the other hand, some samples in scientific research are anonymized without any information of the donor's characteristics such as heredity, and in those cases, donors cannot withdraw their consent to the research. In addition, Article 6, a) of the Universal Declaration on Bioethics and Human Rights, which is the basis of this document, says that "the consent should, WHERE APPROPRIATE, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice". So the word "WHERE APPROPRIATE" should be added to paragraphs 15 and 30 as well as to some other related paragraphs.

PARAGRAPH 53

JAMAICA	It is not clear how the right of withdrawal of consent would be applied.

PARAGRAPH 66 AND FOLLOWING (SECTION III.1.5 – EMERGENCY SITUATIONS)

JAMAICA	Jamaica feels that this could rightly be dealt with under both clinical practice and biomedical and clinical research. The discussion on consent in emergency situations could be more direct especially where no directives exist or there is an unidentified person. Who accepts the responsibility for decision-making to fulfill the duty of the health care practitioner as set out in paragraph 66?

PARAGRAPH 67

UNITED STATES OF AMERICA	Paragraph 67 implies that a provider cannot invoke his or her personal conviction and must provide a procedure requested by the patient. But doctors have rights too.

PARAGRAPHS 73 AND FOLLOWING

UNITED STATES OF AMERICA	This discussion confuses informed consent with organ donation. The donation by or on behalf of a non-living person does not involve consent; it is a donation. The concept of consent — based on an understanding of the risk and benefit of a procedure — does not fit with donation (except for living donors consenting to the removal procedure).

PARAGRAPH 85

UNITED STATES OF AMERICA	Paragraph 85 seems to imply approval of a court decision that children, if able to understand, may receive contraceptive information over their parents' objection. This ignores the other values that are involved in this question.

PARAGRAPH 98

UNITED STATES OF AMERICA	Paragraph 98 states that in some cases medical personnel can compulsorily detain mentally ill patients. Presumably one would want to require judicial involvement in these matters.

PARAGRAPHS 100 AND FOLLOWING

UNITED STATES OF AMERICA	These sections of the Report imply that the principles of the Declaration need not be applied in developing countries because of a lack of resources. The Declaration is not a legally binding instrument. No country is obligated to comply with it; it is guidance. And every country will find aspects that are difficult to carry out in certain circumstances. But it is contrary to the purpose and the spirit of the Declaration to carve out *ad initio* exceptions and lower expectations for certain countries. That is not fair to the citizens of those countries.

PARAGRAPH 103

UNITED STATES OF AMERICA	Paragraph 103 states that a provider need not tell the patient of possible treatments if they are not covered by the relevant coverage. We do not believe that is appropriate. Patients should be told of available treatments; coverage for them is a separate question. Financial considerations should not restrict the health information the patient receives.

PARAGRAPHS 116 AND 117

UNITED STATES OF AMERICA	These paragraphs seem to imply instances in which group decision can override individual autonomy for consent. Much of the discussion is actually about property law within the group rather than the individual's consent, but the language implies a broader exception. In fact, Paragraph 117 says: "such cases should not be used as a basis for concluding that cultural considerations can dictate that for members of some groups communal authority must always override individual autonomy" (emphasis added). It thus implies that in other cases — but not always — group decision can override individual consent. Social and economic context cannot override the principle of individual consent.

IV. SUMMARY OF SPECIFIC COMMENTS FORMULATED ORALLY DURING THE DISCUSSION AT THE FIFTH SESSION OF IGBC

General comments

- In order to avoid any misinterpretation of the Report of IBC on Consent as a step back from the Universal Declaration on Bioethics and Human Rights, it is necessary to restate that the Universal Declaration is the statement of Member States and as such remains a prominent instrument. The Report should clearly state that it is subordinate of the Declaration and should be read in its light, and the language of the Report should be consistent with that of the articles of the Declaration (Canada, Italy, Mexico).
- The Report would benefit from a legal and philosophical analysis of the origin of the principle of consent and an overview of the international human rights instruments and other texts produced within the United Nations system that contain related provisions (for instance, the Convention on the Rights of Persons with Disabilities) (Mexico, Netherlands, Uruguay).
- The Report would benefit from an in-depth analysis of the relation between the principle of consent and the principles of autonomy and freedom (Cuba, Mexico, Uruguay).
- The distinction between clinical practice and medical research should be better defined, as well as the difference between research on human beings and research on biological material (Canada, Germany, Mexico).

Paragraph 7

- The Report should insist on consent as being an ongoing process in which the responsibilities of both actors (the person concerned and the provider of the information) are relevant (Mexico).

Paragraph 12

- This paragraph implies a requirement to provide information about the provider's financial benefit as part of the consensus process, which could potentially open up a number of irrelevant issues, unnecessarily complicating the consent process (United States of America).

Paragraph 23 and below

- The definition given in the Report of advance directives should be more nuanced: advance directives should be considered as a means to manage in certain cases the difficulty/impossibility for a person to express his/her consent, rather than as a means to obtain consent (France).
- A difference exists between advance directives in which the patient requests that something not be done (negative), and directives where something is asked to be done (positive). The document as a whole must reflect the different consequences from these two different types of directives: negative can be binding, but the positive can never be binding (Netherlands).

Paragraph 30

- The Report should include procedures or modalities of withdrawal and the need to inform the patient about them. The document should clearly point out that the limitations on the right to withdrawal of consent should be made clear at the time of the consent (Canada).
- The Report should clarify the meaning of "correct information" used in this paragraph (Italy).
- The paragraph does not take into account those cases where the sample is anonymized, which makes it impossible to withdraw consent. Therefore, borrowing from the text of the Declaration, the formulation "where appropriate" could be used in this paragraph (Japan, Republic of Korea).

Paragraph 32

- This paragraph seems to be at odds with paragraphs 116 and 117 in regards with community versus individual consent (United Kingdom).

Paragraph 42

- The formulation of the paragraph could wrongly imply that altruism is a form of compensation (Italy).

Paragraph 54

- In order to reflect the current reality of bio-banks, retrievable unlinked data should be taken into account within the framework of discussion on "blank consent" (de-codification can, in some cases, make the data retrievable) (Republic of Korea).

Section III.1.4 - Public health

- There exist generally accepted principles that grant exemptions to the principle of consent in this context, and these principles should be extensively discussed in the Report (Germany, United Kingdom).

Paragraph 67

- The paragraph implies that a provider cannot invoke his or her personal conviction and must provide a procedure requested by the patient. However, the Report should also refer to providers' rights (Netherlands, United States of America).
- Concerns have been expressed on the use of a case study on Jehovah Witnesses as an example of autonomy and free and informed consent as well as on the use of a case referring to an adolescent (France).

Paragraph 73

- The concept of consent — based on an understanding of the risk and benefit of a procedure — does not fit with donation (except for living donors consenting to the removal procedure) (United States of America).

Section III.2.1 – Lack of capacity to consent

- The Report seems to contain confusion regarding the definition of lack of capacity to consent. On one hand, lack of capacity to consent is a temporal issue – at any particular point people may lack the capacity to consent, so the focus of the Report should be on a continuing process of capacity judgment on consent. On the other hand, while the Report ascribes competence and incompetence to various groups, it would be more appropriate to look at individual standards of competence, and not that of entire groups (Mexico Netherlands, United Kingdom).

Paragraph 85

- This paragraph seems to imply approval of a court decision that children, if capable to understand, may receive contraceptive information over their parents' objection. This ignores the other values that are involved in this question (United States of America).

Paragraph 100

- While economic context can affect the process of obtaining consent, the principle of consent should be accorded a clear and unequivocal priority. This paragraph should not give the impression that the principles of the Declaration could not be applied in developing countries because of a lack of resources (Netherlands, United States of America, Uruguay).

Paragraph 103

- Paragraph 103 seems to have a very paternalistic tone (Netherlands).
- Financial considerations should not restrict the health information the patient receives (United States of America).

Paragraph 121

- Social perception and religious beliefs should not be mentioned in the same context (Italy).

Paragraph 143

- Paragraph 143 should mention the right of the patient to request other therapeutic interventions (Kazakhstan).

Bibliography

- Only books and papers that were used to write the Report should be included, with proper citation and complete information (Japan).