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TWENTY-FIRST SESSION OF THE INTERNATIONAL BIOETHICS COMMITTEE OF UNESCO (IBC)

UNESCO Headquarters, Paris, 8-12 September 2014

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JOINT SESSION OF THE IBC AND THE INTERGOVERNMENTAL BIOETHICS COMMITTEE (IGBC)

UNESCO Headquarters, Paris, 9-10 September 2014

DRAFT REPORT

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I. INTRODUCTION

1. The 21st (Ordinary) Session of the International Bioethics Committee of UNESCO (IBC) was held at UNESCO Headquarters in Paris from 8 to 12 September 2014, attended by 32 of the 36 IBC members. Private meetings of the IBC were held on 8, 11 and 12 September 2014.

2. In order to streamline the working methods of the IBC and the Intergovernmental Bioethics Committee (IGBC), the public meetings of the 21st Session of the IBC were held in conjunction with the Joint Session of the IBC and the IGBC from 9 to 10 September 2014, with more time allocated for the discussion of each topic so as to provide ample opportunities for members of both Committees, as well as observers, to express their views. These public sessions attracted approximately 252 participants from 78 countries, gathering representatives of Member States as well as representatives of international organizations and NGOs, as well as other external partners. 33 of the 36 IGBC Member States were represented as follows: Argentina, Brazil, Cameroon, Canada, Côte d'Ivoire, Denmark, Dominican Republic, France, Germany, Georgia, Greece, Guatemala, India, Indonesia, Jordan, Kenya, Kuwait, Lebanon, Lithuania, Madagascar, Mexico, New Zealand, Niger, Pakistan, Republic of Korea, Russian Federation, Singapore, Slovakia, Thailand, Togo, Tunisia, Turkey, and Zambia.

3. In accordance with the work programme of the IBC for 2014-2015, the two main topics that were discussed during these Sessions were the elaboration of the principle of the sharing of benefits, as set out in Article 15 of the Universal Declaration on Bioethics and Human Rights (2005), and the update of the IBC's reflection on the human genome and human rights. In addition, the revision of the Recommendation on the Status of Scientific Researchers (1974) (henceforth referred to as "the 1974 Recommendation") was included in the Sessions to ensure that the comments of the two Committees are taken into consideration in this process. The outcome of this reflection fed into the discussion of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) on this item during its Extraordinary Session in October 2014. This represents a first step towards closer collaboration between the IBC, the IGBC and COMEST. Furthermore, an item on the current global reflection on addressing the ethical aspects of converging technologies was included on the agenda, and was presented by the Council of Europe's Committee on Bioethics. It should be pointed out that this item is not a part of the IBC's work programme, and was included to ensure that the IBC and the IGBC were informed on an emerging discussion currently taking place within the international community. It is envisioned that such global reflection items will be included on the agenda of future sessions as a way of strengthening the sharing of information by the members of the UN Interagency Committee on Bioethics (UNIACB) with the IBC and the IGBC, as well as the strengthening of the role of UNESCO as the Permanent Secretariat of UNIACB. Furthermore, at the initiative of the French Delegation to the IGBC, the Joint Session of the IBC and the IGBC also considered a statement expressing solidarity with ongoing international efforts to respond to the Ebola virus epidemic in West Africa.

4. This document is a consolidated report covering both the public and private meetings that took place during the week of 8 to 12 September 2014. The first part of this report outlines the discussion during the Joint Session of the IBC and the IGBC and the public meetings of the 21st Session of the IBC (held in conjunction) on 9 and 10 September 2014. The second part of this report outlines the discussion during the private meetings of the 21st Session of the IBC on 8, 11 and 12 September 2014.

II. JOINT SESSION OF THE IBC AND THE IGBC AND THE PUBLIC MEETINGS OF THE 21ST SESSION OF THE IBC

5. The Joint Session of the IBC and the IGBC and the public meetings of the 21st Session of the IBC were co-chaired by Mr Stefano Semplici, Chairperson of the IBC, and Mr Peter Monette, Vice-Chairperson of the IGBC. Mr Monette was invited by Mr Yongyuth Yuthavong, Chairperson of the IGBC, to co-chair the meeting on his behalf as he was unable to attend due to other commitments.

6. The Rapporteurs for this part of the report are Mrs Ewa Bartnik, Rapporteur of the IBC, and Mr Roland Tomb, Rapporteur of the IGBC.

II.A. OPENING CEREMONY

7. The Sessions were opened by Mrs Irina Bokova, Director-General of UNESCO, via a video message. In her welcome speech, she reminded participants of the importance of ethics as the cornerstone of sustainable promotion of human rights and human values. While reaffirming the power of science to tackle health and environmental challenges, she stressed that scientific progress for sustainable development must not come at the expense of fundamental values, and that a link between ethics and science is therefore integral to the achievement of UNESCO's larger humanistic vision. She also emphasized the crucial work of the IBC and the IGBC in the elaboration of UNESCO's bioethics declarations, and commended the hard work and commitment of these Committees to applying the principles enshrined within these instruments.

8. In his opening address, the Chairperson of the IBC highlighted that as the result of feedback received from members of the IBC and the IGBC, innovation in working methods of the Joint Session had been introduced so that more time could be allocated for public discussion on each topic, and better consultation could be fostered between the two Committees. It was also indicated that in a meeting convened in May 2014, the Chairpersons of the IBC, the IGBC and COMEST expressed their shared commitment to move towards better synergies between the three bodies. Mr Semplici pointed out that as part of the changes to the working methods of the IBC and the IGBC, two concept notes on the work topics of the IBC for 2014-2015 were prepared by two small IBC working groups at the beginning of the year. He emphasized that these documents were not exhaustive and did not represent the opinion of the IBC as a whole. Instead, they contain some ideas identified by the working groups to stimulate further suggestions and comments from both members of the IBC and the IGBC, as well as from COMEST on the two work topics. Mr Semplici indicated that this process was intended to increase synergy between the three Committees, and he reinforced the independence of the IBC in taking its own decisions as it moved forward on its work in the two areas.

9. On the topic of human genome and human rights, Mr Semplici noted the phenomenal developments in genetic technology while highlighting the reality that such advances require deep consideration of serious ethical issues. He continued onto the issue of cloning and in particular spoke of the need for ethical reflection on nuclear transfer techniques that involve the use of mitochondrial DNA of a third party to prevent the birth of children with serious mitochondrial disorders. The importance of debating such issues in the public sphere was underlined, as public awareness of and input on difficult bioethical questions is crucial for the formulation of culturally-suitable guidelines and policies. On the second topic concerning the sharing of benefits, Mr Semplici emphasized the need to clearly define the scope of Article 15 in

order to effectively implement a principle that is theoretically extremely expansive. He went on to express a number of questions relating to the nature of scientific research, demonstrating the complexity and range of issues that can be considered in defining the principle of benefit sharing.

10. Mr Monette presented the speech of the Chairperson of the IGBC, who conveyed his apologies for not being able to attend the meeting and thanked the IGBC Vice-Chairperson for agreeing to replace him as co-chair for the session. He also expressed thanks to members of the IGBC for re-electing him as Chairperson of the IGBC, and congratulated all IGBC Bureau Members elected by the Committee at the end of 2013. The Chairperson of the IGBC then considered the task of revising the 1974 Recommendation and acknowledged the invitation to all participants of the Joint Session to provide some preliminary thoughts on the issue. He explained that the 1974 Recommendation was intended to establish guidelines for the obligations between scientific researchers and society, and that given changes in the geopolitical, economic and cultural context of research, it is necessary to rethink the approach to defining such obligations. The second topic highlighted by the Chairperson of the IGBC was the global reflection on the ethical issues surrounding converging technologies, which was described as an innovation in the proceedings of the Sessions that enables other UN agencies and intergovernmental organizations to share information about their activities in bioethics. He indicated that inclusion of this occasion, proposed by the Secretariat, was in direct response to repeated calls by IGBC Member States for closer coordination on bioethics at the international level, and furthermore will be extremely valuable for the upcoming meeting of COMEST, in which the topic will be discussed in depth.

II.B. PROGRESS REPORT ON THE UNESCO BIOETHICS PROGRAMME

11. Mrs Dafna Feinholz, Chief of the Bioethics and Ethics of Science Section, presented a summary of changes and important developments within the Bioethics Programme since the 20th Session of the IBC.

12. Mrs Feinholz reported on the progress of capacity-building activities, in particular the Assisting Bioethics Committees (ABC) Project and the Ethics Education Program (EEP). Since the last session of the IBC in June 2013, trainings have been provided to National Bioethics Committees (NBCs) in Chad, Ecuador, El Salvador, Gabon, Guinée, Malawi, Malaysia and Togo through the ABC Project. UNESCO has also provided technical advice on the functioning of the new NBC in Dominican Republic; on the establishment of new NBCs in Argentina, Colombia, Paraguay, Trinidad and Tobago and Uruguay; and on networking of research ethics experts in Peru and Ecuador. Within the framework of the EEP, Ethics Teacher Training Courses (ETTCs) were conducted in Croatia, Jordan, Kenya, Tanzania and Oman, with both local and regional participants. Furthermore, the first UNESCO Asia Pacific Conference on Ethics Education for All will be held in Thailand in October, on the topic of “Searching for a new paradigm of learning to live together”, and Memoranda of Understanding were signed with universities in Argentina and Brazil to implement the UNESCO Bioethics Core Curriculum. In addition, a training session for journalists on how to address important issues in bioethics will be conducted in Colombia in October 2014, from which a bioethics handbook specifically for journalists will be produced. She also presented the work of Redbioética, a network of bioethics experts in Latin America, which have established the UNESCO Online Regional Journal on Bioethics that has released three issues since October 2013. The network will also be holding a meeting on the topic of “bioethics and vulnerable groups” in Peru in December 2014.

13. Mrs Feinholz then highlighted the open roundtable that was held on 6 September 2013 to celebrate the 20th anniversary of UNESCO's commitment to bioethics. As a follow-up to this roundtable, and in order to build a multidimensional perspective on UNESCO's role in the future of global bioethics, a number of bioethics experts were invited to collaborate on a book, to be published at the end of 2014, which outlines the achievements of UNESCO's 20 years of activities in bioethics, identifies major challenges and expected development in the field, and assesses the future role of UNESCO in bioethics.

14. Mrs Feinholz also highlighted the decision of the Director-General to reform the Organization in 2010, emphasizing that bioethics was rated as a high priority by Member States. She outlined the creation of the Section for Bioethics and Ethics of Science, a new structure that brings together the Bioethics and Ethics of Science and Technology Programmes, for the purpose of increasing their overall cost effectiveness and impact in the long term. In particular, this new Section will now ensure the Secretariat of the IBC, the IGBC and COMEST, in order to streamline the working methods of the 3 bodies through fostering closer collaboration and discussion in areas of shared interest. In developing a strategy for how to best move forward, consideration was given to the outcome of the meeting between the Chairpersons of the 3 Committees, as well as to the written consultation carried out with members of the IBC and COMEST, from which it was determined that improvements to the Committees' working methods, and building synergies within the content of their work. She reminded participants that early consultation through the use of concept notes was an innovation in the working methods that was already being implemented in the current session. Other changes that were suggested include extending the time for private meetings by the IBC on the substance of their work, and promoting more active discussion between the IBC, the IGBC and COMEST. Holding of joint sessions of the 3 Committees was also considered, and it was further proposed that an online forum, which has already been established for past and present members of the IBC, be established for members of COMEST, and for collaboration between members of the 3 bodies. Regarding the content of the Committees' work, it was emphasized that issues to be identified should allow both the IBC and COMEST to focus on themes specific to their respective expertise; specifically, the IBC should focus on bioethics and the impact on health, and COMEST should focus on the ethics of science and technology in general. On this point, Mrs Feinholz stated that the Chairpersons of the Committees had agreed to contribute to the revision of the 1974 Recommendation. The Chairpersons also agreed that the post-2015 Sustainable Development Agenda and the principle of global justice would constitute a unifying framework for building the future work agendas of the Committees.

15. Finally, Mrs Feinholz elaborated on UNESCO's collaboration with other UN agencies, regional agencies and international organizations. She explained that the 13th meeting of UNIACB, for which UNESCO is the Permanent Secretariat, provided an opportunity to share experiences and determine future opportunities for collaboration. During this meeting, UNESCO raised the issue of global justice and its link to Article 27 of the Universal Declaration of Human Rights, and the Council of Europe introduced the topic of prenatal sex selection. During the 10th Global Summit of National Ethics/Bioethics Committees (NECs) in Mexico City (June 2014), for which the World Health Organization (WHO) is the Permanent Secretariat, UNESCO assisted in conducting a survey of NECs with the objective of learning about their compositions, working methods and challenges faced at the national level. It was indicated that this represents an important step towards enhancing the collaboration between UNESCO and WHO in the area of capacity building. Mrs Feinholz also explained that UNESCO is a member of the Advisory Board of the "Researchers using Existing Workflows to Archive Research Data" (REWARD) project funded by the European Union (EU), which focuses on the relationship between the protection

of intellectual property rights, acknowledgement and reward for innovators, and fair access to health services and medication for those most in need. In this context, a seminar conducted on 6 June 2014, was organized to discuss the issue of global justice and the provision of life-saving medicines to the poor, the details of which can be found on the UNESCO website. Furthermore, UNESCO is also a member of the “Stakeholders Acting Together On the ethical impact assessment of Research and Innovation” (SATORI) project, another initiative funded by the EU, which aims to bring together knowledge from multiple stakeholders, including academics, researchers, scientists and journalists, in order to develop an ethics assessment framework to ensure that ethical principles and laws in research and innovation are respected and adapted to the evolution of technologies and societal concerns.

16. Participants of the sessions indicated their support for the new and ongoing developments within the Bioethics Programme, and many expressed their appreciation to the Secretariat for their efforts.

17. With regards to the outlined structural reform, a number of Member States of the IGBC expressed support for closer collaboration between the IBC, the IGBC and COMEST in order to avoid duplication of efforts and to promote efficiency. On this point, however, there was also concern that collaboration may result in a narrowing of issues considered by the Committees, in which case it was stated that the Committees should look for synergies while maintaining their respective expertise to address ethical issues from a wider perspective.

18. Further comments were made on the type of bioethical inquiry that the IBC engage in, as a concern was expressed that the reduction of bioethical analyses to scientific research only may promote the misconception that bioethics is confined to issues solely related to biotechnology and medicine, when in fact the UNESCO Universal Declaration on Bioethics and Human Rights supports a broad perspective of bioethics. It was stated that discussion on bioethics should come back to a very broad definition of life, and therefore should involve considerations that go beyond just research. In support of this view, it was also suggested that bioethics should contribute to discussions on broader issues and not narrow challenges, including new ethical principles for international research. The point was illustrated by reference to the Ebola outbreak in West Africa; it was stated that the Ebola crisis has led to many intriguing headlines about a possible new vaccine or experimental treatments, but from experience with other infectious diseases, it is clear that environmental factors, for example, sustainable healthcare systems, access to clean water, and education play the most important role. Hence the Ebola outbreak is essentially a social justice issue, and failure to address these broader bioethical issues will lead to the draining of resources and the emergence of new catastrophes.

19. It was also suggested that the IBC should work on emphasizing the importance of education and culture in discussion of bioethical issues, as these are key elements for the development of ethics and respect for ethical standards. Such a focus can then lead bioethics to be a more significant part of UNESCO’s work in the future. Mrs Feinholz responded that a broad perspective on bioethical issues is indeed supported, as shown by the establishment of the global justice framework from which topics considered by the IBC are to be selected. This was acknowledged by several participants, and it was emphasized that the Committees should pursue a practical approach to their work, with a focus on effective dissemination of information and teaching materials.

20. Madam Chafica Haddad, the Chairperson of the Intergovernmental Council for the Information For All Programme of UNESCO (IFAP) took the floor to support the work of the IBC over the past 20 years, and proposed that possible cooperation between the IBC, the IGBC and COMEST should be explored to build synergies with IFAP in the future.

II.C. REVISION OF THE RECOMMENDATION ON THE STATUS OF SCIENTIFIC RESEARCHERS (1974)

21. Mrs Feinholz indicated that revision of the 1974 Recommendation was requested in 37 C/Resolution 40 of the General Conference of UNESCO. This process would take place from 2014 to 2017. In the above mentioned resolution, the General Conference considered that the 1974 Recommendation “should be revised to reflect the contemporary ethical and regulatory challenges relating to the governance of science and the science-society relationship, taking account, inter alia, of the 1999 Declaration on Science and the Use of Scientific Knowledge, and the 2005 Universal Declaration on Bioethics and Human Rights in order to provide a powerful and relevant statement of science ethics as the basis for science policies that would favour the creation of an institutional order conducive to realization of Article 27, paragraph 1 of the Universal Declaration of Human Rights.” She emphasized that the specific mention of the Universal Declaration on Bioethics and Human Rights implied that ethics experts should be closely involved in all stages of the revision process, and therefore the IBC and the IGBC are invited to present their views on the 1974 Recommendation, in particular to express what is considered to be missing or in need of change, given current political and scientific developments.

22. Mrs Feinholz pointed out that discussion at this session of the IBC and the IGBC will be part of an informal public consultation period, the summary of which will be provided to COMEST in October 2014, and relevant discussion by COMEST will also be reported back to the IBC and the IGBC accordingly. The first round of this informal public consultation process is from May to November 2014, with a second round planned from February to July 2015. A large number of institutions had already been invited to send written advice and comment to the Secretariat as part of this process, and participants of the sessions were encouraged to solicit responses from their respective organizations. The Secretariat will prepare and circulate a summary of the inputs received during this informal public consultation that may then be used by Member States during the formal consultation process to begin in early 2016. Member States will study the report, provide comments, and consider options for modifications to the 1974 Recommendation. She further explained that an Expert Committee will be formed by Member States in early 2017 in order to prepare a draft text containing proposed revisions to the 1974 Recommendation. It was noted that membership of this Expert Committee may be drawn from representatives of the IGBC. At the final stage of formal consultation, Member States will debate and decide on the changes to be adopted during the General Conference in 2017.

23. Mrs Feinholz concluded by highlighting that Paragraph 1 of Article 27 of the Universal Declaration of Human Rights refers to the “right to freely participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits,” and, with reference to a 2012 report by the UN Special Rapporteur for this right, underlined that the purpose of revision therefore distinctly echoes the IBC’s work on benefit sharing, which may in turn be fed into the revision process for the 1974 Recommendation.

24. Both the IBC and the IGBC expressed appreciation at being consulted on the revision of the Recommendation, and underlined their interest in being part of the revision process beyond

this initial stage. It was generally agreed that revision of the 1974 Recommendation should be driven by principles of social responsibility. Within this context, both committees drew particular attention to a lack of adequate reference to the **relationship between scientists and society**, and specifically, the obligations scientists owe to society. Relevant to this point is the comment that the text fails to instill a sense of ethics in scientists by the absence of any recommendation for scientists to adopt some kind of **common code of ethics** or to be trained in the ethics of science. It was also suggested that a focus on the science-society relationship is supported by the need to promote principles of **global justice**, as science, technology and innovation should be used for the benefit of all society, with particular regard to the divide between the rich and poor and between those who have access to technological advancements and those who do not.

25. The comments expressed during the session may be categorized into eight main themes: vulnerable populations in research, engagement and cooperation within the international community, scientific education and open access, freedom of research, improper use of scientific research, protection of intellectual property rights, policy-making and the role of scientists, and the relevance of the social sciences. Participants also made some general comments on the structure of the document.

26. On the topic of **vulnerable populations in research**, it was firstly highlighted that the 1974 Recommendation needs to have some reference to the issue of **gender inequality** in scientific research, in particular, regarding working conditions of women scientists. It was also stated that there should be emphasis on the protection of participants in scientific research in general. Secondly, participants commented on the **responsibilities of developed nations** and the issue of **exploitation of developing nations** by developed countries. Regarding the former point, it was stated that the 1974 Recommendation should highlight the responsibility of developed countries to ensure developing countries have effective access to medicines and scientific technology available in the developed world, that are important for the health and well-being of developing country populations. On the latter point, it was noted that research occurring in developing countries as a result of sponsorship by developed countries raises concerns that should be taken into account more seriously in the 1974 Recommendation.

27. Many participants commented on the topic of **scientific education and open access**, with emphasis on the need to achieve fair access to scientific knowledge and to promote the objective teaching of science to society in order to enhance scientific literacy. It was noted that such aims are essential to achieve the fairest use of scientific knowledge in the implementation of social goals, and that this aspect of cooperation between society and science should emerge as a salient feature of revision of the 1974 Recommendation. However, it was also warned that open access must be **monitored** so as to avoid the publication of inadequately reviewed journal articles and uphold dissemination of quality research. Some participants underlined the role of **public debate** in accessing information and highlighted the importance of access to research from all countries, noting the difficulty for scientists in some countries, in particular, Africa and India, to publish their work. Furthermore, it was stated that **funding bodies have a role** in promoting open access to scientific information by allowing the publication of sound research despite any conflicts with commercial objectives. On the issue of **patents** and open access, it was stated that the revised 1974 Recommendation should address the point that patents have two antagonistic elements: on the one hand, there is the right to benefit from the discovery of new knowledge, and on the other hand, there is the societal need to have access to such knowledge. On a relevant point, it was expressed that **knowledge is a public universal good** and as such scientific benefits should be made available to the public respective of copy rights

in accordance with international conventions. Tying in with the topic of responsibility of developed countries to assist developing countries, it was further stated that science and the products of science that are essential for addressing significant public health issues should be made available to all countries, especially those that provide facilities for research.

28. Some speakers focused on the topic of **engagement and cooperation within the international community**. It was suggested that engagement between developed countries, developing countries and individual researchers for the development of science and technologies is a moral imperative and is closely related to issues of open access, scientific education, questions of brain drain and loss of resources. On a relevant point it was also stated that, in light of restrictive immigration policies of wealthy countries, the 1974 Recommendation should address the need to harmonize the issue of **brain drain** with the right for researchers to move freely across borders.

29. Another issue brought up in discussion was **freedom of research**. Participants underlined that freedom of research is a fundamental principle that should be adequately taken into account in the revision of the 1974 Recommendation, as supported by the fact that many countries give it a high constitutionally protected status. In particular, it was suggested that the rights and freedoms of scientists should be emphasized and should include reference to who (whether it be the individual researcher(s), research institution or funding body) has ownership of the research and its applications. However, it was also recognized that a tension exists between scientific freedom and the intentions of some modern research; an example was given of research on children, with the suggestion that freedom of research should be tapered by ethical considerations. It was further noted that the objectives of Article 9 of the 1974 Recommendation, which relate in part to the encouragement of young people to pursue careers in scientific research, should be highlighted in light of the **growing precariousness of the work of scientists**, who, for example, are increasingly required to work within tender systems which seek short term, rather than long term, more innovative results.

30. **Improper use of scientific research** is a further topic that was emphasized. The dual use of research was identified as an issue, as it was stated that the **misuse of results**, for example, for terroristic purposes, is a major problem. On this point, it was suggested that the 1974 Recommendation should adequately address the need to monitor the use of research outcomes at the national and international level. **Fraud** was also highlighted as a relevant issue that should not be neglected. In addition, it was expressed that the issue of **research secrecy** should be elaborated in the 1974 Recommendation, and it was explained that, given recent scientific and technological advances, in particular in the field of genetics, scientists owe a responsibility to research subjects to keep their information private.

31. The issue of the **protection of intellectual property rights** was raised by the World Intellectual Property Organization (WIPO), which expressed the importance of such protections in the field of research and development within private and public companies. This was supported by the statement that intellectual property rights enable entities to commercially exploit the outcomes of scientific and technological research in order to grant more funds for the entity itself as well as for the development of new research and technologies. It was explained that this process is consistent with the role of WIPO in assisting public entities develop their own intellectual property policies and create technology transfer offices, which facilitate the diffusion of innovation within public entities and within society itself. Such offices can, for example, help universities connect with the business world and thereby promote economic growth in developing countries.

32. Some participants highlighted the need for the 1974 Recommendation to include a **dialogue between the natural sciences and the social sciences**. It was stated that the 1974 Recommendation is more or less written for the natural sciences and reference to the social sciences is important in order to draw a closer link between the two fields, especially in consideration of the need to address ethical and social issues.

33. The 1974 Recommendation's reference to the **role of scientists in policy-making** was noted by some speakers, who commented that the issue should be elaborated to clearly define at which level or levels of policy-making scientists are to have a role. Such clarification is useful to ensure an appropriate level of contribution so that there is adequate translation of research findings into policy. In considering the application of scientific research in national policy-making, it was further suggested that (in Article 6) there should be reference to health as a priority issue.

34. Comments by participants also focused on the **structure of the 1974 Recommendation**, emphasizing that the structure needs to be clearer and simpler so that it is easy to identify vital elements of the text. It was also suggested that a hierarchical approach be adopted so that the 1974 Recommendation is structured, for example, in order of content relevant to scientists, society, NGOs, and then governments. It was further mentioned that the 1974 Recommendation's title should be more consistent with its content, as the title only references scientific researchers, whereas the content is about the structure of research and addresses a range of other relevant stakeholders.

II.D. ELABORATION OF THE PRINCIPLE OF THE SHARING OF BENEFITS (ARTICLE 15 OF THE UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS)

35. Mrs Delia Sánchez Varela, Vice-Chairperson of the IBC, presented the key questions outlined in the Concept Note on Article 15 of the Universal Declaration on Bioethics and Human Rights, as well as some of the written comments received as part of the consultation on this document. She pointed out that the IBC's reflection should strive to meet the aspirations enshrined in this article, especially to ensure that "benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries." In this regard, written comments received highlighted the need to define Article 15 in light of the other principles in the Declaration, including the principle of Benefit and Harm. It was also underlined that it might be reasonable to provide an explanation on the decision-making process concerning the use of benefits in the context of Article 15.

36. With regards to the production of knowledge in the life sciences, Mrs Sánchez Varela asked the question of what makes scientific and technological knowledge production different from other human endeavors whose benefits are not shared. She suggested that the IBC could conclude that this is based on the very nature of scientific knowledge itself, which is seen as an achievement of the human race as a whole, and therefore a property of all humankind; in other words, recognizing scientific knowledge as a universal public good. Although this idea was reflected in some of the written comments received on the Concept Note, she pointed out that there was also a different perspective questioning whether this assertion is valid, emphasizing that scientific knowledge is intentionally created and should be the property of those who participated in its creation.

37. She also highlighted that one of the questions raised in the Concept Note is whether access to knowledge referred to in Article 15 includes access to existing knowledge and to the production of new knowledge, which would have profound implications for education. There was also a question of whether access to knowledge could be equated to a “right to knowledge”, to which this did not receive consensus in the written comments received. It was also emphasized that Article 27 of the Universal Declaration on Human Rights refers to “the right to freely participate (...) in scientific advancement and its benefits,” which cannot be interpreted as open and universal access to all knowledge, and thus, any policy advice for Article 15 of the Universal Declaration on Bioethics and Human Rights should focus only on the sharing of benefits derived from advances in the life sciences.

38. Mrs Delia Sánchez Varela further highlighted a number of other questions raised in the Concept Note, including the approaches to sharing of benefits in research that is currently the focus of intense debate at the international level; extending the interpretation of Article 15 beyond the production of knowledge; the scope of beneficiaries covered under the article; the scope of the benefits to be shared with research participants, the responsible parties in this regard, and the way to operationalize this aspect; and what constitutes improper inducement.

39. There was strong consensus among the participants that **Article 15 is to be understood in relation to all articles of the Declaration** and in that sense is framed within the broad concept of human welfare and linked inextricably with principles of global justice. It was therefore considered that the overarching purpose of Article 15 is to share the benefits of scientific research and its applications for the overall promotion of the health and well-being of society, and in particular, vulnerable populations. The need to reinforce **one ethical standard for all** populations was also clearly underlined.

40. Some speakers further considered it necessary to specify that, though there are many sources of knowledge, for example experience, tradition and culture, Article 15 focuses on **scientific knowledge in the life and biomedical sciences**, and the type of scientific knowledge that comes within the meaning of Article 15 is only that which can be used for the benefit of society. It was recognized that this focus on scientific knowledge is relevant when we consider that such information has in the past been reached with disregard for the physical, mental or social well-being of human beings who participated in research. On this point, participants generally agreed that a clear distinction should be made between sharing the benefits of research with the **wider society and the sharing of benefits with individual research participants**, both of which are espoused by Article 15.

41. Different views were expressed regarding the role of **intellectual property rights** in the sharing of benefits. On the one hand, some of the participants indicated that a fair balance must be struck between intellectual property rights and benefit sharing, and that it is important to ensure the principle of benefit sharing is not in conflict with intellectual property rights. On the other hand, it was suggested by some other speakers that intellectual property rights should not even be a consideration in a discussion of Article 15; interpretation of the principle should not be in terms of values relating to profit, intellectual property rights or economic incentives for research, but should be driven by higher humanistic values related to the promotion of health and wellbeing. On a relevant note, it was also suggested that intellectual property rights are indeed consistent with the principle of benefit sharing as their use is a means to promote the production and application of scientific knowledge.

42. On the topic of the sharing of benefits with research participants, a recurring theme amongst some speakers was the importance of **engaging and cooperating with the community**. It was emphasized that such action is necessary for the sharing of scientific knowledge and requires clear communication to research participants and their community of the benefits and risks of research before, during and after the trial. It was noted that such communication is needed in order for researchers to clearly establish what they can offer to participants and their community.

43. A further concern voiced by several participants was in relation to the **role of pharmaceutical companies, universities and other research funding bodies** in the sharing of benefits. It was suggested that there must be a clearer understanding of the obligations such institutions have in conducting clinical trials, particularly in developing countries, and that effective regulations should be enforced where necessary. The need to understand the extent to which market forces dictate the sharing of benefits by pharmaceutical companies in cases of rare health issues was also underlined, and it was expressed that the formulation of an ethical process to enable individuals or institutions to request sharing of benefits in such cases should be considered.

44. In discussion of the above issues, participants further noted the importance of dissemination and use of documents that have already been prepared by other expert bodies, for example, other declarations by UNESCO, the Council of Europe and the European Union. Members of the IBC and the IGBC agreed that a practical, concrete approach to the preparation of the report by the IBC should be pursued in order to make Article 15 operable for the community and Members States.

II.E. UPDATING THE IBC'S REFLECTION ON THE HUMAN GENOME AND HUMAN RIGHTS

45. Mrs Ewa Bartnik, Rapporteur of the IBC, presented on this topic by highlighting the ethical implications of developments in the field of biology and medicine over the past 5 to 10 years. She pointed to the progress in genetic testing and analysis of the human genome, explaining that the sequencing of the whole genome is becoming more accessible and less costly, and in some clinics, has become a routine procedure. As a result, the problem of incidental findings has become a major concern which requires consideration of issues related to tiered consent, and non-discrimination and non-stigmatisation. She also highlighted direct-to-consumer (DTC) genetic testing, noting the potential for such services to mislead consumers given the complexity involved in interpreting results and the lack of any general regulations or laws to enforce quality control. The need for regulation as well as public education was therefore identified as an important discussion point.

46. Mrs Bartnik also considered the issue of cloning, indicating that human cloning is now theoretically possible and that, though most countries have banned the practice, there are issues relevant to human cloning that should still be discussed. It was explained that ethical issues arise from the practice of human cloning as the result of the use of embryonic stem cells. This is because research with induced pluripotent stem (iPS) cells, which do not in themselves raise ethical problems (as an embryo is not needed to obtain iPS cells), can involve the use of human embryonic cells for the purposes of comparison, so that researchers can create iPS cells which are as close as possible to embryonic stem cells. She stated that even though consensus on this matter will be difficult to reach, the need to discuss and be aware of such developments is important.

47. On the issue of nuclear transfer to avoid mitochondrial diseases, she outlined two techniques developed to prevent mitochondrial diseases and indicated the different ethical challenges associated with each. The first method, which involves pronuclear transfer, requires the creation of two embryos, with the destruction of one; whilst the second method, involving maternal spindle transfer, does not create an embryo to destroy but is still considered genetic manipulation.

48. Lastly, Mrs Bartnik reflected on the topic of personalized medicine and data protection regulation. She explained that personalized health care can involve analysis of large amounts of genetic data which can lead to a number of ethical issues. For example, research coordinators who develop patient consent forms are not able to predict how such data might be useful in the future nor can they guarantee that the data will remain protected. Furthermore, most diseases are multifactorial, causing interpretation of genetic data to be a highly complex and potentially misleading process. She therefore highlighted the need to find a balance between the protection of data and benefits of scientific research.

49. Participants commented on two aspects relating to the IBC's work on the human genome and human rights: the general role that the IBC should adopt in addressing ethical issues relating to the human genome; and the particular topics that the IBC should address.

50. Discussion on **the general role of the IBC** emphasized the importance for the Committee to make a distinct, effective contribution to the material that has already been published in the field of ethics and the human genome. As such, it was generally agreed that in progressing its work, the IBC should be aware of and understand existing relevant publications in order to avoid duplication of efforts. Furthermore, it was suggested that the Committee apply a 'broad brush' approach to their work so that, for example, ethical issues and important sources of information are identified in order to produce something similar to a guidebook for people generally working in the field of genetics. Noted also was the fact that the IBC, consisting of representatives from all regions of the world, has a unique position as the only global bioethics committee and as such represents meaningful moral authority. The Committee should therefore undertake its tasks with the understanding that its work is an important reference for Member States and other international organizations worldwide.

51. There were six specific topics that were considered during discussion: the human genome, direct-to-consumer genetic testing, mitochondrial diseases, biobanks and data protection, genetic screening and cloning.

52. Comments by a number of participants on the **human genome** in general, focused on the need give consideration to how human genome analysis and its applications influence understandings of health and well-being. This was considered important in light of the moral debate between therapy and the prevention of sickness on the one hand, and enhancement or the creation of 'designer babies' on the other hand. It was determined appropriate for the IBC to avoid any leaning towards the promotion of any particular view on the acceptability or otherwise of eugenics, and to instead remain focused on providing indications of clear ethical limits. It was further commented that the IBC should seriously consider all possible consequences of their work, and in particular, be careful to not equate the conventional meaning of health with happiness. It was further commented that therapeutic research on the human genome should not be conflated in a way that undermines the importance of promoting healthy behaviors and lifestyles, particularly in light of the need to support the sustainability of healthcare systems.

53. On the topic of **direct-to-consumer (DTC)** genetic tests, participants agreed that it was important to increase public awareness of the risks regarding use of such services given the complexity involved in interpreting results and the lack of any regulation requiring the guidance of a healthcare provider. It was also noted that, in advising for the regulation of DTC genetic testing, consideration should be given to the potential need for international consensus on the issue given the possible undermining of national regulation where individuals are able to access the same services through countries in which such tests are not regulated and are hence cheaper. Though, that the view was also expressed that, consistent with the key objectives of UNESCO, the IBC should focus on the importance of empowerment and education rather than the need for regulation.

54. The need to address ethical issues on the topic of **mitochondrial donation** was considered essential, especially given the fact that mitochondrial transplants are already being carried out. In particular, it was stated that the cultural implications of such practices require serious reflection. It was explained that in Muslim societies mitochondrial donation is culturally unacceptable as it results in the birth of a child who is the product of a man and a woman who is not the birth mother. Such cultural challenges should be addressed so that all countries have the opportunity to benefit from important scientific advances.

55. Some speakers also commented on the topic of **biobanks and data protection**. It was expressed that the need for clear guidelines regarding management and protection of data should be considered, given difficulties that arise when other countries or international institutions request that data be made available to them. It was also highlighted that it is important to be aware of the activities of not just traditionally renowned genetic and scientific education institutions such as Stanford or MIT, but of countries and organizations that are beginning to make significant contributions to the field of genetics, including China, who currently have the largest genetic sequencing center globally. The emergence of these institutions also raises the need to consider how such large amounts of data can be effectively managed. A different comment indicated that data protection should be considered within the framework of global justice, as there should not be an asymmetrical relationship where data is produced but not shared. It was further suggested that the conflict between individuals' right to privacy and the use of data for the progression of scientific research may be tapered where a system of reciprocal benefit of data sharing is realised. On this point it was explained that genetic data could become part of an individual's health records so that medical professionals would be obliged to use such information in decision-making processes for the purposes of, for example, verifying that a patient has no contraindications to a particular drug or medical procedure. The data that is part of the healthcare system could then be made available to the research community. It was stated that this type of system represents a form of benefit sharing, where information is willingly provided to fulfil collective rather than individualistic interests. The **protection of data** was also identified as an issue relevant to **mass genomics** and the responsibility of the State to ensure individuals' right to privacy, as the concern was that, where requests to undertake mass genomics research are made directly to government, institutions bypass requirements for individual consent.

56. Participants expressed a number of views on the issue of **genetic screening**. Firstly, it was stressed that, while it is true that consensus has been there should be no universal screening of women of child-bearing age for breast cancer, it is important to be aware of the work of prominent geneticist, Mary-Claire King, who advocates for universal screening of such persons. It was noted that this single authority is significant enough to warrant serious

consideration of the issue. On this point, a further comment expressed concern as to the level of scientific evidence that should be accepted before the practice of universal screening can be justified, and suggested that this matter be determined before committing to either side of the issue. This is, in particular, with regard to the significant expense and medical issues that arise when screening of a whole population is implemented. Emphasized also was the responsibility to properly inform patients of test results, the accuracy of some forms of testing, and the risks involved in knowing the information. Another comment underlined the importance of informing the public of the lack of substantive knowledge on the efficaciousness of genetic testing and further questioned the net benefit to humankind of genetic testing, particularly in light of the significant number of people in the world who are suffering from a the basic lack of food and water.

57. The issue of **cloning** was mentioned by some participants, who reinforced a dominant view that cloning of human embryos is ethically wrong, should be prohibited by national legislation, and should be closely monitored. Reasons given to support this position included: cloning of human stem cells involves the intentional destruction of a live human embryo which is a natural stage of human development; the success rate of cloning of animals is only 2% to 3%, which is indicative of the success rate of cloning in humans; and human cloning can lead to the dehumanization of human life. A further comment encouraged anticipatory ethical reflection on scientific developments which aim to create germ line cells from single body cells, noting that longstanding moral debates about cloning and stem cells are likely to come to the fore.

II.F. GLOBAL REFLECTION: ADDRESSING THE ETHICAL ASPECTS OF COVERGING TECHNOLOGIES

58. The Vice-Chairperson of the IGBC reminded participants that the issue of converging technologies is not part of the IBC's work programme and that the presentation by the Council of Europe is a novel, though hopefully not the only, occasion for the IBC and the IGBC to broaden their understanding on the bioethics activities of other UN agencies and intergovernmental partners. It was emphasized that such sharing of information represents a constructive step towards strengthening collaboration at the international level.

59. The presentation was given by Mrs Anne Forus, Chairperson of the Committee on Bioethics of the Council of Europe (DH-BIO), and focused on the Committee's ongoing work in addressing the ethical aspects of the rapid convergence in nanotechnology, biotechnology, information technology and cognitive science (NBIC technology). Mrs Forus explained that the specific objective of the Committee is to identify the human rights implications of the developments and application of NBIC technologies in order to determine whether existing legal frameworks are sufficient to meet new ethical challenges. She stated that two studies are being used to inform conclusions: the first, which has already been published, was performed by the Rathenau Institute and involves "mapping the landscape" of relevant technologies, their use and convergences; and the second, which will be completed by the end of the year, is being performed by the Centre for the Study of the Sciences and the Humanities, and aims to analyse the ethical implications of converging technologies.

60. Using findings reported in the first study ('the Rathenau report') and samples from the media, Mrs Forus presented examples of NBIC technologies to illustrate present and emerging technological possibilities. On the topic of **nanotechnology**, she described examples of **lab-on-a-chip technology** and **implantable medical devices**. The 'MiniLab' uses a lab-on-a-chip platform to measure lithium levels or other substances from one drop of blood in a few minutes,

whilst 'The Domino' can amplify and detect targeted sequences of DNA and can, for example be used to detect malaria. There is also the possibility that implantable biosensors can be used to permit interfacing semiconductor devices with living tissues so that, for example, an implanted glucose sensor can be coupled with an insulin release system and help sufferers of diabetes control their sugar levels without the need for insulin injection. Implantable drug delivery systems may also be used to provide more consistent regulation of drug concentration in the blood, which may make treatment more effective and reduce side effects. She underlined that although such developments appear promising, serious thought must be given to mapping associated **risks**, as there is currently insufficient knowledge of how to control the use of these technologies.

61. On the topic of **biotechnology**, she indicated the need to promote public education on DTC genetic testing and outlined some main concerns on the issue of whole genome sequencing which relate to the responsible storing of huge amounts of information and the need to deal with unsolicited findings or findings that cannot yet be interpreted.

62. On the topic of **information technology**, she explained how big data sets could be used to prepare for individual illnesses and hence promote advances in **personalised medicine**; and on a population scale, could be used to anticipate outbreaks of disease. Furthermore, it was indicated that big data can also be gained from the internet and used for **analysis of work-related behaviour**; for example, researchers at the MIT Media Lab have developed a system that can track employee interactions so that the data gained can be used to predict productivity or creativity, for instance in successfully predicting the winning team in a business pitch contest. On this point, Mrs Forus noted that such activities also raise issues of privacy and autonomy in that personal information is being controlled by third parties without the individual's consent. She went on to describe how large scale data collection of online behaviour can be used for **persuasive technologies**, which are systems, such as mobile phones, websites or video games, which are designed to influence the choices or behavior of their users through persuasion and social influence. Persuasive technology can be employed to help people make better choices, for instance personal health systems can be designed to persuade people to exercise more through using motivating feedback, social cues and personalised arguments.

63. On the topic of the **cognitive sciences**, she described a brain stimulation technique called Transcranial Direct Current Stimulation (TDCS), which was originally developed to help patients suffering from brain injuries and may now possibly be used to enhance overall cognitive performance of healthy adults. It was also explained that research on direct brain to brain communication by brain-computer interaction appears to be progressing and hence the need for regulation should be a priority consideration.

64. Mrs Forus then moved on to reflect on some of the **key points of the Rathenau report**. She explained that NBIC convergence points to the gradual dissolving of the narrow borders between the physical and the biological sciences, which promises a strong increase in new types of interventions into living organisms and in bio-, cogno- and socio-inspired artefacts. The report further shows that new types of developments are occurring within the medical domain, and that NBIC convergence enables the application of biomedical technologies outside the professional medical domain and practices of professional health care and research. Three **examples of ethical issues** identified in the report were then presented: for nanotechnology, she explained that new options for intervention in the body and new forms of large-scale data-generation which open new possibilities for monitoring of individual health states and early

diagnosis of disease entail a range of risks that have not been sufficiently mapped; for information technology, the issue was raised that massive amounts of biological data that is collected via sensors built into consumer products can challenge individuals' physical and mental integrity and causes concerns as to ownership of biological information; and for neurosciences, it was highlighted that the issue of deep brain stimulation raises issues regarding autonomy and free will.

65. She also briefly elaborated on the **scope and objectives of the second study**, explaining that it aims to identify and provide analysis of the ethical issues raised, with particular attention to emerging technologies in the field of neurosciences, genomics and other "omics" technologies, nanotechnology, and the NBIC-convergences. The study will identify the ethical principles that may be at stake, as well as possible legal issues. It will refer to the different arguments that may be expressed in discussing the issues, and provide a basis for consideration of possible actions to be undertaken at the European level to address the issues identified.

66. Lastly, she informed participants that a conference will be held during the Plenary of DH-BIO in June 2015, which will be structured around main 'policy' related issues, including intervention and control, collecting and processing, access and benefit sharing, and governance. These issues will be discussed in light of emerging technologies and their possible challenges to ethical principles and human rights.

67. In reference to the media sources that were used during the presentation, some participants acknowledged that, although such resources are useful for exhibiting the level of public attention surrounding the issues, it is most beneficial when conveying information to have reference to original academic papers. This is to assist in upholding the legitimacy of work and any conclusions reported. Participants further noted that the IBC's report on non-discrimination and vulnerability, which partly addresses ethical concerns regarding advances in neuroscience and nanotechnology, may provide useful information for research on the ethical implications of emerging technologies and the NBIC convergence.

68. Many participants commented on the **importance of regulation** of NBIC technologies and expressed various strategies for appropriate governance. The point was made that what is needed is not the creation of new regulatory bodies, but rather **smarter regulation** by existing bodies. Hence, as technologies progress, regulatory bodies should also move forward; for example, institutional review boards should be empowered to be educated about new and emerging technologies. To assist this process, it was suggested that serious thought be given to the issue of **science journalism** and the quality and credibility of reporting, as poorly informed publications may adversely affect public perception about certain innovations, which may then encourage the implementation of overly restrictive regulations. In relation to this point, it was further considered that regulation also has a role in reducing the level of anxiety surrounding the progress and convergence of NBIC technologies, which is important for public support and the promotion of advancements in science.

69. A further comment indicated agreement that a new strategy of governance is needed but expressed uncertainty as to what such scheme would precisely entail. It was proposed that, rather than a top-down approach to regulation, a **bottom-up, soft law approach** should be used, as this is more straightforward to implement and more likely to be effective. For example, an established community of researchers could be used to develop soft law that addresses ethical issues of NBIC technologies, and this could be taken to government where it could be

implemented into legal governance and then broadened to create hard law or at least more soft law.

70. A view was expressed that **new legislation is in fact not needed** to protect patients from ethical concerns arising from technological innovations as current laws remain relevant and already provide the necessary protections. For example, existing regulations governing the privacy of medical records can apply to regulate technological innovations in the same way as they do for present situations; the mechanization of procedures does not alter individuals' legal responsibilities to uphold ethical behaviour.

71. It was also underlined that **neutrality should be maintained** in progressing work on these matters and in analysing the ethical issues associated with NBIC technologies. It was therefore considered important to consult with experts who are open-minded to innovations in technology and new research procedures, and who do not allow personal agendas to influence their judgement.

72. The need to focus on matters of **global governance** was also emphasised. It was stressed that information regarding the short, medium and long term evolution of NBIC technologies must be disseminated worldwide, as many countries do not have the knowledge or resources to control or regulate such technologies. Furthermore, it was considered insufficient for countries to merely have access to such technologies where basic issues such as water availability, hygiene and control of infectious disease remain a concern. As such, it was stated that ethicists, scientists and researchers should give serious consideration to the risk-benefit balance of implementing these technologies globally.

II.G. STATEMENT OF THE JOINT SESSION OF THE IBC AND THE IGBC ON THE EBOLA VIRUS EPIDEMIC

73. At the initiative of the French Delegation to the IGBC, the Joint Session of the IBC and the IGBC adopted by acclamation a statement expressing solidarity with ongoing international efforts to respond to the Ebola virus epidemic in West Africa (see Annex 5). This statement was proposed in recognition of UNESCO's unique role in bioethics within the international community and the current state of emergency posed by the Ebola health crisis. The statement seeks to reinforce the principles enshrined in the Universal Declaration on Bioethics and Human Rights, and to strengthen international support for ending the Ebola virus epidemic. In particular, it also highlights the need to take into account the ethical, social and cultural dimensions of the affected countries when addressing this international public health crisis, in order to ensure an ethical management of the epidemic, a point that was strongly emphasized by many members of the IBC and the IGBC. After some technical and substantive modifications to the initial draft, this statement was adopted by acclamation.

II.H. CLOSING CEREMONY

74. Mrs Lalla Aïcha Ben Barka, the interim Assistant Director-General for the Social and Human Sciences presented some closing remarks for the public sessions. She expressed her gratitude to all contributors for their valuable input to the meeting and commended members of the IBC and the IGBC for their commitment to issues that go directly to the core of UNESCO's purpose. Mrs Ben Barka further emphasized the need to confront issues of global justice head-on, noting the relevance of debates on benefit sharing, converging technologies and revision of the 1974 Recommendation, and the role of the IBC, the IGBC and COMEST in appropriately

keeping these issues in the forefront of ethical discussion. Recognizing that bioethics affects many aspects of all humanity, she highlighted the importance for decisions on bioethical questions to be informed by the views of those representing a range of professions, vocations and perspectives, and underlined that the joint public meeting, with its incredible diversity of membership and participation, exemplifies the type of open discourse encouraged at UNESCO and in the UN system as a whole.

III. PRIVATE MEETINGS OF THE 21ST SESSION OF THE IBC

75. The private meetings of the 21st Session of the IBC were chaired by Mr Stefano Semplici, Chairperson of the IBC. Mrs Ewa Bartnik, Rapporteur of the IBC, is responsible for this part of the report.

76. There were five meetings reserved for members of the IBC, and one training session for new members of the IBC. During the training session, which was held on the morning of 8 September 2014, presentations were given on UNESCO's Bioethics Programme, the functions and working methods of the IBC and the IGBC, the IBC's Work Programme for 2014-2015, and UNESCO's Priority Gender Equality. On the afternoon of 8 September 2014, members were informed of the new structure of the Social and Human Sciences (SHS) Sector of UNESCO, as well as the outcomes of the first Meeting of the Chairpersons of the IBC, the IGBC and COMEST. This afternoon session was also an opportunity to present the work of the IBC since its 20th Session in Seoul, and to begin preliminary discussion on the work topics of the IBC. The two working groups of the IBC met on 11 September 2014 to thoroughly discuss and debate the way forward on their respective work on benefit sharing and the human genome and human rights. The outcomes of these discussions were presented to and debated in the plenary of the IBC on 12 September 2014.

III.A. GOVERNANCE AUDIT AND SELF-ASSESSMENT

77. Prior to the start of the first reserved meeting, Mr Semplici reminded participants of an audit requested by the 37th Session of the General Conference of UNESCO, through its decision 37 C/Resolution 96, on the Organization's governance structure, including the IBC and the IGBC. It was explained that the objective of the governance audit is to observe the working methods of the IBC and the IGBC with a view to formulating governance reform and cost-saving measures within UNESCO. He also recalled that a self-assessment questionnaire for the audit was sent to IBC members for comments. Mr Semplici thanked the five IBC members who responded to the email, and indicated that their comments had been integrated into the questionnaire which was then sent to the External Auditor. He added that the External Auditor would send a person to observe the public meetings of the IBC on 9 and 10 September, and that participants might be individually approached to answer questions. Mr Semplici then informed the members of the IBC of a request by the External Auditor to access the private meetings of the Committee and asked if there were any objections to this. As there were no objections, the External Auditor was invited to enter the meeting.

III.B. RESTRUCTURATION OF THE SHS SECTOR AND OUTCOMES OF THE MEETING OF THE CHAIRPERSONS OF THE IBC, THE IGBC AND COMEST

78. Mrs Feinholz outlined the new structure of the SHS Sector, especially the creation of the new Section for Bioethics and Ethics of Science, bringing together bioethics with ethics of science and technology for a coherence approach to this aspect of UNESCO's mandate. She

also noted that this new Section would facilitate better synergy between the IBC, the IGBC and COMEST since it is now the Secretariat for all 3 Committees. She further explained that in seeking to establish effective ways for the IBC, the IGBC and COMEST to collaborate, a meeting between the Chairpersons of the 3 bodies was held where discussion focused on two topics: the working methods of the Committees, and the shared issues that could be addressed by each Committee.

79. With regards to working methods, it was indicated that some of the ideas considered and agreed upon had already been put into practice since May. These include the initiative for closer consultation between the IBC and the IGBC, as well as with COMEST and UNIACB, and changes to the structure of the public meetings during the current session. It was further noted that as a result of suggestions and comments by members of both the IBC and the IGBC, the use of concept notes was introduced to facilitate early consultation between the IBC and the IGBC on the work topics. She also highlighted the discussion on the Avicenna Prize for Ethics in Science, which aims to promote ethical reflection on issues raised by advances in science and technology, and explained that the Chairpersons were considering ways in which the purpose of the Prize could be enlarged to include recognition of bioethics, rather than merely the ethics of science in general.

80. Regarding issues of shared interest for the 3 Committees, the importance of identifying issues that are of mutual interest to each Committee and that at the same time allow the Committees to utilize their separate expertise was underlined. It was decided that each Committee will address the revision of the 1974 Recommendation. It was further noted that the current work of COMEST on the relationship between science and society, and of the IBC on benefit sharing, may inform and supplement work on this task.

III.C. WORK OF THE IBC SINCE ITS 20TH SESSION IN SEOUL

81. Mr Semplici emphasized that the changes implemented in the IBC's working methods to facilitate stronger collaboration between the IBC, the IGBC and COMEST is the result of much thought and consideration. He noted that though it is difficult to anticipate the fruitfulness of such activities, he was optimistic in light of the persistent efforts of the Committees so far. He also commented that the IBC's work on traditional medicine as well as on non-discrimination and non-stigmatization that were completed by its 20th Session in Seoul demonstrate the Committee's commitment to address persistent and emerging issues in bioethics, while taking into account the needs, interests and values of the worldwide population. The topics that the Committee will discuss this biennium therefore further reflect its commitment to remain true to its function as a global forum. Finally, Mr Semplici indicated that discussion in Seoul emphasized the importance of networking between former and present members of the IBC to make effective use of available resources. He explained that an IBC online forum has been created to facilitate more active communication between these individuals, and that a proposal regarding the creation of a young bioethicists' network is being considered.

82. With regards to the introduction of concept notes to collect written comments the IGBC on the topics of benefit sharing and the human genome and human rights, several IBC members were concerned that the use of these documents could lead governments to dictate recommendations to the IBC, and as such, poses a challenge to the independence of the Committee. Other members of the Committee viewed the use of concept notes as a genuine effort to facilitate collaboration between the IBC and the IGBC to advance the work of the Committee. It was suggested that, while the IBC needs to remain independent, it should also be

open to the needs of governments so that it is able to reach practical outcomes and promote the social values of science. In support of this view, it was noted that the concept note process allowed more time for private discussions within the IBC working groups, and does not in itself prevent the IBC from making independent choices on how to proceed in its work. Mrs Feinholz clarified that the aim of the concept note process was to allow Member States the opportunity to inform the Committee of policy-related needs that could be useful for the IBC to address. She further expressed that it was important for the IBC to continue to share their views on the working methods of the Committee in order to help determine the usefulness of such changes.

III.D. ELABORATION OF THE PRINCIPLE OF THE SHARING OF BENEFITS (ARTICLE 15 OF THE UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS)

83. In discussing the points to be covered in the introduction of the report, it was decided that the history of the principle of benefit sharing should be briefly outlined. Elements of the public discussion were also adopted in deciding that the principle of benefit sharing is to be understood in relation to all principles of the Declaration, and that sharing of ‘scientific knowledge and related applications’ is specifically with reference to the field of life and biomedical sciences, rather than science or knowledge in general. A follow up comment clarified this point by making a distinction between ‘sharing’ knowledge and making knowledge ‘accessible’. In order to stay true to the words of the Declaration, it was considered appropriate to accept that Article 15 intends for *all* scientific knowledge and the products derived from it to be shared; however, taking into account the broad concept of human welfare which informs the context within which Article 15 is to be interpreted, it is only scientific knowledge in the specific field of *life and biomedical sciences* which must be made *accessible*, and this should be the main concern.

84. It was also deemed important for the introduction to specify that Article 15 refers to two overlapping perspectives: the perspective of society and the international community in general, and the perspective of the individual directly involved in research. Members of the IBC further agreed that the importance of gender equality should be made clear in every chapter of the report.

85. It was decided that the first topic to be elaborated on would be about people and groups participating in research. Sub-topics that would be covered in the report include: different aspects of improper inducement and the roles of various stakeholders involved, the issue of double standards, the burden of participating in research, and assistance to persons and groups that have taken part in research. Reflecting sentiment expressed in public discussion, an ancillary point was made that communication between researchers and research participants at times before, during and after research remains a key issue, as common understandings of the responsibilities of both parties and the benefits and risks of participation should be clearly established. This is, in particular, in order to prevent participants from inaccurately associating research trials with quality healthcare and unexpectedly withdrawing from studies.

86. Tying in with public discussion on community engagement and cooperation, it was agreed that the second topic to be included in the report would be about the importance of participation and cooperation in the sharing of benefits as distinct from merely a top-down beneficence approach to benefit sharing. It was decided this theme would include discussion on the concept of solidarity (as stated in Article 13 of the Declaration), capacity building, brain drain, empowerment and open access. In particular, the point was made that a dialogue

between international organizations, governments and researchers is important to reinforce and establish the responsibilities each party has for the progression of benefit sharing objectives.

87. It was decided that the third topic to be covered in the report would be about access to health care and the sharing of benefits with society and the international community as a whole. On this subject it was determined that the following issues would be discussed: the role and influence of intellectual property rights, science education and information, good governance structures and a possible framework for implementing benefit sharing, and adaptation of appropriate technologies.

88. Mr Semplici suggested that a provisional draft of the report be finalized by April 2015, either during a meeting of the Working Group, or a meeting between the Coordinator of the Working Group, the IBC Bureau, and the Secretariat, following which the text will be circulated to the IGBC for written comments, and then finalized during the IBC session in September 2015. At the end of the discussion on this topic, the IBC agreed on a preliminary roadmap for the report based on these milestones.

III.E. UPDATING THE IBC'S REFLECTION ON THE HUMAN GENOME AND HUMAN RIGHTS

89. During its private meetings, the IBC had the opportunity to listen to a presentation by Mr Calum MacKellar, Director of Research of Scottish Council on Human Bioethics, on the technical and ethical aspects of maternal spindle transfer and pronuclear transfer, currently under consideration by the Government of UK.

90. There was debate regarding the technical wording of what the IBC should consider to be its task, as some members were concerned that 'updating' the IBC's reflections on the Universal Declaration on the Human Genome and Human Rights (1997) and the International Declaration on Human Genetic Data (2003) would not be sufficient to produce a practical impact on the actions of relevant stakeholders; whilst other members considered that to otherwise change the original wording of the Declarations would be to act beyond the scope of the IBC's responsibilities and go against the main value of the texts. The issue was resolved upon agreement that the purpose of the report would be to consider the content of both Declarations in light of advancements in the field of biomedical sciences, and upon acknowledging that it is appropriate for the IBC to *recommend* revision of the Declarations where necessary.

91. In recognizing the importance of producing work that will have some practical impact on the decision-making processes of governments and institutions, participants further agreed that the introduction of the report should clearly explain why it is important to update the content and terminology of these two declarations. It was considered that the report should not only summarize what is new, but should also identify and elaborate on specific subjects in order to highlight the ethical issues, with recommendations, and that this should also be explained in the introduction.

92. Members decided that the report would also broadly elaborate on the technical advancements and ethical challenges related to human genetic analysis and the institutional and transnational framework for genetic research. It was agreed that an explanation of technical advancements would include reference to the reality that genetic testing is now cheaper, faster, more comprehensive, increasingly commercial, and more and more predictive. Also, members considered it important to convey that results of genetic tests often indicate risks and

probabilities rather than a yes-or-no-diagnosis. On the topic of ethical challenges in general, it was decided that the report would broadly summarize the impact of technical developments on ethical issues, including autonomy, data protection, stigmatization and discrimination, protection of vulnerable groups and persons, understanding of health and disease and its impact on justice, and solidarity in health care systems. Furthermore, for the issue of autonomy, consideration of informed consent in research and clinical applications, the right to know or not know, and the right to informational autonomy was underlined. In light of prevalent and expanding issues relating to globalization, members also decided to include reference to the institutional and transnational framework for genetic research, emphasizing in particular the need to consider issues relating to patients' right to privacy and right to have access to results, and requests by institutions to use health data for scientific research purposes.

93. It was further agreed that the report include a section on selected areas of application in order to highlight the main ethical problems and provide specific normative statements with reference to the broad ethical challenges identified in the points explained above. Participants noted that by situating specific issues within a broader, general framework, commonalities between issues can be underlined which draw connections to the conceptual umbrella of human rights. The Committee determined that the selected areas of application would include: DTC tests, non-health care related analysis, personalized/precision medicine, biobanks, Personal Genome Project (participatory medicine), non-invasive pre-natal diagnosis, somatic nuclear transfer, spindle- and pronuclear transfer (mitochondrial diseases), and gamete formation from iPS-cells.

94. It was also considered that in order for the report to have a practical effect it should include clear recommendations that are drawn from the analyses of the selected areas of application, and that target a range of stakeholders and activities. It was suggested that to increase coherence, in-text references should be used to refer readers to the recommendations in a section at the end of the report, as it would otherwise be too repetitive to integrate recommendations into the body of the text. As previously indicated, members emphasized the importance of recommending revision of the two declarations where appropriate, as it was anticipated that some principles will be found to be outdated in light of rapid advancements in human genetics over the past decade. Though, a concern was raised that recommendations to revise may be ineffective, as the fast-paced progression of science may render advice outdated before political consensus can be achieved on adoption. As such, it was suggested that the IBC could create an explanatory note that will be easy for the Committee to update in the future. In either case, the point was made that the IBC should show clear intention to not change the core values and principles that underlie the declarations. Finally, it was suggested that determination of the content of recommendations should be based on consensus, and where consensus is not attainable, the pros and cons of the main options for action should be outlined.

95. Mr Semplici suggested that the Working Group on this topic adopts the same deadlines and procedures as the other Working Group on benefit sharing. At the end of the discussion on this topic, the IBC agreed on a preliminary roadmap for the report based on these milestones.

III.E. CLOSING OF THE PRIVATE MEETINGS

96. In addressing members of the IBC at the close of their reserved meetings, Mrs Angelo Melo, Director of the Division of Ethics, Youth and Sport, welcomed the new members of the IBC and thanked all members for their thoughtful contributions and commitment to the global bioethics debate. She congratulated the Committee on their extremely valuable and productive

meetings, noting the exemplary work undertaken through their cooperation with the IGBC, international bodies and outside experts in the field, and their engagement in frank and open discussions on crucial bioethical dilemmas. She went on to outline the role and activities of the Division of Ethics, Youth and Sport, emphasizing its objective to promote the implementation of bioethical principles in a way that adequately protects individuals and communities. She concluded by acknowledging that the work accomplished by the IBC is essential for applying the notions of benefit sharing to real-world situations, and for adapting UNESCO's human rights approach to the genomics age.