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Report of the IBC on the Principle of the Sharing of Benefits

Within the framework of its work programme for 2014-2015, the International Bioethics Committee (IBC) decided to elaborate Article 15 (Sharing of Benefits) of the Universal Declaration on Bioethics and Human Rights. This article will be linked to Article 27 (the right to share in scientific advancement and its benefits) of the Universal Declaration of Human Rights and Article 15 (the right to enjoy the benefits of scientific progress and its applications) of the International Covenant on Economic, Social and Cultural Rights. Prior to the 21st Session of the IBC and the Joint Session of the IBC and the Intergovernmental Bioethics Committee (IGBC) in September 2014, a concept note was prepared by a small working group of the Committee, providing a preliminary outline of potential areas of reflection for this topic. Members of the IBC, the IGBC, the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), and the UN Interagency Committee on Bioethics (UNIACB) were invited to submit written comments and suggestions on the concept note. Both the concept note and written submissions were then discussed during the sessions in September 2014. Following this discussion, the IBC established a larger working group to prepare a draft report on the topic, which was discussed during the 9th Session of the IGBC in July 2015. The draft report was then revised to take into account the comments of the IGBC. The final draft of the report was further discussed, revised and adopted during the 22nd Session of the IBC in October 2015.

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EXECUTIVE SUMMARY

Article 15 of the *Universal Declaration on Bioethics and Human Rights* states that "benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community." The principle of benefit sharing was embodied in the Declaration immediately after the two articles dealing with solidarity and social responsibility and health. In this context, Article 15 makes specific mention of individuals and groups that take part in research, access to health care and scientific and technological knowledge, capacity building, and benefits as possible cause of improper inducement.

In order to clarify the meaning and scope of the principle, the International Bioethics Committee decided to deal separately and in depth with:

a. **People and groups participating in research and the issues they face**: improper inducement to participate in research; burdens and benefits of participating in it; possible existence of double standards; post-trial obligations.
b. **Access to health care, which is sharing of benefits with society as a whole and the international community**, including the possible trade-off with the protection of intellectual property and patents, the adoption of appropriate technologies and transnational practices.
c. **Sharing as participation and not as top-down beneficence**, including the concepts of capacity building and science education, brain circulation, open access to health-related information, and empowerment and participation in the production of knowledge.

The issues to address do not correspond to an 'either/or' situation, but rather to successive and interconnected layers of rights and responsibilities. Building on this awareness, the International Bioethics Committee makes the following main Recommendations, which are to be intended as an open list for States, governments, scientists, and all actors of civil society both at the domestic and the international level.

States and governments are called on to adopt legislative and other appropriate measures to improve research, access to health care and international solidarity.

a. No double standard approach can be accepted in research activity: national legislations and international guidelines should affirm unequivocally that all human beings share the same rights when they enter a research project. Considerations on different levels of resources actually available, cultural peculiarities, or the capacity to sustain treatments in the future should not be used as arguments to justify multiple standards of respect for human dignity.
b. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being. People should always be given treatments according to their need and not their ability to pay. At the domestic level, health care systems should be organized building on this principle and avoiding serious inequalities depending on wealth.
c. Special protection and specific policies for inclusion ought to be developed with regard to the most vulnerable sections of the population: economically or culturally disadvantaged groups and individuals, but also refugees and migrant workers. No one should be discriminated against or marginalized depending on their age, gender, disability, ethnicity, race, religion, or sexual orientation.

d. Capacity building is a priority for any sustainable development agenda. The flow of financial resources for international cooperation and development both from governmental and intergovernmental actors ought to be allocated accordingly.
e. The concept of sharing entails also a specific responsibility towards future generations, so that sustainable access to human biological resources ought to be ensured. In this perspective, it is necessary to promote and implement documents such as the *Convention on Biological Diversity* of 1992 and the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits* of 2010.

Scientific researchers and the community of science are called on to comply with the highest ethical standards of research, "sharing" them at the global level.

a. Research protocols should always be designed, funded, reviewed and implemented building from the very beginning both on the wish to generate new knowledge and the respect of the fundamental rights of every individual and group. This is a "shared" responsibility. International agreements and national legislations are obviously essential, as well as the activity of Research Ethics Committees. However, this responsibility should become also a building block in the education of every scientific researcher.
b. Possible conflicts of interest should always be disclosed and their consequences adequately addressed. An environment in which researchers receive incentives from industry may boost medical progress. However, the agenda of priorities should never be driven primarily by the interests of industry to increase profit.
c. Sharing should always be pursued through active participation. Brain circulation and open access are essential, in order to avoid the advantage of the 'hubs' of knowledge remaining in the hands of a privileged few.

Economic actors and for-profit companies are called on to make personal interests and legitimate profit compatible with the respect of fundamental human rights and the concept of knowledge and health as common good of humankind.

a. Companies should never take advantage of weak legislations to use double standard procedures or prevent people participating in research from benefiting from its results.
b. In certain contexts and conditions of social or economic vulnerability, incentives can become improper inducement, if not hidden exploitation. It is essential that possible reimbursement for harm and/or inconvenience is reasonable according to the local market values and social policies. These payments should never be used as a tool to remove obstacles to participate in research, especially when subject recruitment is particularly problematic due to the nature or characteristics of the research.
c. The implementation of the different modalities of benefit sharing implies the participation of institutions, companies or services from more than one country. In case controversies arise, especially between the intellectual property regime and the fundamental right of every human being to have access to quality health care, they should not be treated as commercial or trade problems, but as ethical ones, with a focus on human rights and in an arena that is appropriate to this approach.

Media and educators are called on to promote the values of sharing and help change the mindset which considers it as just a matter of beneficence rather than political responsibility.

a. Education to share the benefits of science entails obviously the commitment to eradicate illiteracy and set adequate standards for scientific education, starting with primary school. Other means and strategies include: the creation of training centers, ongoing dissemination of the programs of various institutions, the mounting of exhibitions and documentation, individual and collective training at work, ongoing

assessment of the progress, and finally, evaluation and dissemination of these advances.

b. Benefit sharing entails the awareness of belonging to one and the same community of human beings. We use our intelligence and capacities to fight against the consequences of our limited means and our fragility and to improve the conditions of our life on earth. By accepting the idea of universal human rights, we acknowledge that these advancements cannot be a privilege. Progress cannot deepen the existing faults of inequality between peoples and countries. At the same time, we acknowledge that solidarity through participation and not beneficence is the bond of sharing that we need to boost. This is the only way to bring together development and respect for all.

REPORT OF THE IBC
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I. INTRODUCTION

1. Article 15 of the *Universal Declaration on Bioethics and Human Rights* of 2005 (hereinafter "the UDBHR") states that "benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community". In this context, the Article made specific mention of individuals and groups that take part in research, access to health care and scientific and technological knowledge, capacity building, and benefits as possible cause of improper inducement.

2. The definition of benefit sharing and the theoretical basis for claiming there is an obligation regarding it are not matters of unanimous agreement. Some preliminary clarification is therefore required, while taking into consideration the main international documents that have already made use of this notion.

3. Benefit sharing is linked to the concept of "common heritage of humankind" in the *United Nations Convention on Law of the Sea* (UNCLOS) of December 1982 and FAO'S *International Undertaking on Plant Genetic Resources* (IUPGR) of 1983. UNESCO's *Universal Declaration on the Human Genome and Human Rights* of 1997 and the *Statement on Benefit sharing* by the Human Genome Organization (HUGO) Committee on Ethics (2000) also use this approach and explicitly refer to the principle of solidarity. The *UN Convention on Biological Diversity* (CBD) of 1992 refers to resources as "common concern" rather than "common heritage" of humankind.

4. The right of the individuals participating in research to share the resulting benefits, in particular, was introduced in *The Declaration of Helsinki* in its 2000 version, in what is known as post-study or post-trial obligations, which later underwent several modifications:

> At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study (Art. 30).

5. The *International Ethical Guidelines for Biomedical Research Involving Human Subjects* adopted by the Council of International Organizations of Medical Sciences (CIOMS) in 2002 approached this issue from the collective point of view in Guidelines 10, 12 and 20 and from both the individual and the community point of view in Guideline 21.

6. Against this background, the principle of benefit sharing was embodied in Article 15 of the UDBHR, immediately after the two articles dealing with solidarity and social responsibility and health. Wording was kept as similar as possible to Article 19 of the *International Declaration on Human Genetic Data*, which had already been approved by the UNESCO Member States.

7. A benefit, in general, is something that promotes or enhances well-being of people, both in the material and the spiritual meaning of the term. Therefore, its 'value' can be assessed in very different ways: financial gain, advantage or utility of various kinds, promotion of the good for individuals and communities. The noun "benefit" also refers to special assistance for those who are most in need. Article 15 focuses on the benefits resulting from scientific research and its applications in the field of medicine and life sciences, building on the scope and aims of the UDBHR. As stated in Article 1, the Declaration's scope covers "ethical issues related to medicine, life sciences and associated technologies as applied to human beings taking into account their social, legal and environmental dimensions". Article 2(f) affirms that one of the aims of the Declaration is "to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those

developments and the sharing of benefits, with particular attention to the needs of developing countries".

8. The concept of sharing, which refers to enjoying or using something jointly with others, evokes the challenge of justice. Scientific research and its applications produce benefits somewhere as the result of someone's capacity, investment of resources and successful effort. Article 15 states unequivocally that these benefits should be made available to society as a whole and the international community. By introducing this normative statement, Article 15 triggers the decisive question of the possible limits of this sharing and of the means to achieve the goal. At the same time, it underlines the idea of the strong interdependence of all human beings.

9. In this perspective, one of the most visible manifestations of the interplay and complementarity between the principles of the Declaration – expressed in Article 26 – is the close relationship between Article 15 and Article 13, which deals with solidarity and cooperation. International cooperation is explicitly mentioned in Article 24, where it is recognized as an ethical challenge to be taken by the signatory States. The word comes from the Latin 'co + operare', which means 'work together' or 'working together'. In the various fields of knowledge, cooperation entails always the idea of mutual advantage or benefits coming from interactions developed between organizations, institutions, groups or individuals.

10. Solidarity, in turn, is understood as a cooperative process between society, business actors and the States, with the aim of improving respect for individuals and providing better living conditions to populations or historically vulnerable peoples. In the context of bioethics, solidarity means not only a vertical and episodic intervention, but also genuinely cooperative relationships that contribute to effective improvement of the life of individuals, groups and countries. All human beings are intimately related *in solidum*, i.e. as an indivisible whole.

11. In the specific context of Article 15, the idea of solidarity is expressed within the framework of human rights. Solidarity is defined as "social value". Consequently, it incorporates the moral obligation to help, assist, and support others as part of personal responsibility. Many countries have already included the concept of solidarity in their constitutions, interpreting it as a principle related to the construction of free and fair societies.

12. In order to clarify the meaning of the principle of benefit sharing and contribute to a fuller application of it, this Report deals separately with:

a. **People and groups participating in research** and the issues they face: improper inducement to participate in research; the burdens and benefits of participation; possible existence of double standards; post-trial obligations.

b. **Access to health care,** which is sharing of benefits with society as a whole and the international community, including the possible trade-off with the protection of intellectual property, the adoption of appropriate technologies and transnational practices.

c. **Sharing as participation** and not as top-down beneficence, including the concepts of capacity building and science education, brain circulation, open access to health-related information, and empowerment and participation in the production of knowledge.

13. The UDBHR, according to Article 1(2), was addressed to States. At the same time, it was intended to provide guidance "to decisions or practices of individuals, groups, communities, institutions and corporations, public and private". The same applies to this Report: governments and all sectors of society, both at the domestic and the international level, are

called upon to share benefits because they 'share' the responsibility for the promotion of health and social development of their peoples (Article 14 of the UDBHR).

II. PEOPLE AND GROUPS PARTICIPATING IN RESEARCH

14. In this Report, the people and groups participating in research refers to the researchers, the participants, the sponsors and the pharmaceutical companies and medical device manufacturers.

II.1. Benefits as improper inducement

15. Article 15(2) states that "benefits should not constitute improper inducements to participate in research". However, the term "improper inducement" is subject to differing interpretation and evaluation. What is considered improper in one context may be viewed otherwise in another context. For example, some cultures and communities might be offended by incentives offered, while others might expect to receive such incentives as a social norm under local custom. Despite these differences, it is still possible to reach a common interpretation of improper inducement that is applicable to all contexts.

16. Reimbursement for inconvenience and expenses incurred (not amounting to profit) during research participation will not be covered in this discussion. The focus will be on improper inducements, which may sometimes be disguised as reimbursement.

17. The term *improper* inducement clearly shows that not every incentive to participate in research is seen as unethical. Therefore, it is important to define the term 'improper' rather than eliminating all types of incentives that motivate subject to participate in scientific research.

18. It has been suggested that what characterizes inducement as improper is that the offer has the potential to undermine a person's ability to make a free choice and causes her or him to accept certain risks imposed by participation against her or his better judgment. What is of relevance is not the attractiveness of an offer but the potential of the offer to undermine the subjects' ability to evaluate the situation as well as the risks that it could entail. According to this premise, three elements should be taken into account when determining improper inducement.

19. The first is the nature and seriousness of the risks that might be caused by participation. Physical or bodily harms are not the only ones to be considered, because risks to privacy or moral integrity may be as important. Along these lines, inducing participation in which physical risk is minimal (for example when blood is extracted) but the risks posed to privacy are high due to the lack of sufficient guarantees of data protection could be considered improper inducement. Research Ethics Committees (RECs) always have a very important role to play, so that specific projects and the potential risks they entail are evaluated appropriately and subjects considering their participation in research are given adequate information.

20. The second element is the impact of an offer on the decision making process of the subject. What appears as an autonomous decision given by the subjects may be caused by the circumstances that they face. The IBC has elaborated the scope and content of Article 8 of the UDBHR in its Report on *The Principle of Respect for Human Vulnerability and Personal Integrity*, which focuses on special vulnerabilities and takes into account conditions that impinge on the capacity to live as an autonomous individual and the right to live in a world where significant inequalities and everyone's basic needs are adequately addressed. Vulnerable populations include racial minorities, economically or culturally disadvantaged groups and individuals, migrants, seriously ill persons, and prisoners. The need for health care requires the greatest attention as a possible premise for improper inducement. The fact that participating in a clinical trial can be in some contexts the only way to get access to

some treatment underlines a serious and persisting challenge for the principles of equality and justice.

21. Inappropriate information provided to research participants on the possible benefits is the third element that can lead to improper inducement. In principle, participation in research should be based on altruism, and not solely on the right to enjoy the benefits of scientific development. It is important to ensure that patients participating in research are not victims of a therapeutic misconception or mis-estimation, where they over-estimate the benefits they might gain from the research or under-estimate possible harms.

22. Once the aforementioned issues have been addressed, the debate remains open on whether the provision of free participation may offer the most effective means to avoid ambiguous situations, where it is easier for inducement to become improper, even under the pretext of respect for autonomy. Organ donation is one of the primary examples of the way free provision operates as a guarantee against compromising situations. Free provision of this kind strengthens the idea of solidarity among human beings, promotes the altruistic motivation for research participation and encourages the principle of sharing the benefits of scientific research. Many people consider the threshold which separates reimbursement from true remuneration as the limit of what ought to be considered as 'proper', even though this does not exclude the possibility of other symbolic yet meaningful incentives, such as public reward and acknowledgment. Some may disagree, also pointing at the fact that the line between reimbursement and remuneration appears unclear. For example, this leads to the question whether participants in phase 1 clinical trials should be compensated for their time or exposure to heightened risks as compared to mundane time-based labor costs.

23. Article 15 considers improper inducement as a risk for research participants, whose interests should always be protected in the decision making process. However, it is important to observe that researchers themselves can be *induced* to orient their activity towards something else than public good and the interest for the enlargement of knowledge. Thus, it is worth analyzing some ethical dilemmas posed not only from the perspective of the research subjects, but also from the perspective of researchers. An environment in which researchers receive incentives from industry may encourage the development of research and therefore boost medical progress. However, such an environment also encourages researchers to carry out research in specific areas of interest, which are likely to be driven primarily by the interests of industry for profit. The impact on the agenda of priorities should be carefully considered.

II.2. Burdens and benefits of participating in research. Criteria of justice

24. During the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor patients, while the benefits of improved medical care flowed primarily to more affluent patients. Too often, research has been carried out through the means of exploitation or even of crimes against humanity. It is worth recalling that the *Nuremberg Code*, which is considered the first pillar of contemporary medical and research ethics, was written under the impact of the atrocious experiments committed in concentration camps during World War Two. Scientific research entails fundamental issues of human rights.

25. Human subjects' participation in research is protected by the three basic ethical principles of the Belmont Report: respect for persons, beneficence and justice. The principle of justice stipulates that the selection of the subjects must not be discriminatory and most of all that the benefits and burdens of research should be equally shared. Certain groups, including ethnic and racial minorities, may be systematically selected to participate because they are easily available and can be manipulated and victimized and not necessarily because the problem being studied appears uniquely or disproportionately in that population.

26. Informed consent should be obtained prior to research participation. RECs should consider and decide on the justification for the possible inclusion and exclusion of certain groups of people prior to approving the proposed research. Particular care should be taken with vulnerable persons as they require additional protection. Researchers should take into account social, economic, and cultural circumstances of the participants, groups and communities before enrolling them into studies. People should not be inappropriately included in research based on their circumstances and they should not bear the unfair share of direct burdens of participating in research nor should they be unfairly excluded from the potential benefits of research participation due to incapacity to consent, age, gender, disability, ethnicity, race, religion or sexual orientation.

27. Women have been traditionally excluded from participating in research. The exclusion has delayed the advancement of knowledge, denied potential benefits to women, and exposed women to harm when research findings from research projects with only male participants were generalized inappropriately to women, as has often been the case in drug trials. The inclusion of women in research advances the commitment to justice and improves the generalization of research findings to them. Therefore, the exclusion of women from research projects should be justified.

28. Pregnant and lactating women have distinctive physiologies and health needs. Research necessary to obtain knowledge relevant to the health needs of the pregnant and lactating women must be considered. Research in pregnant women should only be initiated after careful consideration of the best relevant data and all the risks involved for the mother and the foetus. In no case should the permission of another person replace the requirement of individual informed consent by the pregnant or lactating woman.

29. Research involving children may present important challenges for research design and the consent process, as they are vulnerable due to their lack of capacity to consent. As a result, researchers have often avoided the inclusion of children in clinical trials so as to eliminate any risks. However, clinical trials conducted only with adults may yield poor understanding of the results that apply to children. The inclusion of children in research to improve our knowledge and ability to respond to their needs, on the basis of the informed consent by the legally authorised representative, should be encouraged as long as the conditions set forward in art. 7 of the UDBHR are fulfilled.

30. Elderly people should not be inappropriately excluded from research solely on the basis of their age. In many countries, they are the highest consumers of drugs, yet many of these treatments have not been tested adequately on them. It would be of great practical use if elderly people were included in research protocols. In order to do so, methodological and safety questions regarding the co-existence of multiple pathologies would need solving prior to participation. As with other vulnerable groups, the elderly are often disadvantaged in many societies and special care should be given to their informed consent process.

II.3. Double standards

31. The last Consideration presented in the Preamble of the UDBHR asserts that “all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research”. This assertion is complemented by Article 11 of the Declaration, which deals with Non-Discrimination and Non-Stigmatization: “No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms”. A form of discrimination is the existence of double standards of care. Though this has been highlighted particularly with regard to multinational research protocols, double standards often exist also within countries, as it is the case, for instance, when different groups of people are offered different quality of health services according to their type of health coverage, which usually corresponds to differences in socio-economic status.

32. In the context of international biomedical research, the term ‘double standard’ arose in the early 1990s to describe the slackening of ethical standards for research sponsored or designed in high income countries and then applied in low income countries. There was criticism, particularly in poor countries, of research which included control groups with placebo, even when proven treatment for the diseases studied existed.

33. In the second half of the 1990’s the discussion was quite fierce due to the identification of other clinical studies conducted in poor countries where the use of double standard methodology was proven. A study published in the *New England Journal of Medicine* in 1997 evaluated fifteen clinical trials that had been set up to study the prevention of vertical transmission of HIV/AIDS from pregnant mothers to their babies, in low income countries, using control groups treated with placebo. It showed that even after the efficacy of the treatment had been proven, these studies on HIV denied antiretroviral medications to one group of subjects. This approach was criticized by some authors as reminiscent of the way that the Tuskegee study denied penicillin to subjects with syphilis. Similar objections were raised against other projects, fuelling the debate on the possible unethical use of a vulnerable population.

34. Ethical standards appeared to be different when applied to poorer countries. Therefore, many studies carried out in these countries might be limited to making observations on subjects to monitor results that could have been prevented, as occurred in the case of the studies on pregnant women mentioned earlier. The use of placebo has remained a very controversial issue since early 2000. In addition, some institutions proposed as the standard of care to comply with the existing standards in the host countries of the study. These host countries are usually among the poorer ones and the existing standards may fall far below the best proven treatment. Although these proposals aim to facilitate the conduct of clinical trials to advance medical knowledge, this comes with the cost of slackening the rules of safety and protective measures for research participants. As a reaction to this state of affairs, many professional and social movements in low and middle income countries, as well as critics in the developed world, strongly rejected these changes as weakening the ethical standards and defended this position in the international context.

35. The unavailability of treatments in a country or its lack of capacity to sustain the best proven treatment in the future does not deny the fact that other human beings, in other parts of the world, already ‘share’ these treatments and this capacity. Human dignity and health should be protected in the same way when people enter a research project. It is true that this approach could introduce another form of inequality among the poor themselves rather than between the poor and the rich and also entail improper inducement, as it would be the case if the best proven treatment rather than placebo would be given in the control group in a trial carried out in a country where the best proven treatment is not available or is not affordable to many people. To overcome this possible contradiction, however, it is necessary to broaden access to quality health care rather than to perpetuate double standards in research.

36. This debate about double standards thus highlights the lack of access of the poor to existing technologies and interventions that are available for wealthier peoples. Most human beings do not have access to what already exists. At the same time, the poor continue to be vulnerable ‘subjects’ recruited for biomedical research. Such populations that are discriminated against and stigmatized due to their lack of resources should not be subjected to biomedical research which proposes ethical and safety standards below those applied to more affluent societies.

37. It is not acceptable that certain kinds of research which would be denied approval in their country of origin are conducted elsewhere, especially in countries which might lack a strong ethical review system or are not in the economic position to refuse. Strengthening the capacity of RECs, particularly in resource-limited settings, is a key way of ensuring that

vulnerable participants are not subjects of research that will not benefit them. The ethical standards of these studies should be the same for everyone.

II.4. Post-trial obligations

38. Principle 20 of the most recent revision of the *Declaration of Helsinki* (2013) is directed at research with vulnerable groups: “Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research”. Furthermore, Principle 34 discusses the post-trial obligations of researchers: “In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process”. As to the definition and implementation of the most appropriate way to meet this obligation, several approaches have been discussed.

39. The participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries proposed the *fair benefits* approach (FB), based on *collaborative partnership* and *transparency*. First, the benefits should be proportional to the risks of research and the benefits to the other party (fair benefits). Second, benefits from research should be determined by the population itself, which can consider benefits from both the conduct and results of research. Third, a central repository and community consultations should be established, allowing comparative assessments of the benefit agreements to ensure fairness.

40. CIOMS emphasized a *reasonable availability* approach (RA). Guideline 10 from the 2002 *International Ethical Guidelines for Biomedical Research* states: “Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that […] any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community”.

41. Still, other authors refer to the concept of *rectificatory justice*, moving the ethics focus in international research from the micro-level of informed consent and of quasi-consensual transaction procedures to a level of deliberation that includes issues of macro-level distribution of basic goods and opportunities. The goal is not simply to ensure compensation, but to change the kind of relationships between human beings, building on the concept of their equal dignity and mutual respect.

42. These different proposals aim at complying with the same duty underlined in Article 15, that is, the duty to provide “special and sustainable assistance to, and acknowledgment of, the persons and groups that have taken part in the research”. Vulnerable populations need to be protected against the risk of exploitation, sometimes concealed as improper inducement. This happens *before* trials. All persons participating in research have to receive complete, transparent information and should never be exposed to unnecessary risks or double standard procedures. This happens *during* trials. A fair, reasonable, sustainable approach should never be intended to convey the message that, *after* trials, a substantial difference could be made between those who directly contributed to the success of a research project and those who were just waiting to receive the possible benefits.

43. In any case, according to Article 14 of the UDBHR, it should always be reaffirmed that the standard of health that every human being is entitled to enjoy as one of her or his fundamental rights is simply “the highest attainable” standard. This is not to deny the existing differences. This is to reaffirm that when life itself is at stake, the maximum of equality remains the ultimate goal to pursue.

III. ACCESS TO HEALTH CARE

44. The advancements and new opportunities provided by science and technology should help reduce and not deepen the inequalities that prevent many human beings from enjoying the highest attainable standard of health, both at the domestic and the international level. Sharing at the domestic level entails the capacity to cope with the many faults of inequality and potential vulnerability that shape contemporary societies, including the new risks of exclusion and marginalization linked, for instance, to the conditions of refugees and migrant workers. The obligation to pay particular attention in sharing benefits with developing countries stresses the need for a *global* framework for justice and solidarity.

45. Persons and groups participating in research are obviously the target of stronger obligations. Nonetheless, the standard of health care that is available for all becomes a touchstone of the *social* value of science and research. On the one hand, the benefits that Article 15 is about are related to research and dissemination of biomedical knowledge and its applications: special and sustainable assistance to, and acknowledgment of, the persons and groups that have taken part in the research; access to scientific and technological knowledge; capacity-building facilities for research purposes. On the other hand, there are the goals related to the responsibility to promote health for individuals and peoples, which is a "central purpose" for governments and all sectors of society, according to Article 14 of the UDBHR: access to quality health care; provision of new diagnostic and therapeutic modalities or products stemming from research; support for health services.

46. The right to health care requires the development of health services, within the limits of available resources and the respect for the free self-organization of society. As a consequence, the sharing of medical achievements and the appropriate use of biotechnologies should take into account both the demands of the common good and other legitimate interests, including intellectual property rights, so long as this does not collide with the right to health care itself.

III.1. With society as a whole

47. There are major ethical issues to be faced with benefit sharing both in high income countries (HICs) and in low and medium income countries (LMICs)[1]. There is probably not a society or country in the world which is able to provide for all the health needs of its population. There is an ever-widening gap between resources and health needs for which there are a number of reasons.

48. First, there is the very success of health research and health care provision in improving the quality of life, including its extension, of vast numbers of citizens. Thus, in developed countries and in the wealthier parts of society in developing countries we see a remarkable growth in the proportions of elderly people. This group constitutes an additional challenge to health care budgets both in its size and in the peculiar demands it makes upon health and welfare services.

49. Second, breakthroughs in treatments of diseases and injuries have provided remarkable possibilities of cures and increases in the wellbeing of citizens. But these treatments have been vastly expensive in their research and development and are, in many cases, very costly to deliver. Thus, once again, success in delivering health care has widened rather than narrowed the demand for services.

50. Health resources in all countries are therefore coming under increasing strain and, given the nature of things, will continue to do so. The question of what conditions should be treated and which patients should receive those treatments is becoming a challenge in every

[1] The UDBHR and many other international documents refer to developed and developing countries, but it is perhaps more appropriate to use this more nuanced and comprehensive definition in this context.

country. In those parts of the world where few of these benefits have yet been enjoyed the time will come when the arrival of treatments and services so needed by their populations will confront health service providers with precisely the same dilemmas. For these reasons, Article 15 should alert all countries to the need to devise systems of sharing which embody respect for Articles 10, 11, 13 and 14 of the UDBHR. In particular, any proposed system of possible rationing should be carefully examined for the manner in which it endeavours to preserve respect for fairness and inclusiveness.

51. Some economic models embody the idea that the possibility of maximum benefit should dictate which patient receives a service in order to ensure that resources are not wasted. The multipliers consistently used to achieve these calculations are the increase in quality of life of patients and the time period for which such a benefit will be enjoyed. Apart from the vagaries of calculating either of these variables it is important to note that their employment in health provision is problematic, especially if you have to choose between interventions for different disease groups.

52. People should be given treatments according to their need. Much has been done in many countries to produce in health care some kind of mechanism by which the scarce resources that are available are allocated to the numbers of people who could receive it. Good medical practice acknowledges the role which the notion of need plays in health care decisions. For example, the familiar distinction between acute and elective cases in surgery employs a calculation of the degree of need of a patient for an indicated intervention. An acutely ill patient will jump the queue in a surgical list over the heads of patients who can safely wait a little longer for the intervention. A patient whose condition indicates that they are likely to die or suffer irreversible negative health consequences if not treated immediately will be regarded as being in greater need of the intervention at the time. Difficult though it might be to achieve fair decisions in these situations the outcomes must be better than the employment of the criterion of the ability to pay or other ethically irrelevant criteria.

53. Fortunately there are some situations where the nature of health interventions and economic considerations will be aligned. These will be where the cost of each intervention is relatively low and the health gains are very high for extremely large numbers of recipients. Such cases will almost always occur in public health activities such as vaccination programmes against infectious diseases.

54. In order to share benefits with society as a whole, the issue of financial and human resources and the issue of the context remain crucial. In the *Joint Statement on the Ebola virus epidemic*, made on 10 September 2014, the IBC and the Intergovernmental Bioethics Committee called upon the States and the international community to “take into account the particular context within the affected countries, including their ethical, social and cultural dimensions” and to “reinforce the capacities of the health systems of the States”, so that “they may face the epidemic financially, materially and from an organizational and human point of view”.

55. The *Summary* of the *Human Development Report 2013* recommended a “strong, proactive and responsible State” as one of the essential conditions to boost access to quality health care. This is not intended as an obligation for States and governments to run the entire health system directly. However, they are called upon to develop “policies for both public and private sectors – based on a long-term vision and leadership, shared norms and values, and rules and institutions that build trust and cohesion”. The IBC, in its *Report on Social Responsibility and Health* (2010), has already acknowledged that “because of their greater resources, more is expected of high-income than of low-income countries”, yet underlining at the same time that “the right to health also imposes some immediate obligations, such as non-discrimination and the requirement for States to have a national plan for health care and protection” (§ 36).

56. Education and information are also key. Understanding the importance of health science will help improve the rate of morbidity and mortality towards a better quality of life. It may take time. UNESCO, which has a long history working for education in different cultural and social contexts, as well as other international organizations, are called upon to contribute to bring the goal closer. Health education is a shared responsibility for the international community, governments, social actors and individuals in their everyday life.

III.2. Possible trade off with the protection of intellectual property

57. The debate on the best way to make the right to share and intellectual property rights compatible is open. The huge returns from investing in health further strengthen this moral and political commitment. An example of this trade-off was the case of Novartis versus the Supreme Court of India. It dealt with the company's right to patent Gleevec (imatinib mesylate) in India after the country changed its patent law. By the time the company wanted to patent the drug, generic versions were already being manufactured in India, thus providing affordable access to a medication that effectively changed the prognosis of chronic myelogenous leukaemia. This case took ten years to be resolved and the Indian Supreme Court decided that the substance that Novartis sought to patent was indeed a modification of a known drug (the raw form of imatinib, which was publicly disclosed in the 1993 patent application and in scientific articles) and that therefore the patent application was properly rejected by the patent office and lower courts.

58. The international community has already addressed this crucial issue. An illustrative example of the idea of not abusing intellectual property rights was the accepted international principles adopted in *The Doha Declaration on TRIPS and Public Health* of 2001, enshrining the right of countries to use patent-protected technologies in emergency health situations. Whatever the solution, it is to be reaffirmed, according to the *Venice Statement on the right to enjoy the benefits of scientific progress and its application* of 2009, that where there is a direct threat to fundamental rights, most notably the rights to life, health and food, the intellectual property regime, which is a temporary monopoly with a valuable social function, "should be managed in accordance with a common responsibility to prevent the unacceptable prioritization of profit for some over benefit for all".

59. This is not to say that benefit sharing and the protection of intellectual property should be seen as opposite. The process of developing and manufacturing new drugs, treatments and devices is becoming more and more costly and a fair return on investment, especially when the latter is a private one, should be guaranteed. Without intellectual property protection, this kind of research might be impossible. However, it is important to enhance the availability of financial resources free from this constraint, as may be the case with public funds for international cooperation as well as contributions from non-governmental organizations. It is all the more important for health technologies where there is little or no perceived commercial market, and for which for-profit companies are unlikely to assume the related risks and costs.

60. The researcher's incentives are also to be considered. In some LMICs, and increasingly in HICs, departments are expected to be self-sustaining due to limited funds from governments. It is felt that research should lead to patents which could be commercialised, with the unavoidable consequence that funding should be sought from those who will take the research to market. Benefit to the consumer might not be of paramount importance. The issue of the ownership of the research products and of who then decides what is to be done and pursued is as important. Article 14(1) of the UDBHR appears to put the responsibility on governments, but here again, in poorer countries where the need for subsidised medicines might be greater, funds for research are often derived from grants or loans with stringent terms attached. The funds serve as an incentive and encourage the researchers to make discoveries which can be patented.

III.3. Adapting appropriate technologies

61. Before adopting new technologies in LMICs, some preparation and adaptation may be required. Technology does not only refer to overtly technical instruments, for example, an agricultural implement or an X-ray machine, but also to drugs, vaccines and other preventive and therapeutic interventions.

62. The concept of appropriate technologies arose in the 70's as an alternative to the problems created by the transfer of modern technologies (mainly in the field of agriculture) to resource-poor settings. Appropriate technology is defined as that which is simple, small scale, low cost and non-violent. In the context of health care, it is to be reaffirmed that this concept is not intended to pave the way to the temptation of accepting substantially different standards for people with the same physical condition but different socio-economic circumstances.

63. The right to enjoy the highest attainable standard of health entails the right to comprehensive health care that responds to every person's health needs in the course of their life, provided in a timely manner, in an affordable way, based on current scientific knowledge and respectful of people's beliefs and traditions. Unfortunately, this is still far from reality for many people in the world. WHO's push for Universal Health Coverage moves in that direction, building on the *Declaration of Alma Ata* and many other international documents. As there is a difference between efficacy and effectiveness, the former being what works in laboratory controlled conditions and the latter what works in real-life conditions, we refer to appropriate technologies as those that are most effective in each situation. Therefore, health technologies introduced into the market once their efficacy and safety have been proven, should be subject to a more comprehensive process of technology assessment.

64. At the international level, there are important collaborative efforts, such as the Cochrane Collaboration and the Campbell Collaboration. They use a standardized methodology, resorting to systematic reviews and meta-analysis of the existing literature. Their production is of high quality and extremely useful, but the comprehensiveness of reviews depends on the availability of scientific literature, and it is often the case that cultural sensitivities are not as widely discussed in the literature as biological issues. Thus, assessments tend to miss some important social questions. The use of systematic reviews for health policy decision-making is the objective of EVIPNet. This network tries to bridge the gap between academic systematic reviews and meta-analysis and context-specific policy-making by applying the review methodology with local teams.

65. In order for all these technology assessment efforts to be effective, it is necessary to strengthen the quality and quantity of scientific production in LMICs. Sufficient knowledge about the effectiveness and cost-effectiveness of interventions, as well as the capacity to produce and not only receive knowledge, is required to offer everyone the possibility to enjoy the related benefits. An effective governance framework is also necessary to ensure timely adoption of appropriate technology, especially those that are vital for human health. In the past, vital technologies such as the hepatitis B vaccine took decades to reach people in LMICs while they were adopted much faster in wealthy countries.

66. It is better to design technologies *ab initio* with a view for their adoption and use in LMICs than to change/adapt technologies specifically developed in, and for, high income, technologically advanced markets. For each technology, factors that need to be considered include initial and life-long cost, ease of use and maintenance, whether the technology can function efficiently without the use of electricity and/or water, and the context of real-life in LMICs. The meningitis vaccine for Africa that has been introduced recently was developed by a partnership that took into account such factors. As a result, the vaccine has been very successfully deployed, with impressive and sustainable health outcomes. A subtle but

important consideration here is that technologies developed *ab initio* for LMICs may tend to perpetuate unacceptable conditions of some health care facilities; this should also be taken into account and avoided whenever possible. At the same time, the high cost for importing technologies into LMICs is challenged as development of such technologies in HICs often uses the LMICs' resources or knowledge.

67. For successful adoption, a needs assessment is important, so that technologies are deployed in response to real needs. In the case of vaccines and drugs, testing should include the populations where the products will be used, as there is variation in the response to such technologies. Important issues include not only the appropriateness but also the affordability, availability, and accessibility of the technology. This is to achieve successful adoption without sacrificing quality while taking into account international ethical standards.

III.4. Transnational practices

68. Based on Article 21 of the UDBHR, which covers transnational practices, the implementation and use of Article 15 may be represented in this perspective as follows:

a. States, institutions, and professionals associated with transnational activities should endeavour to ensure that any scientific (including medicine and life sciences) activity undertaken, funded or otherwise pursued in whole or in part in different States is consistent with the principles set out in the Declaration;

b. International research, when conducted in different States or otherwise pursued as international in any form of its applications should aim at gender, cultural and social equality and be free from double standards and any types of discrimination and stigmatization in all stages of research. For this purpose all research should have ethical evaluation in all the States involved;

c. The benefits of transnational research should be referenced to the individuals and community in all States involved in such research and should be established with equal participation by all States involved in research;

d. Another transnational aspect of Article 15 should be related to the aspect of intellectual property, which has already been addressed.

69. The UNESCO *Recommendation on the Status of Scientific Researchers* of 1974 has urged Member States to "actively promote the interplay of ideas and information among scientific researchers throughout the world, which is vital to the healthy development of science and technology". This interplay is obviously essential. However, it is not enough. The issue of resources and the setting of the agenda are just as crucial to improve *global* health. Many initiatives have been taken, involving both governmental and non-governmental actors, such as the Global Forum for Health Research and the Grand Challenges in Global Health. The causal relationship between a poor social context in the broad meaning of the word and poor standards of health, which is a fact even at the domestic level, becomes appallingly evident at the international level. The neglect of diseases associated with poverty is an example. This is the relationship to overturn, first and foremost through networking actors and resources and shifting to an active participation approach.

IV. SHARING AS PARTICIPATION AND NOT ONLY TOP-DOWN BENEFICENCE

70. Benefit sharing has often been understood as a matter of beneficence. Knowledge is produced (mostly in the highly developed countries that can invest more in scientific research) and subsequently, disseminated throughout the world (so that, sometimes soon and too often very late, the poor may also enjoy its applications). It is now time to change this approach and reshape the goals and regulations of the international community

accordingly. The only way out of growing inequalities is active *participation* of all relevant research actors in producing scientific and technological progress.

71. In order to boost participation which is one of the cornerstones of solidarity, it is necessary, in particular, to establish new networks and hubs of knowledge and research. This is also to comply with Article 24 of the UDBHR, which calls on States to "foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge". Bilateral and multilateral agreements are among the instruments proposed for this purpose.

IV.1. Capacity building and science education

72. Article 15(1)(f) of the UDBHR states that the benefits of scientific research can be shared "through capacity-building facilities for research purposes". The issue of capacity building and its relevance in promoting ethical research, particularly in international collaborative research conducted in LMICs, is important, in order to give everyone the possibility to become active participants of the scientific endeavour of humankind.

73. In the 1950's and 1960's the term 'capacity development' was used, but from 1990-91 onwards, this term was dropped in favour of 'capacity building'. Since 1991, the United Nations Development Program, which focused on reducing inequalities between different geographical areas and within countries, has appropriated the term to refer to a long-term process of improving knowledge, skills, organizational structures and political institutions.

74. Capacity building is the implementation of the conditions in which individual subjects, institutions and society as a whole take upon themselves the power to conceive and pursue their goals, meet their mission, produce change and development in a sustainable way. This involves active participation and empowerment and requires resources, adaptation to changes and challenges of the globalized world, the development of leadership with responsibility and sensitivity, the use of new technologies of organization, and effective methods of management control.

75. Sharing of scientific and technological knowledge is one of the aims of the UDBHR (Article 2(f)) and the first, fundamental premise of capacity building. Considering that access to knowledge is part of education, scientific knowledge must be disseminated to everyone at the early stages of formal education. Children and adolescents should be encouraged through adequate pedagogical methods to develop their natural sense of curiosity towards scientific analysis, which enables them to understand the language and methods of research when they reach adulthood. This aim must be included in educational programs everywhere.

76. Sharing of knowledge does not just mean dissemination of scientific information, but also the ability of the groups/communities of a country to understand and apply the knowledge for their local development, according to their cultural and social context. The UNESCO *Declaration on Science and Use of Scientific Knowledge* (1999) reminds us that poor people and nations are too often excluded from the production and the benefits of scientific knowledge, but that access to this knowledge is part of the human right to education, necessary for human development and for the formation of active informed citizens, who are the solid base of society.

77. Capacity building is important in all stages of the research process: from ethics review, to community engagement, participant recruitment, data collection, data analysis and dissemination. According to the CIOMS guidelines, capacity building may include the following forms: establishing and strengthening independent and competent ethical review processes/committees; strengthening research capacity; developing technologies appropriate to health care and biomedical research; training of research and health care staff; and educating the community from which research subjects will be drawn. Over the

years, there have been several efforts by various funders and sponsors of research to build and in some cases strengthen both human and infrastructure capacity for research purposes in many LMICs. This has enabled researchers and institutions to contribute to important research projects locally. While the obligations of HICs to support capacity building in LMICs are widely acknowledged, it must also be emphasized that LMICs and their governments have a responsibility to contribute to initiatives to strengthen local capacities.

78. In bioethics, special importance is given to the fact that recipient countries acquire the ability to investigate for themselves the medical advances and knowledge of life sciences in general, so that they can contribute within their country and worldwide in this regard. Another important aspect is that these countries learn to manage technology related to the environment and to administer and care for it to avoid intrusion (exploitative, in many cases) of international companies.

IV.2. Brain drain, brain circulation

79. Brain drain is defined as the depletion or loss of skilled, intellectual and technical labour through the movement of such labour to more favourable geographic, economic or professional environments. According to a study submitted to the Executive Board of UNESCO in 1987, brain drain is an abnormal form of scientific exchange, characterized by a one-way flow in favour of the most highly developed countries. The WHO, in its 2006 World Health Report, listed a number of reasons why health workers moved from LMICs including: inadequate living conditions, lack of facilities, heavy workload, lack of promotion prospects, poor management, declining health services, violence, and crime. Developed countries provide prospects for better remuneration, gaining experience, a safer environment, and better facilities.

80. The ethics of brain drain is complex and finding the right balance between respecting individual rights to choose where people want to make a living and protecting the skilled workforce and knowledge resources of a country can be very challenging. The *WHO Global Code of Practice in International Recruitment of Health Personnel*, adopted in 2010 by the Sixty-third World Health Assembly, states that effective measures should be taken "to educate, retain and sustain a health workforce that is appropriate for the specific conditions of each country, including areas of greatest need". All Member States "should strive to meet their health personnel needs with their own human resources for health, as far as possible" and consider "adopting measures to address the geographical maldistribution of health workers and to support their retention in underserved areas, such as through the application of education measures, financial incentives, regulatory measures, social and professional support" (Art. 5).

81. In the *Introduction* of the publication entitled *Migration of Health Workers: WHO Code of Practice and the Global Economic Crisis* (2014), which was prepared by WHO, the Migration Policy Institute and the Social Medicine Institute of the University of Rio de Janeiro, it was reaffirmed that "developed nations have become more and more reliant on international migrants to fill health workforce positions across the skill spectrum", while "WHO estimates that the basic health-care system of 57 countries is affected by shortage of human resources and about one-third of these countries are the emerging market economies". Sub-Saharan Africa, that bears 24% of the world's disease burden, but has only 3% of health workers, is paying the greatest price in this unbalanced relationship. According to recent studies, these countries have lost $2 billion because of trained doctors leaving home to find work in richer nations.

82. While work environments and benefits are very attractive to skilled workers in LMICs, it is worth noting that migrant workers leave their home countries at their own free will and have the right to choose where they want to work. On the other hand, skilled workers such as health care professionals are often trained by their governments with the expectation that

they will contribute to the country's development after their training. Is it ethical to leave the country without contributing or paying back? Is there justice for less developed countries as highly developed countries benefit from this human capital? Or should there be some form of benefit sharing in this brain flow for both individual skilled workers and their countries?

83. Some economists argue that brain drain might have some positive impact on LMICs. The World Bank, already in 2012, estimated that remittances to LMICs, after surpassing the $400 billion mark that year, will reach $534 billion by 2015. While most of these remittances often go to individual families, they also indirectly impact positively on the economy of the country. However, this result remains a consequence of brain drain rather than an alternative to it.

84. The very challenge to address is that of turning 'brain drain' into 'brain circulation'. There are important opportunities that can change the practice of a consolidated one-way flow into a 'brain gain' for the benefit of both developed and developing nations. Many studies have demonstrated the contribution not just of revenues, but also of networking between scholars abroad and the institutions in their country, allowing them to disseminate knowledge and its technological applications and boost the standards of research in terms of methodology and regulations. These exchanges should be supported and implemented, so that many countries can become hubs of knowledge for the global circulation of researchers, especially in domains where possible benefits are most relevant.

85. Another way forward could be in the form of agreements entailing the obligation for developed countries to make a significant 'contribution' for every skilled worker they employ from a less developed country, possibly proportional to the cost of their training. Skilled migrants from LMICs should also have an ethical obligation to contribute to the development of their home countries, whose governments should create at the same time incentives and the enabling environment to attract such investments. The initiatives of WHO or non-profit organizations for research on prevalent diseases of poor countries represent an opportunity for researchers of poor countries to return home and these sponsors must give them priority to conduct such research projects.

IV.3. Open Access

86. Open Access has been defined as the provision of unrestricted online access to peer-reviewed scientific literature, primarily to journal articles, but increasingly also to book chapters, monographs and theses. Depending on the research field, open access may also include access to global databases of nucleotide sequences, proteomes, and structural biology.

87. Several studies have demonstrated a link between quality of health care and access to biomedical information. In the report entitled *International Policy and Practice on Open Access for Monographs* (2014), prepared for the Federation of the Humanities and Social Sciences, it was underlined that:

> For its proponents, open access benefits all. The public will have free access to information; authors and their work will have greater visibility; funders of research will obtain greater return on investment; and publishers will gain a greater distribution of their products. Governments, too, will gain by an increase in the general good.

Still, there are numerous examples of researchers, practitioners and decision-makers not being able to access full-text journal articles due to the publishers' policy of charging for granting access to them. Traditional journal subscriptions are also stretching the finances of universities and research institutions. It is important that availability and accessibility are not adversely affected by copyright issues or the cost of publishing, be it carried by the researchers or the readers.

88. The Internet and online publishing have great potential to ensure universal access to research results without compromising authors' rights. The *Bethesda Statement on Open Access Publishing* of 2003 specified how Open Access materials can be used. It says that an Open Access Publication is one that meets the following two conditions:

a. The author(s) and copyright holder(s) grant(s) to all users a free, irrevocable, worldwide, perpetual right of access to, and a license to copy, use, distribute, transmit and display the work publicly and to make and distribute derivative works, in any digital medium for any responsible purpose, subject to proper attribution of authorship, as well as the right to make small numbers of printed copies for their personal use.

b. A complete version of the work and all supplemental materials, including a copy of the permission as stated above, in a suitable standard electronic format is deposited immediately upon initial publication in at least one online repository that is supported by an academic institution, scholarly society, government agency, or other well-established organization that seeks to enable open access, unrestricted distribution, interoperability, and long-term archiving (for the biomedical sciences, PubMed Central is such a repository).

89. In Europe, the European Science Foundation (ESF) published in 2012 the Science Policy Briefing No. 47 on *Open Access in Biomedical Research*. The policy brief describes two alternative routes towards Open Access: (1) 'Green' Open Access, understood as self-archiving but preserving authors' freedom to publish where they choose; or, (2) 'Gold' Open Access through publication in Open Access journals.

90. As increased access to and sharing of knowledge leads to opportunities for equitable economic and social development, as well intercultural dialogue, Open Access is at the heart of UNESCO's goal to provide universal access to information and knowledge. The overarching goal is to foster an enabling environment for Open Access in Member States so that the benefits of research are accessible to everyone through the public Internet. UNESCO published the policy guidelines for development and provision of Open Access in 2012. The Open Access strategy was approved by the Executive Board at its 187th session and further adopted by the 36th General Conference as an up-stream policy advice to Member States.

It is always important to underline that the unprecedented opportunities of 'sharing' offered through the internet and online publishing may entail higher risk of low quality information circulating without appropriate scientific review. The 'publish or perish' approach to the evaluation of researchers' activities could trigger behaviours which are not compliant with the ethics of scientific research. The greatest attention is required to address this risk, starting obviously with the scientific community.

IV.4. Empowerment

91. The notion of empowerment epitomizes the conceptual and concrete premises of sharing as participation. It refers to increasing the economic, political, social, educational, gender, or spiritual strength of a person or a group. It is the process of obtaining these basic opportunities either directly, or through the help of non-marginalized others who share their own access to these opportunities (solidarity). Empowerment also includes encouraging and developing the skills for self-sufficiency that will allow individuals and communities to overcome obstacles in life or at work, and develop themselves and their society, by enhancing a global perspective of life.

92. The concepts of empowerment and engagement are strictly linked to one another both at the individual and the community level. These two layers of commitment were

explicitly linked as key tracks to address the issue of promoting health and development by the 7th Global Conference on Health Promotion, which was held in Nairobi in 2009. Community empowerment was defined as something "more than the involvement, participation or engagement of communities. It implies community ownership and action that explicitly aims at social and political change. Community empowerment is a process of re-negotiating power in order to gain more control".

93. Empowerment builds therefore on participation and engagement, even though it does not overlap completely with them. The idea of 'community engagement' can be integrated within the different steps of research itself and implies:

a. Sharing with local academics and the general public the possibility of a future research project in the country or community;

b. Involving those who make decisions and the general public in the discussion on benefit sharing policies. Building capacity of local RECs should also be the object of national and international regulations that take into account the benefits and risks for the development of poorer countries;

c. Facilitating local and international supervision of the fair conduct of research, with research funding agencies taking the financial responsibility of providing the promised benefits;

d. Strengthening the capacity of local collaborating institutions involved in international research, through the transfer of knowledge and technologies;

e. Making available to the general public the knowledge generated from the research once completed, whenever it is of public interest. This access might be achieved through the creation and reinforcement of platforms of free access and should be managed by organizations created for the purpose of disseminating knowledge.

94. These steps constitute necessary conditions for community engagement in research, but they are not sufficient if local research actors (researchers, RECs, participants, regulatory authorities) do not have the ability to control how research is conducted. Cultural behaviours, histories of foreign domination, lack of democratic participation, and lack of education are obstacles that need to be reversed. It is necessary to know these factors and to deal with them to achieve real empowerment. A multidisciplinary approach to research in countries where these problems are more serious will mean a real change in benefit sharing.

95. When research contributes to economic benefits, a portion of it should be allocated to countries where the projects were conducted to support medical programs, health education, and technology, and to strengthen human training resources including bioethics issues, research methodology and statistical analysis. At the same time, it is only fair to recognize the work of researchers in the production of knowledge, so as to improve their salary and conditions of work, as well as their academic and societal recognition. This is also a way to empower local researchers and to diminish brain drain.

96. Scientific knowledge should take into account all the components of life as necessary for health. Article 17 of the UDBHR states that "due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity". The *Convention on Biological Diversity* of 1992 underlined the importance of technical education and training pertaining to identification, conservation and sustainable use of biological diversity, as well as of the joint development of technologies, effective participation in biotechnological research activities, appropriate access to and transfer of relevant technologies, and fair and equitable sharing of the benefits

arising from the utilization of genetic resources. These are all essential factors of empowerment. The normative content of the Convention was reaffirmed by the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits* of 2010.

97. In this perspective, biodiversity-rich countries should negotiate with researchers and companies from wealthy nations seeking to conduct research on their biological resources. Together, they could insist that the educational, health, research, training, technology and welfare interests and needs of local communities in the host-countries are given due consideration. The global scientific community can only justify that the biological resources of cash-poor but bio-diversity rich countries are used to improve knowledge by putting the interests and needs of local communities in the host-countries first.

V. RECOMMENDATIONS

98. These recommendations are to be understood as complementary and interrelated.

99. The Report has focused on three clusters of issues that need addressing: 1) the questions that arise before, during and after carrying out the research activity, that is the conduct of research, the recruitment of and the duties towards people that take part in it; 2) the conditions in which societies may ensure access to health care, so that the benefits of research reach all those who need it in a timely and affordable manner; 3) the ways to boost a *participatory* rather than *top-down* concept of solidarity, starting with the development of research capacity.

100. The Millennium Development Goals called for a boost in “global partnership for development”, which was and remains key to pave the way to strengthen and consolidate the achievement of the other seven goals: eradicate extreme poverty and hunger; achieve universal primary education; promote gender equality and empower women; reduce child mortality; improve maternal health; combat HIV/AIDS, malaria and other diseases; ensure environmental sustainability. The principle of benefit sharing, as enshrined in Article 15 of the UDBHR, is essential to make this partnership effective and many of the challenges that the post-2015 agenda will have to address converge on it. The aim of this Report was to highlight some crucial points with the awareness that the promise of quick fix solutions is deceptive. A long term commitment, based on sound methodological assumptions and the acknowledgment of essential priorities is required.

101. The issues to address do not correspond to an ‘either…or’ situation, but rather to successive and interconnected layers of rights and responsibilities. This is why a ‘shared’ commitment for the promotion of benefit sharing is crucial. States and governments are called on to take into consideration the following recommendations and adopt appropriate legislative measures to improve research, access to health care and international solidarity accordingly. The main actors of scientific research and market economy, which are the most powerful drivers of globalization, are called on to make personal interests and legitimate profit compatible with the respect of fundamental human rights and the concept of knowledge and health as common goods of humankind. Education systems, media, protagonists of civil society both at the domestic and the international level are called on to promote the values of sharing and help change the mindset which considers it as just a matter of beneficence rather than political responsibility.

Research

102. As to the responsibilities towards those who are directly involved in research, it is necessary to reaffirm that no double standard approach can be accepted: all human beings share the same rights when they enter a research project. The scientific debate on the use of placebo in clinical research has been a critical issue for decades and required continuous updating of international guidelines. The method of scientific research is certainly worth

further reflection by the IBC and other expert bodies. However, considerations on different levels of resources actually available, cultural peculiarities, or the capacity to sustain treatments in the future should not be used as arguments to justify multiple standards of respect for human dignity.

103. Recruitment remains a challenging issue. The provision of incentives for subject participation, including through public and symbolic rewards, cannot be considered an unethical practice in itself. However, it is important to recognize that in certain contexts and conditions, incentives can become improper inducement, and as such be ethically inadmissible. This is the case, for instance, when determinants of special vulnerability impinge upon autonomy. Among other factors, the need for health care requires greater attention as a possible premise for improper inducement, besides the fact that participation in certain clinical trials can offer the possibility to have access to new – although experimental – drugs. It is also essential that possible reimbursement for harm and/or inconvenience is reasonable according to the local market values and social policies. This is to ensure that these payments do not disguise improper inducement aimed at removing obstacles posed by the patient in agreeing to participate in research, especially when subject recruitment is particularly problematic due to the nature or characteristics of the research project.

104. In order for research to generate new knowledge and reduce international and domestic inequities, this dual goal should be borne in mind from the time when a research protocol is designed, funded, reviewed and implemented in the field. RECs are the main custodians of participants' and societies' rights with regard to health research. But sometimes ethics review boards are not enough to guarantee the respect of these rights. That is why national legislation and overseeing structures are necessary, as well as clear international agreements on the rights and obligations of all research participants. Funders, sponsors, researchers and research institutions should engage potential research participants and communities in a meaningful and sustainable process, in the design and implementation of research and in the dissemination of research findings.

Health care

105. Benefit sharing understood as a means to improve access to health care poses relevant issues both at the domestic and the international level. In this perspective, Article 15 is strictly linked to Article 14 of the UDBHR, which reaffirms that the enjoyment of the highest attainable standard of health "is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition". People should always be given treatments according to their needs and not their ability to pay. At the domestic level, governments are called on to adopt and use all possible instruments (legislative and other) to comply with this principle. Public resources and public policies will remain essential to this aim. At the international level, both a stronger intergovernmental cooperation and a more widespread and effective practice of solidarity and sharing are required. Deep inequalities become unacceptable inequities when life itself is at stake.

106. Special protections and specific policies for inclusion ought to be developed with regard to the most vulnerable sections of the population: economically or culturally disadvantaged groups and individuals, but also refugees and migrant workers. No one should be discriminated against or marginalized depending on their age, gender, disability, ethnicity, race, religion, or sexual orientation.

107. The implementation of the different modalities of benefit sharing implies the participation of institutions, companies or services from more than one country. In case controversies arise and they may not be solved locally, they should not be treated as commercial or trade problems, but as ethical ones, with a focus on human rights and in an arena that is appropriate to this approach. This is especially to be considered when a conflict

arises between the intellectual property regime and the fundamental right of every human being to have access to quality health care.

Sharing as participation

108. It is essential to consider the commitment to sharing not as a sort of trickling down or top-down beneficence, even though this is not meant to loosen the most immediate bond of human solidarity every time that urgent help is necessary. Sharing should always be pursued through active participation, which is a democratic, horizontal approach entailing collaboration and empowerment of all actors in the research process, particularly communities. Many existing inequities in research capacity, access to scientific knowledge and simply access to health care still exist today. Any research effort should be geared to reducing these inequities, not to maintaining or even deepening them.

109. Capacity building is a priority for any sustainable development agenda. The first and fundamental step is obviously education. It is not only about eradicating illiteracy, but also about setting some minimal standards for scientific education, starting with primary school. Other means and strategies to overcome the obstacles that cause marginalization and exclusion include: the creation of training centres, ongoing dissemination of the programs of various institutions, the mounting of exhibitions and documentation, individual and collective training at work, ongoing assessment of the progress, and finally, evaluation and dissemination of these advances.

110. Brain circulation and open access are essential, in order to avoid the advantage of the ‘hubs’ of knowledge remaining in the hands of a privileged few.

111. The concept of sharing entails also a specific responsibility towards future generations, so that sustainable access to human biological resources may be ensured. In this perspective, it is necessary to promote and implement documents such as the *Convention on Biological Diversity* of 1992 and the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits* of 2010.

112. In the end, benefit sharing is about the awareness of belonging to one and the same community of human beings, who make use of their intelligence and abilities to confront the consequences of their finitude and fragility and improve the conditions of their life on earth. By accepting the idea of universal human rights, we acknowledge that these advancements cannot be a privilege, which would deepen the existing faults of inequality between peoples and countries. At the same time, we acknowledge that solidarity through participation and not beneficence is the bond of sharing that we need to boost. This is the only way to bring together development and respect for all.

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