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**International Bioethics
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**WORKING DOCUMENT ON
THE PRINCIPLE OF RESPECT FOR
HUMAN VULNERABILITY AND PERSONAL INTEGRITY**

The purpose of this document is to stimulate discussion at the sixteenth (ordinary) session of IBC (Mexico City, Mexico, 23-25 November 2009) on the principle of respect for human vulnerability and personal integrity (item 5 of the agenda) and to guide the future work of the Committee on this principle.

I. INTRODUCTION

At the fifteenth (ordinary) session of the International Bioethics Committee (IBC) (UNESCO, Paris, 27-28 October 2008), some members of IBC (namely Mrs Christiane Druml with the contribution of Mrs Meral Özgüc, Mrs Jeanine-Anne Stiennon, Mrs Aïssatou Touré and Mr Claude Huriet) agreed to initiate the work on the principle of respect for human vulnerability and personal integrity by drafting a preliminary document to stimulate discussion at the sixteenth session of IBC in 2009 and to guide the future work of the Committee on this principle. This preliminary document also benefited from the contribution of Prof. (Mrs) Maria do Ceu Patrão Neves particularly with regard to philosophical and historical background of the topic.

II. THE ISSUE

Article 8 of the Universal Declaration on Bioethics and Human Rights (2005) states:

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Like the entire text of the Declaration, the wording is clear. However, it gives the impression that this principle of respect for vulnerability and integrity is so evident that it goes without saying that it would be implemented, which is obviously not the case.

In order for this principle to be implemented the answers to three questions need to be given : the extent of the concept, the recognition and means of protection of individuals or groups, and the respect of personal integrity in applying and advancing scientific knowledge, medical practice and associated technologies.

I) To make reference to “human vulnerability” is to acknowledge that, because of his very existence, every human being is vulnerable. As a consequence, it would be appropriate to define certain criteria of vulnerability, such as “the impossibility – or incapacity? – to say no”. Subtle connections are thus established between consent, autonomy and finally between freedom and vulnerability.

II) “Recognition” of the principle can be complicated in its practical application. By his very existence the human being is vulnerable, living in a society influenced by the interdependence among citizens, when and under what circumstances should vulnerability be recognized? The difference between vulnerability of groups of people according to their condition – children, migrants and asylum seekers, illiterates ...) and special – individual – situations, such as illness, clearly show that “the means of protection” cannot be compared.

III) Respect of personal integrity “in the application and advancement of scientific knowledge of medical practice and its associated technologies” refers back to the necessary protection of persons against abuse they could be victim to in the name of the interests of society for example. Respect of personal integrity and the application of the principle of vulnerability must go hand in hand with the principles of solidarity, justice and equity, as illustrated by access to health care for example.

III. PROPOSED OUTLINE FOR THE REPORT OF IBC

The report of IBC on the principle of respect for human vulnerability and personal integrity could aim at listing groups of persons to whom the term “vulnerability” is applicable, consisting of a distinction of medical treatment, scientific research and public health, discussing vulnerability in various categories of persons and contexts, and providing an historical and philosophical approach with a section summarizing results and offering suggestions.

A proposed outline, together with some textual development is given below.

Proposed outline for a report on respect for human vulnerability and personal integrity

I. INTRODUCTION

Article 8 of the Universal Declaration on Bioethics and Human Rights (2005) states:

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Autonomy is a value that is essential to bioethics and its principles. Individuals behave in an autonomous way when they are capable of acting with self-determination. Medical research or medical practice cannot be conceived without considering the individual's autonomy.

But not every human being is in a state or situation to execute this self-determination. These human beings are called "vulnerable" and need to be given special protection. Society has "special responsibilities" towards them. They need to be protected from all forms of exploitation or abuse, but at the same time must not be excluded from potential benefits of research.

The principle of integrity, which is inseparably linked to the concept of vulnerability, refers to the inviolable character of the individual, to his right not to be "touched" physically or psychologically. Application of this principle demands recognition that the person is more than the summation of his/her objective parts, that in essence are indissoluble. To exclude one of the dimensions of the person and to disengage it from the others is to distort the essence of the human being.

It should be emphasized that vulnerability is not at all events absolute. While some groups of persons can always be considered vulnerable because of their status (e.g. children), others may be vulnerable simply due to a specific situation: persons can be vulnerable in a given situation, but not in another. A person who is obviously vulnerable in a common sense (a handicapped person) might not be vulnerable as a research subject and vice versa.

At the level of ethical analysis, respect for human vulnerability and personal integrity requires that we remain constantly aware of human vulnerability and take into consideration in all our actions an obligation not to take advantage of another's fragilities (negative action) and to reinforce the social and institutional safeguards against them (affirmative action).

II. GENERAL FRAMEWORK

II.1. Medical Practice

II.2. Human Experimentation and Research

Application of the principle of vulnerability with regard to human experimentation does not make autonomy secondary nor renders consent less important but demonstrates that these principles not only fail to protect individuals from every expression of vulnerability but also can be used as a demonstration of shifting responsibility by those who in this relationship detain more power.

There is a need to balance protection from abuse in research and access to new treatments for persons considered vulnerable.

An example: Phase I trial - Except for trials in oncology, where patients are included, clinical trials in phase 1 are performed on healthy volunteers. This poses several problems with regard to the recruitment of these persons. There has to be a balance between the inclusion of members of vulnerable groups while at the same time avoiding exploitation. Specific attention has to be given that only healthy autonomous adults are included. That means that any groups of vulnerable persons like the homeless, immigrants and others should not be considered as participants. Healthy volunteers are usually paid for participation according to time and not to risk. As clinical trials and in particular phase I trials are increasingly becoming a business for the industry and participation is regarded as a "job", special attention must be given.

Another issue is the general exclusion of women in Phase I trials. This leads to a first exposure to new substances in a later stage under less scrutiny. The same applies to children.

II.3. Health Care and Biomedical Research Policies – Public Health (Social Responsibility)

Vulnerability, intrinsic or inherent to every human being can be exploited in a subtle and even non-deliberate way in the realm of health and research policies.

Application of the principle of vulnerability at the level of health care and research policies requires that institutions and States are aware that biomedical progress and/or the reinforcement of the power of those called vulnerable does not always result in diminishing and/or suppressing vulnerability but on the contrary can create and /or aggravate vulnerabilities. It has to be established how healthcare resources will be allocated, and what the criteria will be for the distribution of social benefits.

III. HISTORICAL AND PHILOSOPHICAL APPROACH

III.1 The concept of 'vulnerability' in bioethics

'Vulnerability' is a notion common to everyday language. However, only recently did it acquire a moral meaning. Its relevance was first made known in the bioethical domain, particularly in the context of the ethical-legal regulation of biomedical research with human subjects. Only later, and as the concept gained relevance, did its broader and deeper meaning start to be explored, by retrieving the previous philosophical reflection on the concept. This broader meaning was later also integrated in the bioethical domain. This is, thus a course in two steps.

The 'vulnerability' concept appears in the field of biomedical research with human subjects in 1978, in the *Belmont Report: ethical principles and guidelines for the protection of human subjects of research*. It is also found later: in the 1996 revision of the *Declaration of Helsinki: ethical principles for medical research involving human subjects*; in the first UNESCO declaration on the subject of biomedicine, the *Universal Declaration on the Human Genome and Human Rights* (1997); and in the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, of the Council for International Organizations of Medical Sciences (CIOMS), especially in its third and most complete version (2002).

'Vulnerability' is then invariably introduced with an adjectival, qualifying function, as a characteristic, particular (only for some persons and groups) and relative (persons and groups classified as vulnerable when compared to others that are not), contingent (vulnerability is a situation in which persons and groups may or may not meet) and provisory (being particular, relative and contingent, expressing a fragility, it must be overcome, eliminated, which is accomplished through autonomy and informed consent, in the empowerment of people and groups), of restricted use at the level of human experimentation, extending later to the level of clinical assistance.

In 1998, the *Barcelona Declaration, Basic Ethical Principles in Bioethics and Biolaw* presented 'vulnerability' with two different meanings: the one that we have been referring to and a broader one, grounded in European philosophical thought. The notion of vulnerability gained a new, broader meaning, as a universal condition to all human beings, arising from the reflection dedicated to it by philosophers like Emmanuel Levinas and Hans Jonas. 'Vulnerability' is then presented as a noun, as a reality intrinsic to the living being, universal (for all living beings) and absolute (all living beings are vulnerable), necessary (vulnerability is a condition common to all living beings), permanent (fragility is not eliminable), which, therefore, refers to the principle of human dignity, and of broad application to the entire domain of human activity.

The present concept of 'vulnerability' contains indelibly the two meanings referred to above, in the domain of bioethics.

III.2 *The principle of 'vulnerability' in the Declaration*

The principle of "respect for human vulnerability and personal integrity" was included in the Declaration, following a proposal from the Portuguese Delegation during the second Intergovernmental Meeting of Experts aimed at finalizing a draft Declaration on Universal Norms on Bioethics, which took place in June, 2005. This principle had never appeared in any of the earlier drafts of the Declaration, nor during the first Intergovernmental Meeting.

Two main reasons were decisive for this proposal. A first one took into account the almost exhaustive character of the section on "Principles". Considering that "vulnerability" and also "integrity" had been presented as bioethical principles in 1997 in the Barcelona Declaration, and that the section on the "Principles" of the Bioethics Declaration was becoming more developed and quite exhaustive, the non consideration of these principles could be interpreted as intentional rejection.

The second and more important reason related to the high level of specification of the principle of "Consent". In fact, this principle was becoming evermore extensive and detailed during the Intergovernmental Meeting of Experts, even unfolding into two articles ("Consent" and "Persons without capacity to consent"), in a deliberate effort to contemplate every situation of vulnerability, in view of its eradication. It was, then, necessary to make clear that it is impossible to completely eradicate human vulnerability, becoming instead more urgent to address it as morally significant.

That being the case, the original purpose of the proposal of this principle was to recognize the indelible character of vulnerability, the impossibility to suppress it completely, thus stating the obligation to respect it, that is, of taking it into consideration in the various levels of the human action falling in the bioethics realm. 'Vulnerability' would then be included in its broader sense, as a noun.

The work with the delegations of the various countries during the intergovernmental meeting, in order to find a consensual formulation of this principle, revealed the existence of two different perspectives.

A first one put forward mostly by the so-called developed countries, did not recognize the meaning of 'vulnerability' as a condition and immediately assumed the term as an adjective, as a classification of persons and groups. Consequently, the need for this new principle was not recognized, for it only reiterated the principles of consent, although those countries did not oppose its inclusion. A second perspective, mostly defended by the so-called developing countries, recognized immediately the impossibility of absolute suppression of human vulnerability through those means classically implemented by bioethics, assuming vulnerability as an indelible human condition. Therefore, they welcomed the introduction of this new principle as indispensable for the respect of a person's dignity.

The search for consensus led to the inclusion of the restricted sense of 'vulnerability' along with its broader sense, so that the statement of the principle, as it was approved, reflects the articulation of these two perspectives. Thus: "in applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account" – refers to 'vulnerability' as a human condition, extensive to all human beings (corroborating the perception of the so-called developing countries); "individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected" – refers to it as attribute of some persons, restricting only to these the obligation of respect for "personal integrity" (reiterating the interpretation of the so-called developed countries).

III.3 'Vulnerability' in UNESCO

UNESCO's legal instruments, in the sequence in which they are presented, reflect the very evolution of the meaning of the concept of 'vulnerability' in the social and ethical context. Thus, considering the totality of its Conventions and Declarations, we see that the term first appears occasionally and in its everyday conceptualization in the *Convention for the Protection of Cultural Property in the Event of Armed Conflict with Regulations for the Execution of the Convention*, 1954, (mentioning vulnerable points, such as, for example, an aerodrome, broadcasting station), and in the *Convention on the Protection of the Underwater Cultural Heritage*, de 2001 (mentioning vulnerability of the underwater cultural heritage and the surrounding natural environment). What can be negatively affected is 'vulnerable' - that is, in such a way as to threaten the stability and permanence of reality as it is.

The concept only acquires an ethical meaning in the *Declaration of Principles on Tolerance* (1995) - (the expression "vulnerable groups" appears three times, demanding "particular attention" to these groups), in the *Universal Declaration on the Human Genome and Human Rights* (1997) (articles 17 and 24 refer to 'vulnerability' of individuals, families and population groups, demanding respect and solidarity towards them), in the *International Declaration on Human Genetic Data* (2003) (points out the "vulnerabilities" of developing countries, demanding international cooperation). 'Vulnerability' is always used as an adjective reporting to the human, classifying individuals and groups identified as variously and particularly exposed to be negatively affected. Vulnerability demands protection and, in this sense, it is no longer confined to the descriptive domain, as in the first moment, but spreads out also to the prescriptive domain, in which it gains moral meaning.

The third moment in the development of the meaning of 'vulnerability' comes with the *Universal Declaration on Bioethics and Human Rights* (2005) where, as was said and justified, vulnerability is introduced with a double meaning: that of a characteristic and that of a condition. They are also today's established references for 'vulnerability' not only for its intelligibility but also for the practice it demands. Relying remotely on Habermas, we would say that vulnerability thus understood constitutes the universal foundation of ethics: it is because man is vulnerable that morality exists, as a way of "compensating" and answering by protecting, taking care of that vulnerability. Vulnerability constitutes, then, the ultimate cause or foundation of morality.

IV. VULNERABILITIES IN VARIOUS CATEGORIES OF PERSONS REQUIRING SPECIAL PROTECTION

IV.1. Children

IV.2. Women

Women of childbearing potential should not be excluded automatically from biomedical research. The potential for a woman to become pregnant during a study should not be used as a reason for excluding women in general or limiting their participation. Many research projects still exclude women from participation resulting in the fact that there is not enough information about the safety and efficacy of new therapies or medications in regard to women. This situation leads to a potential deprivation of medication and therapies for all women and thus excludes them from the benefits of research. Furthermore it is opposed to their right of self determination.

Women of childbearing potential have to be informed about the hazards and risks to themselves and to a foetus in case they become pregnant during research participation. Pregnancy tests should be provided by the sponsors of the clinical trial. Measures to be undertaken in order to avoid a pregnancy (contraceptive methods) have to be discussed before inclusion if a research project is started. If access to contraceptive methods is not given, investigators should not include women who might become pregnant in projects with foreseeable risks to a potential foetus.

In some parts of the world women are especially vulnerable, due to their social conditioning and to an eventual additional lack of education. In such areas particular caution has to be given to provide the necessary information in a language understandable for the women as well as to the adequate care to the informed consent procedure for research inclusion.

Pregnant Women: There are conditions and diseases which affect only pregnant women (e.g. Malaria in pregnancy, eclampsia, gestational diabetes mellitus) and can thus be studied only in a given population in order to obtain better knowledge and to develop therapies. Measures have to be taken to include pregnant women in biomedical research, under the requirement that this research is relevant for the population of pregnant women. Investigators and ethical review committees should ensure that women who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancies and to the foetus. Special consideration has to be given to a woman's position in societies where cultural beliefs attribute more importance to the foetus than to the woman's life or health in order to prevent illicit influence for them to participate in research.

IV.3 Handicapped Persons

IV.4 Elderly and Very Old Persons

IV.5 Mentally Ill Persons

IV.6 Temporarily Incapacitated Persons (Emergency Situation and Intensive Care)

Critically ill patients are usually unable to give informed consent, as they are either unable to decide due to myocardial infarction, sepsis or stroke for instance, unconscious or in a state of heavy sedation. There needs to be a differentiation between patients who are incapacitated for a long time and patients who are temporarily incapacitated. One of the prerequisites of clinical research is the informed consent of the patient. If patients cannot decide for themselves due to physical incapacity, consent of the legal representative is necessary. Normally, patients who are temporarily incapacitated do not have a legal representative.

It is necessary to find an ethically acceptable possibility for not depriving such persons from participating in potentially beneficial research. Patients do need protection from unethical and illegal research procedures, but it has to be emphasized that they also need to be protected from the deprivation of potentially beneficial treatments.

IV.7 Immigrants

IV.8 Asylum Seekers

IV.9 Nomads

IV.10 Ethnic and Racial Minorities

IV.11 Unemployed Persons

IV.12 Homeless Persons

IV.13 Prisoners

IV.14 Illiterate Persons

V. VULNERABILITIES IN VARIOUS CONTEXTS

V.1. Persons in Hierarchical Situations

As stated above, some groups of persons can always be considered as vulnerable due to their status (e.g. children), others are vulnerable only due to a specific situation: persons can be vulnerable in a given situation, but not in another situation. They might consent to be included in a research project because they expect a reward for their participation or fear a retaliatory response from the persons above them in the hierarchy if they refuse. The solution is not to exclude them absolutely from any research projects, but to find ways where their autonomy is preserved. This could be done through the inclusion in the information and informed consent procedure of other persons who are not involved in the research project, or through a neutral way of recruitment, for example a poster as advertisement instead of a personal approach.

V.1.1 Students

Students are especially vulnerable persons in regard to the hierarchical position in which they stand towards their teacher(s). A student might consent to participate in a proposed research project led by a superior because he/she might expect a reward by participating or fear harm by not participating. On the other hand the same student would not be considered a vulnerable person in the same project when it is led by somebody with whom he/she has no relation, somebody from outside the institution.

V.1.2 Employees

The same applies to employees (e.g. employees of the pharmaceutical industry, employees of a hospital etc.)

V.1.3 Members of the Armed Forces

V.1.4 Members of the Police

VI. RESULTS AND SUGGESTIONS

VII. FURTHER READING

IV. CONCLUSION

The present document is intended to provide IBC with background information on the principle of respect of human vulnerability and personal integrity and to present a possible outline for the future report of IBC on this topic. It is up to IBC at its sixteenth session to freely discuss the proposal and agree upon a definite outline of the future report.