

NUFFIELD COUNCIL ON BIOETHICS

Commentary on the document *Elaboration of the Declaration on Universal Norms in Bioethics: Third Outline of a Text* proposal for a Declaration on Universal Norms on Bioethics by the International Bioethics Committee of UNESCO

The Nuffield Council on Bioethics is grateful to the International Bioethics Committee (IBC) of UNESCO for the opportunity to contribute further to the deliberations towards a ***Declaration on Universal Norms on Bioethics***.

We offer below our observations in relation to the document ***Elaboration of the Declaration on Universal Norms in Bioethics: Third outline of a Text***¹ (henceforth: *Declaration*). We are aware that our contribution exceeds two to three pages, as specified by the IBC Secretariat. However, in view of the complex issues raised by the most recent version of the *Declaration* we found it necessary to comment in rather more detail. We hope that the IBC's drafting group will find our response useful.

1. General comments

The current draft *Declaration* covers a wide range of issues and has the potential to be a useful reference document for policy makers seeking to devise guidance and regulation in the area of bioethics. However several questions with regard to relation the structure and content of the draft *Declaration* require further clarification. Our principal concern relates to the possible option of addressing 'specific issues' in the *Declaration*, and we would advise against doing so. We also note that several important issues remain unclear in the current draft, especially (a) the relationship between the different Fundamental Principles; (b) the relationship between the norms of the Declaration and the law in individual states; (c) the relation of the concept of 'human being' to the concept of the 'human person'; (d) the relationship between human beings and animals; and (e) the characterisation and role of the concept of 'informed consent.' More detail on these points is provided below.

2. Comments relating to specific sections of the Outline Declaration

Page 1, paragraph 3, line 4 and 5 (and paragraph 4):

As pointed out in our previous submissions, it would be helpful to clarify the way in which the provisions of the *Declaration* relate to the Council of Europe's ***Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine***; and the 'other international and regional instruments',

¹ http://portal.unesco.org/shs/admin/file_download.php/Outline_en.pdf?URL_ID=5343&filename=10884079807Outline_en.pdf&filetype=application%2Fpdf&filesize=107040&name=Outline_en.pdf&location=user-S/

which presumably refers to documents such as the WMA's *Declaration of Helsinki*. Is the relationship thought to be complementary? Is it intended that the *Declaration* provides an overarching framework? Answers to these questions would be useful to avoid conflicts which are likely to arise if the provisions of the *Declaration* contradict the provisions of other guidelines. We note that similar comments appear to have been made at the Fifth Meeting of the IBC Drafting Group and we welcome the decision by the Group 'to make explicit reference to certain texts drawn up by non-governmental organizations that have acquired a place of primary importance in the field of bioethics within the scientific community'.²

Page 2, paragraph 7, line 2:

'...the special needs of developing countries...' It would be more appropriate to refer to the needs of *people* in developing countries, rather than to the needs of *developing countries*. Furthermore, while there is no question that people in developing countries have 'special needs', it may also be useful to acknowledge that living in challenging environments has contributed to the emergence of *special capacities* of people in developing countries. Acknowledging these capacities by rephrasing thus '...taking into account the special needs and capacities of people in developing countries..' appears to be relevant to the discussion of 'Sharing of benefits' under *Article 13*. Technology transfer addressed under point (v) *ibid.* should be sensitive to strategies developed by people in developing countries to deal with, for example, malnutrition or ill health.

Page 3, Article 2 – Aims, paragraph 4

'...ethical principles that respect human dignity and protect human rights...' We note that *moral agents* are capable of respecting human dignity and respecting human rights, but 'ethical principles' are not capable of acting in such, or any other way, and the Article should be redrafted accordingly.

Page 3, Article 3, Human Dignity, Human Rights and Justice, line 2

'...inherent dignity of the human person,...' It is noteworthy that the Article does not consider the inherent dignity of all human *beings*, but of the human *person*. *Article 1 – Scope*, by contrast, states that the *Declaration* is intended to '...apply to human *beings*,...[emphasis added]'. It would be helpful to clarify the relationship between the (scientific) concept of the human being and the (metaphysical, cultural or legal) concept of the human person. This point is particularly important because the application of the concept of human dignity to early developmental stages of human beings is not straightforward. We also observe that the *Universal Declaration of Human Rights*, referred to in recital 2 on page 1 of the *Declaration* states that 'All human beings are *born* free and equal in dignity and rights' (emphasis added).

² Final Report of the Fifth Meeting of the IBC Drafting Group for the Elaboration of a Declaration on Universal Norms on Bioethics, UNESCO Headquarters (Paris), 27-28 October 2004, paragraph 9, see: http://portal.unesco.org/shs/en/file_download.php/8_be80fc111574e6f99db5edae9796626Rap_Gred5_en.pdf ,

Page 3, Article 3, Human Dignity, Human Rights and Justice, line 2

'...the universal principle of justice...' It would be useful to clarify which concept of justice is being referred to: distributive? procedural? Is the intention behind this Article to state that human dignity, human rights and fundamental freedoms *encapsulate* the principle of justice? If so, it would be useful to rephrase the text accordingly.

It would also be helpful to clarify the relationship between the 'universal principles' (referred to here in '...the universal principle of justice...') and the Fundamental or General Principles, which are set out in Articles 3-7: Are some Fundamental or General Principles universal, whereas others are not? It is not clear why the category of 'universal' principles is introduced here (see also the two title-options for the *Declaration*, and Article 5).

Page 3, Article 5, Respect for Cultural Diversity and Pluralism, line 4

'...cultural diversity shall not be invoked to infringe upon the universal principles set out in this *Declaration*...' In this Article it appears that the term 'universal principles' is synonymous with the terms 'General' or 'Fundamental Principles' (Articles 3-7). If so, and if the term 'universal principles' is to be retained, in order to avoid a possible circularity, 'other' should probably be added between 'the' and 'universal', since cultural diversity itself is introduced as a universal principle.

Furthermore, the qualification of this particular principle raises the question of the hierarchical relationship between the various principles, since it appears that 'cultural diversity' is of a lower rank than the other principles. This ranking appears to be in contrast with the outcome of the discussion of the IBC Drafting Group at the Fourth meeting.³ If qualifications concerning the standing of particular Fundamental Principles are introduced it would seem consistent to clarify the ranking of other principles too. In particular it would be relevant to clarify the relationship between Articles 3, 4 and 8. Article 8 does not really seem to be a derived principle, in the sense that it would be a more concrete and particular articulation of a fundamental principle. Rather, it appears to establish priority of Article 3 over Article 4, in those cases where Article 4 could be used to argue for a maximisation of benefits to society at the expense of individual persons. However, if this is the function of Article 8 it appears to be either a Fundamental Principle itself, or, otherwise it could be used as a basis to illuminate the question of the hierarchical order of the fundamental principles. It does not appear that Article 28 (*Interpretation*) offers much help in this respect.

³ See paragraph 7 of the Final Report of Fourth meeting of the IBC Drafting Group for the Elaboration of a Declaration on Universal Norms on Bioethics, UNESCO Headquarters (Paris), 25 -27 August 2004, 'Thus, fundamental principles are the basic principles that cannot be justified by any other principle and that belong to jus cogens, i.e. non-derogable principles. Then come the derived principles that can only be justified by one or more fundamental principles, without implying any hierarchy of these principles'.
http://portal.unesco.org/shs/en/file_download.php/1dd7fc3d3a648b00ea4105fd94bc521aRap_Gred4_en_fin.doc

Page 4 Article 8 Primacy of the Human Person

In this Article, 'primacy of the human person' appears to be introduced with the intention of prohibiting utilitarian 'sacrifices' of individuals. We realise that in theological discussions *primacy* is sometimes used in this way. However, commonly, the use of humans as a *mere* means to an end is viewed as morally unacceptable by reference to the (Kantian) philosophical concept of *autonomy*. The concept of primacy, by contrast, appears to be invoked more often when discussing the moral status of human beings and animals. It would be helpful to clarify both concepts, particularly since Article 10 (Autonomy and Responsibility) would benefit from clearer drafting.

If it is intended to address the primacy of human beings over other forms of life, it is not straightforward to see how this form of primacy can be derived from the Fundamental Principles in Articles 3-7. However, given that the *Declaration* sets out principles which acknowledge that 'human beings have responsibilities and duties towards other forms of life in the biosphere' (*Article 1 – Scope*), it would appear helpful to offer some guidance on the relationship between humans and animals and their relative status. This in turn would suggest that a Fundamental Principle on the matter would be required.

Page 4 Article 11 Informed Consent

'(a) The prior, free, informed and express consent of the persons concerned shall be obtained in all medical or scientific research, treatment or diagnosis. Such consent may be withdrawn at any time.'

It would be desirable if important developments which have arisen from the considerable discussion about the concept of 'informed consent' could be reflected in the *Declaration*. We make three observations concerning: (a) the question of whether informed consent is pragmatically feasible and a sufficient criterion for involving participants in research; (b) the special case of consenting to the use of tissue or data for research purposes; (c) the question of whether consent is necessary for *all* medical or scientific research, treatment or diagnosis.

First, while the provision of information in obtaining consent is important, it should be noted that the ethically significant requirement of consent is not that it be complete, but rather that it be genuine, as, for example, the Council has described in several of its Reports.⁴ Consent can be given to some course of action such as an operation, donation, participation in medical or scientific research, only as described in a specific way. Since description can never be fully exhaustive, consent will always be to action that is incompletely described. Moreover, the descriptions offered are often incompletely understood. This incompleteness cannot be remedied by devising more elaborate consent forms, and fully informed consent is usually an unobtainable ideal.

⁴ See *Human Tissue: Ethical and Legal Issues* (1995); *The Ethics of Research Related to Healthcare in Developing Countries* (2002); and *Pharmacogenetics: Ethical Issues* (2003)

Ensuring that consent is genuine is mainly a matter of care in detecting and eliminating lack of consent. Obtaining genuine consent requires researchers and medical practitioners to do their best to communicate accurately as much as patients, volunteers or relatives can understand about procedures and risks, and to react to the limits of their understanding, and of their capacities to deal with difficult information. This is of particular relevance with regard to research undertaken in developing countries. If all reasonable care is exercised, adequate and genuine consent may be established, although it will necessarily fall short of fully informed consent. Rather than simply reiterating the unobtainable ideal of 'informed consent' the *Declaration* should therefore acknowledge the shortcomings of the concept and highlight the importance of the *process* of obtaining consent.

Secondly, the current drafting of Article 11 is ambiguous in relation to what research participants are required to consent *to*. Is it only their immediate participation in 'medical or scientific research, treatment or diagnosis', or also the use of tissue removed from them during such practices, or the use of patient-related medical data? If the latter two categories are intended to be covered, Article 11 could be interpreted as stating that *each* use of a set of data, or tissue removed from a patient, requires individual consent from that patient. This would be a problematic provision.

It is sometimes desirable to use the samples taken for specific purposes for other types of research at a later stage. Obtaining renewed consent can be difficult, especially if large numbers of people are involved, or if there is some time between the taking of the initial sample and the interest in its renewed use for research. In response to this problem, the concepts of 'broad' and 'narrow' consent have been developed. The latter refers to instances where a sample is only to be used for one single, or a restricted range of purposes, perhaps only for a specific research project, or for research in relation to one particular medicine or condition. Broad consent entails that patients agree that their sample may be used for a variety of future studies which cannot be specified in detail at the time of obtaining consent. Usually, but not always, these future studies will be within the same broad areas of research as the initial project. In order to avoid future misunderstandings, it would be useful to state in Article 11 whether or not broad consent is acceptable.

It would also be useful to clarify the implications of the sentence: 'Such consent may be withdrawn at any time.' Presumably, the assumption underlying this phrase is that once consent has been withdrawn, the person concerned ceases to take part in medical or scientific research, treatment or diagnosis, and also that samples or data obtained during such activities must no longer be used. However, as recognised in *UNESCO's International Declaration on Human Genetic Data (Art 9 (a) (b))*, it will sometimes only be possible to offer a limited range of options for withdrawal of consent to the use of tissue or personal medical data. It would be useful if the *Declaration* acknowledged this point.

Thirdly, there has also been discussion about whether consent is necessary for all types of research. In the UK, the Human Tissue Act (2004) provides that the secondary use of anonymised tissue samples will not require (legal) consent, provided other safeguards are put in place to ensure that the interests of participants in research are protected. Such provisions are of particular importance for the purpose of monitoring public health. The consequences of requiring consent for *all* purposes therefore need to be considered carefully in Article 11. (With regard to public health it would also be helpful to clarify whether 'research' includes activities such as surveillance or monitoring of public health.)

In view of these observations we therefore suggest the following re-wording of Article 11 (a):

"Prior, free, and genuine consent shall be obtained from those participating in medical or scientific research, treatment or diagnosis. Separate consent may be required for the use of tissue or data obtained from persons during such practices. With regard to consent for the use of tissue or medical data, in some cases 'narrow consent' may be appropriate (limiting the consent to one single purpose, or a small range of purposes). In other cases 'broad consent' may be appropriate (extending the consent to the use of tissue or medical data in future studies, the particulars of which may not be possible to specify in detail at the time of obtaining consent). For consent to be genuine, it is crucial that care is taken in detecting and eliminating lack of consent. Consent may be withdrawn at any time, and the options and consequences of withdrawing consent for the use of data or tissue samples from research shall be explained in the consent process.'

Page 5 Procedural Principles

The status of these principles is not clear. Are the procedural principles envisaged as a separate set of Fundamental Principles, differing only in that they relate to procedural issues? Alternatively, are they supposed to be derivable from the Fundamental Principles in the same way as the principles listed under Articles 8-13?

Page 7, Specific Issues

In previous draft versions of the *Declaration*, this section included a relatively comprehensive list of specific issues to which the principles set out in the draft *Declaration* could be applied. The present draft does not include any of these issues, which makes it somewhat difficult to comment on whether or not it would be useful to include specific issues in the *Declaration*. This omission raises a number of questions: should the *Declaration* address *any* specific issues? If so, which issues should be selected, and how should these be addressed? We make some general observations in relation to some possible scenarios:

- a) the *Declaration* does not address any specific issues; the section will be deleted;
- b) the *Declaration* does not address any specific issues, but a general provision is included to the effect that specific issues will be addressed in separate Annexes to the *Declaration*, or in separate Declarations altogether;
- c) the *Declaration* does not address any specific issues, but a general provision is included to the effect that specific issues will be addressed in separate Annexes to the *Declaration*, and these issues are listed in the *Declaration*;
- d) the *Declaration* addresses a few particularly important issues (for example research involving human participants, organ donation, and others), and a qualification is made that contentious areas of research or development which are not included (for example stem cell research, nanotechnology, and others) are therefore neither acceptable, nor unacceptable under the *Declaration*;
- e) the *Declaration* addresses an exhaustive list of specific issues.

Option (a)

According to this option, the primary function of the *Declaration* would be to provide a useful high-level framework which would set out aspirational ideals. Policy makers could use the framework as a reference point for the formulation of national and international legislation. By not addressing specific issues, confusion about whether or not the *Declaration* should be transposed directly into national law would be avoided (see the discussion about the status of the ***Declaration of Helsinki*** in the Council's first submission). On a more pragmatic level, and in view of the IBC's tight timetable, this option would allow for discussion of open questions about the general structure and content of other sections of the *Declaration*, raised, for example, in this submission. Focussing on a high-level framework would also be valuable for achieving consensus among UNESCO member states and other stakeholders, while being sensitive to cultural differences.

Option (b)

This modified version of option (a) would allow the IBC to address more specific issues in light of the provisions of the general *Declaration* at a later stage, and with sufficient time. However, different drafting committees of the various Annexes could interpret the provisions of the general *Declaration* differently, which might lead to inconsistency. An alternative option might be for the IBC to consider a range of specific issues in separate Declarations, in parallel to the already published documents ***The Universal Declaration on the Human Genome and Human Rights*** and the ***International Declaration on Human Genetic Data***.

Option (c)

This scenario would have the advantage of offering transparency with regard to the type of Annexes which are planned. In listing those areas to be addressed it might also be possible to state which of the Fundamental, Derived, Procedural or other principles are important in which areas. However such a list is likely to be repetitive. Furthermore, it is not straightforward to establish a finite list of specific issues which will be addressed in the Annexes, as new technologies continually arise, and pose new ethical challenges.

Option (d)

In this scenario, the difficulty of distinguishing those areas which merit discussion under the *Declaration* is acknowledged. Only a few particularly important areas are therefore addressed within the *Declaration*, leaving open the possibility of considering further areas in Annexes or separate Declarations. In selecting those specific issues which could be addressed in the *Declaration*, it would seem useful to take into account UNESCO's international role, and to focus on issues with global dimensions, such as research involving human participants, organ transplantation, or access to healthcare. Issues mainly of relevance to developed countries, such as stem cell research or nanotechnology, could be given a lower priority. However, even if such a restriction were thought to be useful, it would seem necessary to clarify the relationship between the provisions of the *Declaration* and those of already established guidance, for example the *Declaration of Helsinki*, or the CIOMS Guidelines. This option is therefore likely to pose considerable conceptual and pragmatic difficulties. It is questionable whether it would be possible for the IBC to pursue this option within the envisaged timeframe, as appears to have also been acknowledged during discussion of the *Declaration* at the 170th session of the Executive Board.⁵

Option (e)

While, in principle, this option would allow for a coherent discussion of a range of different specific issues in light of the provisions of the *Declaration*, time constraints alone suggest that this is not feasible. Furthermore it is questionable how desirable a 'complete' *Declaration* is, if new emerging technologies continue to pose new ethical problems.

In view of these observations we recommend that options (a) or (b) be pursued. In our opinion, from both a conceptual and a pragmatic point of view, these options are superior to the others, and any derived options.

⁵ Final Report of the Fifth Meeting of the IBC Drafting Group for the Elaboration of a Declaration on Universal Norms on Bioethics, UNESCO Headquarters (Paris), 27-28 October 2004, paragraph 14, see: http://portal.unesco.org/shs/en/file_down_load.php/8be80fc111574e6f99db5edae9796626Rap_Gred5_en.pdf

Page 8 Article 29

'...no restrictions shall be placed on the principles set out in this Declaration other than those prescribed by law...' It would be important to clarify exactly which principles may be restricted by law. Presumably it is not intended to allow for the possibility that the Fundamental Principles can be restricted by law? If so, does the possible restriction only relate to the derived principles, and/or the procedural principles?

Additionally, in reviewing the wording of Article 29 we would also recommend that account be taken of the nuanced provisions in Article 8(2), 9(2), 10(2), and 11(2) of the ***European Convention for the Protection of Human Rights and Fundamental Freedoms***, which concern the degree to which the law may restrict rights in specific areas.