

Commentary on the document *Elaboration of the Declaration on Universal Norms in Bioethics: Fourth 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: Fourth outline of a Text*¹ (henceforth: *Declaration*). We hope that the IBC's drafting group will find our response useful.

1. General comments

The revised draft *Declaration* is significantly improved. In particular we welcome especially the decision not to include 'specific issues', and to abandon the structure of fundamental, derived and procedural principles. We also welcome the stronger emphasis given to the need for capacity building in ethical expertise. We present below our comments on a few outstanding issues: (a) the relation of the concept of 'human being' to the concept of the 'human person' (b) the characterisation and role of the concept of 'informed consent' (c) the role of public debate.

2. Comments relating to specific sections of the Outline Declaration

Page 1, paragraph 2

'...the unique capacity of human beings...' Some of the attributes ascribed here exclusively to humans are applicable to animals, for example, 'to avoid danger' and 'to seek cooperation'. This should be revised.

Page 1 paragraph 2, Page 2 paragraph 3 and 7, Article 2 (b), and Article 6 (a)

The *Declaration* is inconsistent in its use of the terms 'human being' and 'human person'. It is noteworthy that *Article 6 (a)* does not consider the

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/

inherent dignity of all human *beings*, but of the human *person*. *Article 2 (b) – 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 (see comments on *Article 10* below). 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).

Page 1 paragraph 6, Page 2 paragraph 2

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’, 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.²

Page 5, Article 9, Respect for Cultural Diversity and Pluralism, line 4

‘[...cultural diversity] shall not be invoked to infringe upon the principles set out in this Declaration...’ In order to avoid a possible circularity, ‘other’ should probably be added between ‘the’ and ‘principles’, since cultural diversity itself is introduced as a 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

² 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’, see: 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

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. It does not appear that Article 4 (*Interrelation and Complementarity*) offers much help in this respect.

Page 5 Article 10, Non-Discrimination and Non-Stigmatization

'In any decision or practice, no one shall be subjected to discrimination...' The reference of 'no one' is unclear. Does the term refer to all human *beings*? Alternatively, is it intended to refer to all human *persons*? As we observed above (see page 1), clarity about the distinction between biological and metaphysical concepts is crucial, both intellectually, as well as pragmatically. For example, as currently drafted, *Article 10* would mean that the practice of PGD and termination of pregnancy following PND would not be permissible under the *Declaration*, if the reference for 'no one' is 'no human being'. If it is the intention of the drafting committee to describe such practices as instances of unjustified discrimination and stigmatisation it should state so explicitly. If not, the Article should be revised, for example by replacing 'no one' with 'no born human beings'. Alternatively, the term 'human persons' could be used, provided its meaning is explained, for example in *Article 1 - Use of Terms*.

Page 5 Article 12, Informed Consent

'(a) Any decision or practice in the field of scientific research shall not be made or carried out without the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn at any time.'

It would be desirable if important developments which have arisen from the extensive discussion about the concept of 'informed consent' could be reflected in the *Declaration*, and we reproduce below three observations on the equivalent section in the third draft of the *Declaration*, 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

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

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.

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 12 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 12 (a) and (b) 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

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)

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 12 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 12. (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 replacement for the current Articles 12 (a) and (b):

"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.'

Article 25, Ensuring Public Debate

'States should ensure that citizens have an opportunity for informed, pluralistic public debate...' While we welcome the emphasis on the need for public debate we also note that arranging it successfully is not always straightforward. For example, in the UK, there has been some criticism to this effect about the Governments *GM Nation?* Debate, which was organised in 2003. There are also a number different approaches to be considered, from large public meetings to consensus conferences and citizens juries. We cannot comment here on the suitability of these formats to enhance public debate about bioethical issues, but make some general observations.

First, it is important to create an environment in which all positions are heard *fairly* and in which all participants are treated with the same respect. Secondly, it needs to be clear what the outcome of any public meeting or debate will be. For example, it might need to be clarified at the outset whether the purpose is restricted to stimulating exchange of views, or whether it is undertaken with the aim of increasing ways of participating in decision making processes. Failure to consider the appropriate approach and outcome of any such exercise can possibly lead to more, rather than less polarisation on bioethical issues, as well as to increasing scepticism in public engagement exercises and trust in democratic processes.