Parliamentary Assembly
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Draft additional Protocol to the Convention on Human Rights and Biomedicine, on biomedical research

Parliamentary Assembly

1. The draft additional protocol to the Convention on Human Rights and Biomedicine on biomedical research is the third in the series of additional protocols to the convention, after those on the Prohibition of Cloning Human Beings (1997) and on Transplantation of Organs and Tissues of Human Origin (2001). The Parliamentary Assembly welcomes this further enrichment of the convention.

2. Freedom of research is necessary for the progress of knowledge. It is part of freedom of thought and freedom of expression, and should therefore be recognised as a human right.

3. The development of knowledge in the field of biomedicine, with a view to saving lives, treating disease and improving quality of life, depends on research, including research on human beings.

4. Such research, however, has both cultural and ethical implications. It must respect the dignity and identity of human beings and guarantee to those who participate in it respect for their integrity and all their other rights and fundamental freedoms.

5. The aim of the draft additional protocol to the Convention on Human Rights and Biomedicine is to increase the effectiveness of the protection of human dignity. It does so without imposing unnecessary barriers to the freedom of research.

6. While understanding the difficulty of agreeing a text which states general principles without entering into details of legislation, the Assembly wishes to draw attention to the fact that a number of points are left open to the interpretation of the member states, which are future parties to the protocol.

7. The Assembly welcomes the separation between the approval of research on the basis of scientific merit (Articles 7 and 8) and the review of its ethical acceptability (Articles 9 to 12). However, the definition of "ethical acceptability" (Articles 7, 9.1, 9.2 and 11.1) remains unclear and vague.

8. While the draft protocol focuses in Chapter III on the independence of the ethics committee (Article 10), it does not specify in any way its multidisciplinary composition (Article 9.2). Yet multidisciplinarity is both a fundamental element of an ethics committee and a strong feature which reinforces the committee's independence.

9. The Assembly also insists on the protection of persons not able to consent, and in particular persons in emergency clinical situations (Article 19.2.ii and sub-paragraph xiii in the appendix to the draft protocol) and therefore recalls Article 6.1 stating that "research shall not involve risks and burdens to the human being disproportionate to its potential benefits".

10. Article 27 (duty of care) states that "if research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them". Yet the question arises as to who will assess the "relevance" of such information. Any given information or data may

1. Assembly debate on 30 April 2004 (16th Sitting) (see Doc. 10121, report of the Committee on Culture, Science and Education, rapporteur: Ms Westerlund Panke; and Doc. 10126, opinion of the Social, Health and Family Affairs Committee, rapporteur: Mr Evin). Text adopted by the Assembly on 30 April 2004 (16th Sitting).

only become relevant in the light of new scientific discoveries, while before it may not have been considered relevant. An example of this would be advances in the diagnosis of genetic diseases. The Assembly believes that this issue merits further debate.

11. The Assembly welcomes Article 29 which clearly resolves the problem of research initiated in countries with strict jurisdiction but completed in other states with less stringent rules. The provision of this article requires member states, parties to the protocol, to ensure that the same ethical criteria be respected for the part of the research undertaken outside their jurisdiction.

12. The Assembly is in favour of the draft protocol and in consequence recommends that the Committee of Ministers open it for signature as soon as possible. It urges all states signatories and parties to the Convention on Human Rights and Biomedicine to sign it on the day of its opening.

13. The Assembly regrets that twenty-eight out of the forty-five member states of the Council of Europe have not yet ratified or acceded to the Bioethics Convention and urges them to do so as soon as possible. In addition, it would encourage Observer states also to adhere to the principles of the convention and its additional protocols.