



Opinion 184 (1995)¹

Draft bioethics convention (draft convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine)

Parliamentary Assembly

1. The Assembly has undertaken a considerable amount of work since 1976 with regard to the bioethical aspects of human biotechnology and biomedicine.
2. This work, based on principles designed to protect human dignity and the corresponding fundamental human rights relating to human biology and medicine, led to Recommendations 1100 (1989) and 1160 (1991) which contained proposals for the preparation of a comprehensive European bioethics convention intended as a legal instrument open to non-member states.
3. [Resolution No. 3](#) of the 17th Conference of European Ministers of Justice (1990), recommended that the Committee of Ministers instruct the CAHBI (now the CDBI, the Steering Committee on Bioethics) to examine the possibility of preparing a framework convention and, if so decided, to draft it.
4. The Assembly considers that [Recommendation 1160](#) proposes a convention of a general nature and a series of protocols on specific subjects that can be extended to other subjects if this is considered to be advisable and necessary in the future. This convention should allow codification of existing but fragmented work and fill a legal vacuum. The Assembly is aware that the incorporation of certain principles into the European Convention on Human Rights, which affords better protection, albeit limited to the member states, should be borne in mind for the future.
5. The Assembly has closely followed the various stages in the drafting of the texts of the convention and of the protocols within the CDBI, in which the Parliamentary Assembly has been represented since 1990, and its contributions and suggestions have been largely taken into account and incorporated into the texts.
6. There has been excellent co-operation between the Parliamentary Assembly and the CDBI and the latter has carefully considered the work carried out by the Parliamentary Assembly over the last twenty years, which largely inspired the text of the draft convention.
7. The Assembly notes the fact that the Committee on Science and Technology, the Social, Health and Family Affairs Committee, and the Committee on Legal Affairs and Human Rights have been kept permanently informed by their representative in the CDBI during these years of drafting the convention.
8. The Assembly therefore recommends that the Committee of Ministers review thoroughly the text of the draft bioethics convention as transmitted to the Assembly and set out in [Doc. 7124](#), and amend it as indicated below before opening it for signature:
 - 8.1. At the end of Article 1, add the following new sentence: "They shall introduce the substantial provisions of this convention into their national legislation."

1. Assembly debate on 2 February 1995 (6th Sitting) (see [Doc. 7210](#), report of the Committee on Science and Technology, rapporteur: Mr Palacios; and [Doc. 7223](#), opinion of the Committee on Legal Affairs and Human Rights, rapporteur: Mr Schwimmer). Text adopted by the Assembly on 2 February 1995 (6th Sitting).



8.2. In Article 4, add a new paragraph to read as follows: "Services offered to the public involving the use of the biomedical services and techniques shall be subject, in the interest of the protection of the persons concerned, to control of their quality."

8.3. Amend Article 5, paragraph 1, to read as follows: "No intervention may be carried out in the health field without the informed, free, express and specific consent of the person undergoing it."

8.4. Replace Article 6 by the following text: "Interventions may be carried out on persons who have no legal capacity of giving consent and those who, though legally capable of giving consent, have a reduced capacity of understanding, only for their direct benefit and with the consent of their legal representative or an authority or an individual authorised or designated under his national law. A legally incapacitated person may not undergo medical research unless it is expected to produce a direct and significant benefit to his health. Any refusal by the incapacitated person must always be respected. At national level a body (an independent multidisciplinary ethical committee) should be set up to oversee any intervention involving mentally handicapped persons. For the purposes of this convention, "incapacitated persons" means:

persons who have a reduced capacity of understanding;

persons whose capacity to possess rights and to be bound by obligations is limited, either for reasons of age or because of mental illness;

persons having a de facto incapacity".

8.5. In Article 7, at the end of paragraph 2, add the following words: "and also the free and informed consent of the parent(s) or legal guardian(s) is necessary".

8.6. In Article 7, at the end of paragraph 3, add the following words: "and no intervention may be undertaken without their consent."

8.7. In Article 13 the words: "only if this is done in conformity with appropriate information and consent procedures" are to be clarified.

8.8. Delete the first paragraph of Article 15.

8.9. In Article 15, paragraph 2, delete the word "solely".

8.10. Replace Article 16 with the following text: "An intervention on the human genome may only be undertaken for preventive, therapeutic or diagnostic purposes without any intervention in the human germ cell line."

8.11. At the end of Article 18, add the following words: "and in accordance with the national legislation about data protection."

8.12. In Article 20, delete "according to the conditions and procedure prescribed by law".

8.13. In Article 26, paragraph 2 (and elsewhere), replace "European Community" by "European Union"

8.14. In Chapter V, add a new article worded as follows: "For the purpose of observing the application of the convention on the territory of the Contracting Parties and of interpreting the text of the convention, a monitoring body in connection with the European Court of Human Rights is hereby set up".

8.15. In Article 28, paragraph 1, delete "and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers".

8.16. In Article 30, at the end of the first paragraph, add: "No reservations may be made in respect of Articles 15 and 16."

9. The Assembly also recommends that the Committee of Ministers:

9.1. transmit the final revised text for a definitive opinion to the Parliamentary Assembly except in the event of the Committee of Ministers accepting the changes proposed by the Assembly;

9.2. invite member states and non-member states (according to the procedure provided for in Articles 27 and 28 of the draft convention) to sign and ratify the reviewed and amended convention and to implement it as soon as possible;

- 9.3. invite the CDBI to continue with the preparation of the four draft protocols concerning medical research, organ transplantation, protection of the human embryo and foetus, as well as genetics, in the light of the opinion of the Parliamentary Assembly;
- 9.4. transmit for opinion to the Parliamentary Assembly each draft protocol as soon as it is finalised.