Recommendation 1100 (1989)[1]

Use of human embryos and foetuses in scientific research

Parliamentary Assembly

The Assembly

1. Considering that science and technology, and especially the biomedical sciences and biotechnology, continue to advance and develop as an expression of human creativity, and that their freedom of action cannot be restricted arbitrarily, but only on the basis of, inter alia, professional, legal, ethical, cultural and social principles for the protection of human rights and the dignity of man as an individual and social being ;

2. Noting the contents of the Council of Europe's Parliamentary Assembly Recommendation 934 (1982) and its proposals for the application of genetic engineering on the basis of respect for the genetic heritage of mankind, which shall not be interfered with in individuals save for clearly and scientifically demonstrated preventive or therapeutic purposes ;

3. Noting the desirability of implementing the various parts of the Council of Europe's Parliamentary Assembly Recommendation 1046 (1986) on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, in particular paragraphs 2, 3, 4.A and 4.B, as well as the necessity of ensuring : i. that the human embryo and foetus are treated in conditions appropriate to human dignity, and ii. that products and tissues therefrom may be used solely under strict regulation for limited scientific, diagnostic and therapeutic purposes as defined in Recommendation 1046 which cannot be attained by other methods, and having regard to the diversity of ethical views on this matter ;

4. Referring to paragraph 15 of Recommendation 1046, which instructed the competent committees of the Assembly to prepare a report on the use of human embryos and foetuses in scientific research, takinginto account the necessary balance between theprinciples of freedom of research and of respect for human life and other aspects of human rights ;

5. Considering that it is customary, in the interests of progress, harmony, liberty and social justice, constantly to adapt legislation and regulations to the ethical and social values of human communities, and to scientific and technological knowledge as and when it is acquired ;

6. Considering that it is appropriate to determine the legal protection to be given to the human embryo from the time that the human egg is fertilised, as foreseen in Recommendation 1046 ;

7. Considering that the human embryo, though displaying successive phases in its development which are designated by different terms (zygote, morula, blastula, pre-implantation embryo or pre-embryo, embryo, foetus), displays also a progressive differentiation as an organism and none the less maintains a continuous biological and genetic identity ;

8. Recalling the need for European co-operation and for the widest possible regulation in order to overcome the contradictions, risks and foreseeable shortcomings of exclusively national standards in these fields,

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1. Assembly debate on 2 February 1989 (24th Sitting) (see Doc. 5943, report of the Committee on Science and Technology, Rapporteur : Mr Palacios ; Doc. 5989, opinion of the Social, Health and Family Affairs Committee, Rapporteur : Mrs Hubinek ; andDoc. 5996, report of the Legal Affairs Committee, Rapporteur : Mr Elmquist). Text adopted by the Assembly on 2 February 1989 (24th Sitting).

9. Recommends that the Committee of Ministers :

a. Provide a framework of principles from which national laws or regulations can be developed in as universal and uniform a manner as possible, as proposed by its Recommendations 934 (1982) and 1046 (1986) as well as by this recommendation and its appendix ;

b. Invite the governments of member states :

1. to set up as a matter of urgency the national or regional multidisciplinary bodies mentioned in the above Recommendations 934 (1982) and 1046 (1986), also entrusting them with the task of informing society and the public authorities of scientific and technological advances in embryology and biological investigation and experimentation, of guiding and monitoring the potential applications thereof, evaluating results, benefits and drawbacks, notably in general terms, that is including also the dimension of human rights, human dignity and other ethical values, and authorising, provided there are appropriate regulations or delegations of authority, specific projects of scientific investigation or experimentation in these fields ;

2. to take steps to guarantee that society is informed simply, accurately and sufficiently of activities involving techniques of assisted fertilisation and related techniques, and more specifically of fertilisation in vitro and the use of human gametes, embryosor foetuses for scientific investigation or other purposes ;

3. to establish the requisite national mechanisms for improving knowledge of the epidemiology and incidence of human sterility and genetic or hereditary diseases with a view to their prevention and/or cure ;

4. to promote investigations aimed at :

a. improving technical procedures of assisted fertilisation, strictly as and where permitted ;

b. deepening knowledge of the human cell and of its structures and its functions, and in particular of reproductive cells, of embryological development, of reproduction and heredity ;

c. diagnostic (in particular pre-natal) and/or therapeutic purposes, especially for diseases linked to chromosomes or genes ;

d. industrial and pharmacological purposes, so as to produce medically useful substances in sufficient quantities without either the biological disadvantages or risks of infection or immunological reactions caused by the substances usually used ;

5. to regulate the operations and to draw upnational or regional registers of accredited and authorised centres where research or experiments are undertaken on reproductive material - be it human gametes, embryos or foetuses, or cells, tissues or organs - and to monitor and evaluate such activities, and to require that the biomedical and scientific teams at such centres are properly qualified and authorised to perform such activities and have the necessary resources ;

6. to examine these recommendations in the light of the considerations contained in the appendix to this recommendation, and to provide for the sanctions which failure to comply therewith could entail ;

c. Pursue the study and compilation of all knowledge related to human reproduction and biomedicine, and provide for joint action by all Council of Europe member states, together with non-member states, so that, in addition to purely national action, they contribute to the framing of a common legal instrument, such as a European convention on biomedicine and human biotechnology, which would be open to non-member states also — as already proposed in Recommendations 934 (1982) and 1046 (1986) ;

d. Establish as a matter of urgency, as a safeguard, an international multidisciplinary body to ensure convergent approaches by the national bodies already operating or to be set up in accordance with sub-paragraph 9.B.i. above, and to avoid thereby the creation of ‘‘genetic havens".

Appendix APPENDIX - Scientific research and/or experimentation on human gametes,embryos and foetuses and donation of such human material

A. On gametes

1. Gametes may be used independently for purposes of basic or experimental investigation, subject to the provisions of the following paragraphs ;

2. Investigations shall be permitted :

on fertility, sterility and contraception ;

on phenomena of histocompatibility or immunity related to procreation ;

on the process of gametogenesis and embryonic development, for the prevention or treatment of genetic diseases ;

3. The human gametes employed for investigation or experimentation shall not be used to create zygotes or embryos in vitro for the purpose of procreation.

B. On live pre-implantation embryos

4. In accordance with Recommendations 934 (1982) and 1046 (1986), investigations of viable embryos in vitro shall only be permitted :

for applied purposes of a diagnostic nature or for preventive or therapeutic purposes ;

if their non-pathological genetic heritage is not interfered with.

5. In accordance with paragraph 14.A.iv, eleventh sub-paragraph, of Recommendation 1046, research on living embryos must be prohibited, particularly :

if the embryo is viable ;

if it is possible to use an animal model ;

if not foreseen within the framework of projects duly presented to and authorised by the appropriate public health or scientific authority or, by delegation, to and by the relevant national multidisciplinary committee ;

if not within the time-limits laid down by the authorities mentioned above.

6. Moreover, any proposed investigation which meets the above conditions for authorisation must be excluded :

unless it is accompanied by all the required details on the embryonic material to be used, its source, foreseen time-limits of implementation and the aims pursued ;

unless, on completion of the investigation, those responsible agree to inform the authorising body of its outcome.

7. Embryos at the pre-implantation stage which have been expelled spontaneously from the uterus shall in no circumstances be retransferred back

C. On dead pre-implantation embryos

8. Investigation of and experimentation on dead embryos for scientific, diagnostic, therapeutic or other purposes shall be permitted subject to prior authorisation.

D. On post-implantation embryos or live foetuses in utero

9. The removal of cells, tissues or embryonic or foetal organs, or of the placenta or the membranes, if live, for investigations other than of a diagnostic character and for preventive or therapeutic purposes shall be prohibited.

10. The pregnant woman and her husband or partner must be provided beforehand with as full information as necessary i. on the technical operations to be performed for the removal of cells, and/or embryonic or foetal tissues, or for the removal of the membranes, the placenta and/or the amniotic fluid, ii. on the intended purposes, and iii. on the risks involved.

11. Persons removing embryos or foetuses or parts thereof from the uterus without clinical or legal justification or without the prior consent of the pregnant woman and, where appropriate, of her husband or partner in a stable relationship, and persons using such embryological materials in breach of the relevant legislation or regulations shall be duly penalised.

E. On post-implantation embryos or live foetuses outside the uterus

12. Foetuses shed prematurely and spontaneously and considered to be biologically viable may be the subject of clinical operations solely in order to promote their development and autonomous existence.

13. The performance of any operation on or the removal of cells, tissues or organs from embryos or foetuses outside the uterus shall be subject to, among other things, the parents' prior written consent.

14. Experiments on living embryos or foetuses, whether viable or not, shall be prohibited. None the less, where a state authorises certain experiments on non-viable foetuses or embryos only, these experiments may be undertaken in accordance with the terms of this recommendation and subject to prior authorisation from the health or scientific authorities or, where applicable, the national multidisciplinary body.

F. On dead embryos or foetuses

15. Before proceeding to any intervention on dead embryos or foetuses, centres and clinics shall ascertain whether death is partial (when the embryo is clinically dead, its cells, tissues or organs may still remain alive for several hours) or total (when clinical death is matched by death of the cells).

16. The use of biological matter from dead embryos or foetuses for scientific, preventive, diagnostic, therapeutic, pharmaceutical, clinical or surgical purposes shall be permitted within the framework of the rules governing investigation, experimentation, diagnosis and therapy, in accordance with the terms of this recommendation.

G. Applications of scientific research to the human being in the fields of health and heredity

17. Genetic technology shall only be used for investigations on or with human or recombinant genetic material if appropriate authorisation has been obtained. Such authorisation shall be granted on the basis of the soundness of projects, full details being provided as regards their location, aims, duration and the biological material to be used ; it shall be granted by the competent authorities or, by delegation, by the national multidisciplinary body.

18. Scientific research projects on genetic engineering using genetic or recombinant genetic material shall be permitted, subject to approval :

for diagnostic purposes, as in the case of prenatal diagnosis in vitro or in utero of genetic or hereditary diseases, in order to study the biological materials obtained with a view to the treatment where possible of specific diseases or the prevention of their transmission, provided that the techniques used do not harm the embryo or the mother ;

for industrial purposes of a preventive, diagnostic or therapeutic nature, such as the pharmaceutical manufacture (by molecular or gene cloning) of substances or products for health or clinical purposes in suitable quantities, when they cannot be produced by any other method, natural or otherwise, such as hormones, blood proteins which control the immune responses, antiviral, antibacterial or anti-carcinogenic agents, or the manufacture of vaccines without any extra risk of a biological, immunological or infectious nature ;

for therapeutic purposes, in particular for the selection of sex in the case of diseases linked to the sex chromosomes (particularly the X female chromosome), with a view to preventing transmission ; also for the creation by surgical means of beneficial gene mosaics, by transplanting genetically and biologically healthy cells, tissues or organs from other persons to replace the diseased, damaged or defective counterparts in the person being treated. In this connection, the approval of the use of healthy recombinant DNA to replace pathological DNA causing a specific disease shall depend on the degree of scientific and technical safety which, in the opinion of the scientific and public authorities, can be achieved in the human being with the type of molecular recombination envisaged. Any form of therapy on the human germinal line shall be forbidden ;

for purposes of scientific investigation, for studying DNA sequences in the human genome - their location, functions, dynamics, interrelationships and pathology ; for studying recombinant DNA within human cells (as well as in the cells of simpler organisms such as viruses and bacteria) with a view to

obtaining a better understanding of the mechanisms of molecular recombination, of expression of the genetic message, of the development of cells and their components and their functional organisation ; forstudying the ageing processes of cells, tissues and organs ; and, more particularly, for studying the general or specific mechanisms governing the development of diseases ;

for any other purpose considered useful and beneficial to the individual and to humanity, and incorporated in projects already approved.

19. Investigations or acts involving genetic technology shall only be authorised at centres and establishments which have been registered, approved and authorised for such purposes, and which have the requisite specialised personnel and technical resources.

H. Donation of human embryological material

20. The donation of human embryological material shall be authorised solely for scientific research on diagnostic, prevention or therapeutic purposes. Its sale shall be prohibited.

21. The intentional creation and/or keeping alive of embryos or foetuses whether in vitro or in utero for any scientific research purpose, for instance to obtain genetic material, cells, tissues or organs therefrom, shall be prohibited.

22. The donation and use of human embryological material shall be conditional on the freely given written consent of the donor parents.

23. The donation of organs shall be devoid of any commercial aspect. The purchase or sale of embryos or foetuses or parts thereof by their donor parents or other parties, and their importation or exportation, shall also be prohibited.

24. The donation and use of human embryological material for the manufacture of dangerous and exterminatory biological weapons shall be forbidden.

25. For the whole of this recommendation, ‘‘viable'' embryos shall be understood to mean embryos which are free of biological characteristics likely to prevent their development ; however, the non-viability of human embryos and foetuses shall be determined solely by objective biological criteria based on the embryo's intrinsic defects.