United Nations Educational, Scientific and Cultural Organization
Organisation des Nations Unies pour l'éducation, la science et la culture

International Bioethics Committee (IBC)

Comité international de bioéthique (CIB)

Distribution: limited

BIO-7/00/GT-1/2 (Rev. 3)
Paris, 6 April 2001
Original: English

The Use of Embryonic Stem Cells In Therapeutic Research

REPORT OF THE IBC ON THE ETHICAL ASPECTS OF HUMAN EMBRYONIC STEM CELL RESEARCH

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This Report was discussed at the Seventh Session of the International Bioethics Committee (Quito, Ecuador, 7-9 November 2000) and finalized after the meeting of the Extended Working Group on the Ethical Aspects of Embryonic Stem Cell Research (UNESCO Headquarters, 29 January and 2 February 2001).

Division of Human Sciences, Philosophy
and the Ethics of Sciences and Technology

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I. The Issue

1. There is at present a considerable body of researchers who wish to engage in research on a type of human cell known as the stem cell. This research, they argue, will bring great benefits in that it might lead to the development of transplantable tissues as therapies for a wide range of human illnesses, which are currently considered difficult or impossible to treat. However, the stem cells in which they are particularly interested are derived from the human embryo, and this gives rise to the question: is it ethically acceptable to derive cells from a human embryo prior to its implantation *in utero* in order to cultivate and investigate these cells in the laboratory for therapeutic research? This is the issue which a Working Group of the International Bioethics Committee of UNESCO (IBC) considered at a meeting at UNESCO Headquarters in Paris in April 2000. Later the same year, the IBC debated the matter at its Seventh Session (Quito, Ecuador, 7-9 November 2000). At this Session, the exchange of views underlined the diversity of opinion which surrounds this question. It was decided that any report which the IBC might adopt on this matter should reflect this pluralism. This report, therefore, recognises that there are very marked differences of opinion relating to embryo research. It aims to highlight the various ethical arguments with a view to facilitating the resolution, at national and international level, of a controversial matter. It recognises that the solutions adopted by national ethical committees or national legislatures may well be different. Such differences are inevitable in a pluralistic world where people may sometimes adopt ethical positions which are unacceptable to others.

II. The Scientific Background

2. Stem cells are cells which have the ability to develop into more than one form of human tissue. They may be *totipotent* (such as the early embryo cells, able to develop into all the different types of cells needed for a complete and functioning organism), *pluripotent* (such as embryonic stem cell lines, able to give rise to most types of tissue but not capable of bringing a functioning organism into existence) or *multipotent* (being able to give rise to a limited number of tissue types). These latter stem cells are still present in the adult human body, but their potential to develop is less than those of pluripotent embryonic stem cells, which form the focus of the discussion in this report. Examples of adult stem cells are certain bone marrow cells that give rise to all blood lineages but can turn also into liver cells or cardiac muscle cells. Neural stem cells give rise to neurones and glial cells but can turn also into heart, lung or liver cells. However, for preparation of tissues for transplantation, adult stem cells do not offer of such wide potential to researchers as embryonic stem cells and the ethical issues they may raise are not the same. This report shall therefore concentrate on embryonic stem cells.

3. Embryonic stem cells may be derived from the embryo at the preimplantation stage of its development. The extraction procedure will end the ability of that particular embryo to develop through implantation in the uterus. The removal of the cells, then, brings the existence of the embryo to an end. The embryo-derived cells are not in themselves an embryo - they cannot develop into a human being; they are therefore just like any other human tissue.

4. The embryonic stem cells can be kept alive in an artificial medium and will proliferate more or less indefinitely. It is suggested that in the future it will be possible to facilitate the development of these cells into specific tissue types, thus affording the possibility of growing "spare cells or tissue" which can then be injected or transplanted into recipients. It is possible that, at some future stage, this tissue will be used to construct part of or even entire organs for grafting into human hosts whose organs are destroyed or impaired. Such products will have been derived in the first place from embryos, hence the ethical question: is it acceptable to use embryonic stem cell research for therapeutic purposes?

III. Possible Applications of Embryonic Stem Cell Research

5. Many scientists take the view that the benefits which might flow to humanity from this form of research are so great that it is important that it be allowed to proceed.

6. As far as transplant rejection is concerned, this risk could be avoided by preparing the stem cells from "embryos" created by nuclear transfer (transfer of a nucleus from the patient's own cells). In this process, sometimes called "therapeutic cloning", there is a reprogramming of the donor cell nucleus in the recipient egg, yielding again totipotent embryo cells. The tissues derived from such stem cells would then be autologous to the recipient and not subject to immune rejection.

7. The benefits from embryonic stem cell technologies may also entail some risks, which will have to be carefully weighed. One risk may be uncontrolled proliferation of the transplanted cells and another may be transmission of infectious agents, but the latter risk would be smaller with embryo stem cells than with adult stem cells.

8. Embryo stem cell research could indeed lead to substantial progress in the treatment of various conditions, a few of which are indicated below only for purposes of example.

Nervous System Diseases

9. Many of the conditions which afflict the human nervous system cannot currently be treated or, if treatment is available, can only be treated with difficulty and with disappointing results. The use of embryonic stem cells may significantly change our ability to combat diseases such as Parkinson's, Alzheimer's, Multiple Sclerosis and other neurodegenerative diseases. Laboratory grown tissues derived from embryonic stem cell lines could be used to replace the nervous tissue cells which are lost or damaged in such diseases. It would be possible to transplant neurones that insert themselves in the brain or spinal cord or produce various neurotransmitters that are missing. It would also be possible to transplant glial cells that produce the myelin coating around the nerves. Preliminary work of this nature in animal models has yielded encouraging results. In the clinic, treatment of Parkinson's patients by transplantation of foetal brain cells has been practised on a limited scale but the embryonic stem cell technology could allow many more patients to benefit from neurone transplantation.

Heart Infarction

10. The heart muscle cells that are destroyed when infarction prevents the blood flowing through coronary arteries could be replaced by "patches" of cardiac smooth muscle cells produced by *in vitro* differentiation of embryonic stem cell lines.

Bone and Cartilage Diseases

11. Conditions such as osteoarthritis, which involve damage to cartilage, might be corrected by the insertion of cells, which repair the damaged section. Missing bone, resulting from trauma or surgery, might be replaced by newly-generated bone cells.

Cancer and Immune Diseases

12. Blood and immune cell transplantations are part of cancer treatment allowing more intensive use of cytotoxic anticancer drugs. Bone marrow or cord blood employed today for such transplantations could be more efficiently replaced by injections of hematopoietic stem cells derived from embryonic stem cells with defined immunogenetic potential or autologous to the patients. Repair to the immune system by this method would also be highly beneficial in the treatment of immunodeficiencies such as AIDS, or auto-immune diseases such as Lupus or Multiple Sclerosis.

Diabetes

13. The implantation of insulin-producing cells from pancreatic islets has already met with limited success. Xenotransplantation provides some prospects here, but there are major issues of public safety which restrict this option. The cultivation of beta islet cells, derived from embryonic stem cells, could provide a useful solution to the current shortage of transplantable tissue and rejection problems.

IV. Some Existing Provisions

14. At the international level, there are few regulatory provisions concerning research on human embryos. Many texts proclaim the right to life in general, e.g. the Universal Declaration of Human Rights of 1948 (Art. 3), the International Covenant on Civil and Political Rights of 1966 (Art. 1) or the African Charter on Human and Peoples' Rights of 1981 (Art. 4). Others more specifically proclaim the right to life of the conceived child, e.g. the American Convention on Human Rights of 1969, which stipulates that "every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception" (Art. 4)[(1)].

15. At the European level, 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 of 1997 does not resolve the matter of the permissibility of embryo research and leaves each country responsibility for legislating on this matter, while stipulating two conditions: the prohibition of producing human embryos for

1. Twenty-six countries have ratified the American Convention: Argentina, Barbados, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominica (Commonwealth), Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Suriname, Trinidad and Tobago, United States of America, Uruguay and Venezuela.

research purposes and the adoption of rules designed to assure adequate protection for the embryo[(2)]. An Additional Protocol to the Convention on the Prohibition of Cloning Human Beings was approved in 1998 and took effect on 3 January 2001 in five Member States[(3)].

16. The Charter of Fundamental Rights of the European Union, adopted in Nice, France, in December 2000, expressly prohibits eugenic practices and reproductive cloning, but does not comment explicitly on embryo research. In a Resolution of 7 September 2000, the European Parliament stated its opposition to the creation of supernumerary embryos and to therapeutic cloning. More recently, the European Group on Ethics in Science and New Technologies to the European Commission (EGE) adopted Opinion No. 15 of 14 November 2000 on the ethical aspects of human stem cell research and use, in which it states that "stem cell research based on alternative sources (spare embryos, foetal tissues and adult stem cells) requires a specific Community budget", while pointing out that "it is up to each Member State to forbid or authorise embryo research". On the other hand, the Group considers "ethically unacceptable" the creation of embryos with donated gametes for the purpose of deriving stem cells, and "premature" the creation of embryos by somatic nuclear transfer.

17. At the national level, research on human embryos is permitted in some countries (with varying degrees of supervision), while it is expressly prohibited in others. The second category includes Ireland, where Article 40, par. 3, of the Constitution implicitly prohibits research on the embryo by stating the right to life of the "unborn child" equal to that of the mother. In Germany, the Law of 13 December 1990 on Embryo Protection regards as an offence the fertilization of an ovum for purposes other than its reimplantation in the donor; it takes the same position on the fertilization of a larger number of ova than can be implanted. The situation is similar in Austria, where Law No. 275 of 1992 authorises the creation of embryos only for reproductive purposes. In Hungary (Law No. LXXIX of 1992) and Poland (Law of 7 January 1993 as amended on 30 August 1996), the life of the unborn child must be respected and protected from its conception. In Norway, the Law N.°56 of 5 August 1994 prohibits research on embryos and bans their use for any purpose other than reimplantation in the donor. In Tunisia, the National Medical Ethics Committee has stated its opposition to all experimentation on the embryo which is regarded as a "potential person" (Opinion No.1 of 12 December 1996) and also to any form of cloning (Opinion No. 3 of 22 May 1997). In Switzerland, the Constitution (1999) prohibits the use of medically assisted reproduction for research purposes and the fertilization of more ova than are capable of being immediately implanted (Art. 119, 2c). In Italy, the bill on medically assisted reproduction specifically prohibits the creation of embryos for research purposes and the early splitting of the embryo for therapeutic or research purposes. The Italian National Committee on Bioethics has opposed reproductive cloning, but was unable to reach a consensus on matters relating to the use of supernumerary embryos and on therapeutic cloning (Opinion of 27 October 2000).

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2. Six countries have ratified the European Convention: Denmark, Greece, San Marino, Slovakia, Slovenia and Spain.

3. Georgia, Greece, Slovakia, Slovenia and Spain.

18. As far as Latin America is concerned, in Brazil Law No. 8974/95 on genetic engineering prohibits the production, storage and manipulation of human embryos with a view to their use as biological material. Peru specifically prohibits the fertilization of human ova for purposes other than reproduction, and human cloning (Law No. 26.842). The right to life from the moment of conception is recognised in Peru by the Children and Adolescent Code (Law No. 27.337), in Costa Rica by Law No. 7739 of 1998 and in Ecuador by Article 49, par. 1, of the Constitution (1998).

19. In a number of other countries, the use for research purposes of embryos donated by persons following a treatment against sterility and not intended for implantation (supernumerary embryos) is permitted. In general, the conditions imposed are the prohibition of research after the 14th day of existence of the embryo and the consent of the couple who supplies the embryo. That is the case, for example, in Canada, Sweden (Law No. 115) and Finland (Law No. 488/1999). In Spain (Law No. 35/1988), research on supernumerary embryos is permitted under rigorous restrictions, but their creation for this specific purpose is prohibited. In September 2000, the Observatory of Law and Bioethics of Barcelona did, however, express its support for the creation of embryos for research purposes, both by donation and by cloning techniques. In Australia, the law varies between different States and Territories and, in some, the subject is not regulated by law. For such cases, the Australian National Health and Medical Council has formulated guidelines (The Ethical Guidelines on Assisted Reproductive Technology, par. 6) which, although not legally binding, are influential.

20. Finally, other countries are envisaging authorization of the creation of embryos for research purposes. In the United Kingdom, since 1990 the Human Fertilisation and Embryology Act authorises the use of supernumerary embryos for restricted research purposes - in particular concerning reproductive medicine and for the diagnosis of genetic and chromosomal disorders - and the production of embryos for these purposes. On 22 January 2001, the House of Lords passed a law (already approved in December 2000 by the House of Commons), which permits the cloning of human embryos to derive stem cells, thus allowing the possibility of therapeutic cloning. In France, Law No. 94-654 of 1994, which prohibits embryo research, is currently under review. In accordance with the opinions delivered by the National Ethics Consultative Committee[4] and the Conseil d'Etat[5], the draft bill permits the production for research purposes of stem cell lines from supernumerary embryos and therapeutic cloning. In November 2000, Japan adopted a law prohibiting reproductive cloning and prescribing the adoption of guidelines, which should permit the use of stem cells derived from supernumerary embryos. In the Netherlands, a bill is currently being prepared, which prohibits the production of embryos for research purposes, with many exceptions. However, the bill authorises research into stem cells obtained from supernumerary embryos. In Belgium, similar bills are being debated in the Senate.

21. In the United States of America, although the Federal financing of such activities is prohibited, the authorization of research on the embryo is left to the discretion of each State. To this date, nine States prohibit such research. However, in a

4. CCNE Opinion No. 53 of 11 March 1997.

5. Report to the Council of State, November 1999 «Les lois de bioéthique: cinq ans après » (The laws on bioethics: five years on).

number of States, there is effectively no control over private research of this sort. In 1999, the National Bioethics Advisory Commission recommended that Federal regulations should permit research into embryonic stem cells obtained from supernumerary embryos. However, it remains opposed to therapeutic cloning and to the deliberate production of embryos for the purpose of obtaining stem cells. In August 2000, the National Institutes of Health issued guidelines on the circumstances in which Federally supported scientists might engage in such research. One of the conditions to be met is that no such scientist might destroy an embryo to derive cells: this will have to be done by privately-funded scientists, who will then pass the cells on to their publicly-funded colleagues.

V. Philosophical and Religious Views

22. The debates about bioethics occur in a context of philosophical and religious reflection about the nature of human life, from its commencement to its conclusion, and the respect due to human life as such. Modern international human rights principles, beginning with the Universal Declaration of Human Rights of 1948, attach fundamental significance to the human being and respect for his or her dignity as such. Such principles themselves reflect longstanding debates amongst philosophers and scholars of every cultural tradition in the world.

23. Amongst modern philosophers, there is an active debate about the philosophical foundation for research into, and use of, embryonic cells precisely because of the potential of the human embryo to develop into a human being with the unique and special qualities inherent in that status. Such debates are not confined to a religious and spiritual context. Philosophers of no religious opinion, and humanists approaching the issues in a wholly secular way, have expressed the need for the development of principles to guide the ethical permissibility of embryonic stem cell research and use.

24. The opinions expressed by some major religions have indeed contributed greatly to these debates. Because bioethics concerns itself with fundamental issues of human life, these opinions play an important role in the issue. This has been very much apparent in the discussion of embryo research in general, where it is clear that there are fundamental disagreements as to the extent to which embryo research is compatible with religious beliefs as to the sanctity of human life.

25. On the basis of religious beliefs, there is a broad range of positions on the status of the embryo and on the permissibility of using the embryo for any form of research (including stem cell therapeutic research). Pending an ideal systematic consultation of each and every culture and religion on this issue, suffice it to indicate that some of these consider permissible the use of embryos for therapeutic purposes, or for the purposes of research, while others do not accept the use of embryos for such purposes.

26. The theological basis of these positions itself varies, and it must also be borne in mind that these religious traditions also have a range of views within them. In general, though, it is possible to identify a position which represents an area of broad agreement within that tradition.

27. For example, in the case of Islam, the use of embryos for therapeutic or research purposes may be acceptable provided that it takes place before the point at which the embryo is ensouled, i.e from the 40th day after fertilization.

28. Some branches of Christian thought (in the Protestant tradition) regard full human status as something which is acquired gradually, and which might therefore not be present in the early embryo. Protestant theology, however, is very diverse, and it is more difficult to find a single source of authority on this issue to which reference might be made. It is, in fact, part of the Protestant ethos that moral questions are determined by the individual conscience, and there is therefore room for a variety of stances on this point. Protestant thought, therefore, may accept that this is an issue on which Christians may have very differing views, with these differing views being compatible with Christian beliefs.

29. In Judaism, the Biblical and Talmudic law holds that the full status of a human being is not present at the moment of fertilization, but is acquired after a period of post-implantation development. An important feature of Jewish thinking in this area is that embryos outside the womb, in analogy to gametes, have no legal status unless parental intent gives them life potential by implantation and pregnancy. An embryo made for IVF treatment and maintained *in vitro* without potential for implantation could therefore be donated and used for therapeutic research. This would be in line with the life-saving duty, which is a strong one in Judaism.

30. The most strongly argued opposition to the use of embryos for therapeutic or research purposes is to be found within the Roman Catholic tradition. In the Catholic view, a human being comes into existence at the time of fertilization, and the embryo is therefore considered as a human individual having the right to its own life[(6)]. An individual embryo should therefore be given the opportunity to develop into a mature human being. It is an implication of this position that it is necessary to strictly control the fertilization of ova *in vitro*, and it is impermissible to use supernumerary embryos for therapeutic purposes. This is because the life of that embryo is sacred and it cannot be ended by any human agency.

31. This brief statement of some of the major religious positions on the use of embryos reveals a stark contrast between religious notions of the status of the embryo. If the question is defined as the embryo moral status, the various religious traditions are prone to take opposite positions. If it is defined in a broader perspective, then there may be room for some agreement.

VI. Ethical Arguments: The Status of the Human Embryo

32. The ethical legitimacy of performing human embryonic stem cell research depends, in large measure, on the status which is attributed to the embryo. Although there are other considerations having a bearing on the ethical question - such as the consent of the "owners" or creators of the embryo (the parents) -, the categorising of the embryo is crucial to the question of what can be done with it. Much of the ethical debate in this area has been taken up with the question of just what the embryo is. If

6. The IBC was provided by the Holy See with a note dated 2 August 2000 on embryonic stem cells and the status of the embryo.

the embryo is a human being (or person), then our treatment of it is limited to that which we are allowed to do to other human beings. If, by contrast, it is no more than a collection of human cells, then there are far fewer restraints on our handling of it. Mid-way views on the embryo allow for varying degrees of restraint on its use.

33. It is clear that the human embryo has a unique status in biological terms. Unlike any other cluster of living cells, it has the capacity to develop into a functioning complex organism that will be substantially differentiated from the entity it once was. This difference may be described as the embryo's potential - the potential to become a fully-developed human being. That is, of course, only a biological fact, but it is a biological fact in the face of which we stand in moral awe. In so far as our ethical notions depend upon the valuing of human life, then the human embryo demands respect as the source of the human life to which we attach such significance. But how far should this respect go? Much in nature is respected, but is still used by humankind for its benefit. The real issue is whether the embryo can be brought within full membership of the moral community to which we exclusively admit human persons and human persons alone. If the embryo can be admitted to this community, then it becomes ethically impermissible to use it as a means to an end, and not as an end in itself. More problematic is potential for membership of this community. In one view, the fact that the embryo has the potential to become a human being gives it a particular status, which should protect it from destruction.

34. Arguments about whether the human embryo can be considered a person have been prolonged and marked by a failure to reach agreement. In one view, personhood begins with the fertilisation of the ovum by the sperm; from that moment on, the admittedly primitive organism has an identity which will link it continuously to the infant, to the child, and later to the adult human being it will become. To end the life of the embryo, then, amounts to an ending of the future life of the infant and, indeed, of the child and the adult. Personhood in this view is an ethically significant quality, which human beings have at every stage of their lives, beginning with the embryo and surviving until death brings it to an end.

35. This view of personhood has been challenged by those moral philosophers who see personhood as being dependent on an ability to experience those features of life which lend to life its value and meaning. From the biological point of view, personal individuality can be attributed to the embryo only after the day in its early development when division into normal twins is not possible any more (up to 13 days after-fertilization). Embryos are therefore entitled to respect, but would not enjoy the personhood.

36. A major subject of debate is that of the potentiality of the embryo. The human embryo has the potential to become a person even if it is not yet a person. For this reason, the defenders of a protected embryo status argue that it is wrong to do to the embryo anything that will prevent it from fulfilling this potential. Opponents of this view argue in turn that the potential to become a thing does not give one that status which goes with having become that thing. Ova and sperm are components of the zygote, which later becomes an embryo and then a fetus, but that does not mean that they can enjoy the status appropriate to a zygote or a fetus until that stage of development has been reached. We do not accord fetal status to sperm; why, then, accord human being status to an embryo? Moreover, an embryo resulting from *in vitro*

fertilization, but which will not be implanted in a uterus, has no potential to develop into a human being. The same applies to "embryos" made by nuclear transfer, which should not be implanted for the purposes of human reproductive cloning.

VII. The Direction of the Debate

37. Any perusal of the debate which has been ongoing over the past few decades about the status of the embryo will reveal that this is an area in which strong convictions have been pitted against one another, and that consensus has usually eluded those who enter the debate from opposing starting points. In these circumstances, one might ask whether it is possible for a body such as the IBC to pronounce on the subject, or whether one might simply conclude that the use of embryos for research purposes is a matter of private conviction. From such a perspective, it might be argued that at a national level, each society should determine what appears to be an acceptable national position and regulate the matter accordingly. This might involve the choosing of that position - facilitative or otherwise - which reflects the majority view, or it might involve a compromise between prohibition and permission, perhaps allowing for embryo research in exceptional circumstances and under very strict control. An alternative is to have no laws on the subject at all and indeed no official ethical position. This would mean that embryo research is left a matter of individual conscience, with the organs of society taking no position on the matter. This last option does not appear at present to attract a great deal of support: there is a widespread view that this area of research needs at least some degree of regulation, and this view is reflected in the increasing tendency for national legislative and governmental bodies and national ethics committees to take a position on human embryo research. In these circumstances, it is appropriate for the International Bioethics Committee to clarify the different positions and indicate their ethical implications.

VIII. The Use of Human Embryos for Embryonic Stem Cell Research: Options

38. In relation to the question of embryonic stem cell research, the IBC confined its attention to the human embryo in its early stages of development and before implantation in the uterus: it did not consider the status of the human fetus implanted in the uterus and further along the line of development that will normally result in birth. This is a separate question on which it was not necessary for the IBC to take a view in this Report.

39. Three principal positions have emerged in the national and international debate on the issue of embryonic stem cell research. These are: (a) the position which holds that use of human embryos for deriving embryonic stem cells is intrinsically unethical, (b) the position which holds that such use is ethically acceptable for certain medical purposes and subject to rigorous safeguards; and (c) the position which considers that, taking into account the present risks linked with this research and its possible ethical drifts (*inter alia*, the risks of instrumentalization of the embryo), embryonic stem cell research should not be allowed. The IBC recognises that all these positions are ethically intelligible positions to adopt and deserve deeper discussion.

40. If, at national level, there is no possibility of conducting research on embryos, then embryonic stem cell research is *a fortiori* excluded. If it is considered that embryo research is in principle ethically permissible, the following ethical considerations will have to be taken into account.

41. Several sources of embryo may be identified, with different ethical considerations applying in each case. The various cases are:

(1) the embryo which is created by *in vitro* fertilization (IVF) in order to be implanted in the uterus and identified as suitable for this purpose;

(2) the embryo which has been created *in vitro* to be implanted as in (1), but which is supernumerary (excess embryos having to be created to insure successful pregnancy in infertility treatments);

(3) the embryo which is created by oocyte-sperm fertilisation for purposes of research or for purposes of the development of stem cell lines; and

(4) the "embryo" which is created through the transfer of the nucleus of a donor cell into the denucleated oocyte.

42. The IBC took account of the view that what gave the embryo a status in this context was its individual potential to develop into a person. If this potential were not present in a particular case, because there is no possibility of implantation (e.g., for medical reasons or due to parental decision, excluding any commercial incentive), then it is ethically defensible to use the embryo for medical and therapeutic research needs because it has no potential to develop into a person. The only other option is its destruction.

43. A further consideration is the benefit that flows from deriving stem cell lines from "non-implantable" embryos for medical applications, i.e. use of such embryos for the good of others. Although benefit to others will rarely, of itself, be sufficient to justify a course of action which may be ethically doubtful, this altruistic therapeutic intention can contribute moral legitimacy to the ethical choice of authorising the use of human embryos.

44. If we apply these considerations to the cases listed above, we see that:

(a) an embryo in (1) has a special status as the likely precursor of a human being and should not, in general, be treated in any way likely to prevent the fulfilment of that potential (subject to the exception that some moral traditions and some legal systems allow abortion, especially to protect the mother's right to life);

(b) embryos in (2) have no future. If IVF is allowed, as it is in many countries, then it is ethically permissible to use these supernumerary embryos for research and for therapeutic purposes, the only other option being their destruction;

(c) embryos in (3) and (4) have been created specifically for research purposes. Their use requires special consideration, as expanded below.

IX. Embryos Created for Embryonic Stem Cell Research

45. The creation of human embryos specifically for research purposes is to be distinguished from the research use of embryos which have been created with a view to their implantation but which have not been able to be implanted and have therefore become supernumerary. In the case of the specially-created embryo, the act of creation is intended to fulfil a purpose, which is unrelated to any interest which the created organism might have; in the case of the supernumerary embryo, the organism has not initially been seen as a means to another end, but has been created as an end in itself.

46. Is there any justification for allowing the creation of human embryos in order to derive from them stem cells, which will be used for therapeutic purposes? If the embryo is considered to have a status which goes with personhood, then this would offend the principle prohibiting the instrumentalization of persons. If it is not considered to have such a status, however, there may be no objection to its use for the benefit of others and the potential gains should be weighed against any damage that such a use would entail to any recognised value.

47. Assuming that the embryo is not to be given the status which goes with personhood, it would be permissible to use the embryo for purposes which did not demean it. It would clearly be unacceptable for human embryos to be used for purposes which would reflect contempt for the class of embryos in general (given that some human embryos, those that are either implanted or are to be implanted, are accorded particular respect and protection). If we cherish human life, then we must cherish all manifestations of the body; hence the universal habit of according reverence to human remains and the widespread ethical prohibitions against the casual abuse of the human body. To endorse any use of the human embryo which was not consistent with a reverence for human life would be widely regarded as wrong. Those who believe that therapeutic research on embryos is ethically permissible, might argue that the creation and use of a human embryo outside the context of human reproduction does not necessarily undermine the attitude of respect for the human body and human dignity, provided that the purposes involved in such creation and use are purposes which we would recognise as beneficial ones. Medical uses fall into this category. In this view, it would appear to be quite consistent with an attitude of respect for human life to allow the use of human embryos at an early stage of development, well before the stage at which anything resembling a self can be said to come into existence. Such use promises to provide the possibility of the relief of a great deal of human suffering, a goal which in no sense calls into question respect for the human body.

48. Nuclear transfer provides an alternative way of creating human “embryos” with the purpose of deriving stem cells, although at present this technique is unproven. This is a form of cloning, but it is not reproductive cloning, as the resulting “embryo” is not created for implantation. Because of its purpose, it is sometimes called “therapeutic cloning”. The attraction of this method of producing embryonic stem cells lies in the fact that these cells would be compatible with the cells of the donor of the nucleus. This presents major possibilities for autologous transplantation, in which the problem of rejection is largely overcome.

49. The IBC considered arguments that it may be ethically acceptable to create "embryos" by nuclear transfer in order to produce embryonic stem cells for therapeutic purposes. The implantation of an "embryo" created in this way would not be permissible under the Universal Declaration on the Human Genome and Human Rights and is, indeed, prohibited in many national legislations. Those who argue that nuclear transfer should be allowed point out that benefits of the procedure can take precedence over the fears deriving from this "slippery slope" argument. This procedure puts to the front the same ethical questions as those raised by research involving supernumerary embryos.

50. The IBC also considered arguments of those who strongly oppose nuclear transfer, seeing in it the first steps towards human reproductive cloning. They argue that even if such embryos are not going to be allowed to develop beyond a very limited stage, such steps will assist the development of techniques which could be used one day in reproductive cloning.

X. Ethical Restraints

51. If research is allowed on human embryos with the purpose of deriving embryonic stem cells, then it must be subjected to strict supervision and to severe basic constraints. These include the obtaining of full consent on the part of the donors of the biological material and the requirement that the research be justifiable in terms of the benefit which it offers humanity. The IBC considers that research for non-medical purposes would clearly be unethical, as would research which persisted beyond the very early stages of embryonic development. As expanded upon in section III, the medical applications of embryonic stem cell research must be well-identified therapeutic applications and not trivial or cosmetic non-medical desires, nor *a fortiori* for eugenic enhancement. Imperatives of social justice must be upheld, and the altruistic nature of this research must be reasonably recognised in the process of embryo donation as well as in the commercial applications of the new therapeutic means. Under no circumstances **should** human embryo donation be a commercial transaction, and steps should be taken to discourage financial incentives.

XI. Summary and Conclusions

52. As seen throughout this report, the underlying ethical concern in human embryonic stem cell research is, for many, the status of human embryos and their use for therapeutic purposes. This issue has complex ramifications and the various views are obviously influenced by the concept of human life and personhood particular to each culture, religion or philosophy. There is very serious disagreement on the ethical questions raised by embryonic stem cell research. One view is that the use of human embryos for deriving embryonic stem cells is intrinsically unethical: to use embryos in this way is to instrumentalise human life and seriously to weaken the respect which is accorded to a vulnerable category of persons, namely, human embryos. Another view is that such use is ethically acceptable for certain medical purposes and subject to rigorous safeguards: although the human embryo has a unique status because of its individual potential to develop into a person, it does not entail the respect and protection which goes with personhood. Finally, a mid-way view can be identified

according to which, taking into account the present risks linked with this research and its possible ethical drifts, embryonic stem cell research should not be allowed. The conclusions of this Report need to reflect these differences of opinion.

53. Every society has the right and duty to debate and decide upon ethical issues with which it is confronted. Where there is fundamental disagreement, the society will have to decide where it stands on an issue either because the question involved relates to some fundamental value of that society or because practical considerations demand that the matter be resolved. The use of human embryos for deriving stem cells would appear to be one such issue.

54. Human embryonic stem cell research – and embryo research in general – is a matter which each community (and this will usually mean a State) will have to decide itself. If the decision is reached after serious ethical debate, which allows for the expression of views in different directions, then this must be accepted if one believes in the principle of the democratic resolution of public issues. Examples of this process are afforded by IVF for fertility treatment and by pre-implantation diagnosis with embryo selection: there are differences of opinion on the ethical values involved and yet many States have decided that these medical practices are permissible.

55. The International Bioethics Committee of UNESCO therefore by consensus adopts the following conclusions:

A. The IBC recognises that human embryonic stem cell research is a subject on which it is desirable for a debate to occur at national level to identify which position on this issue is to be adopted, including abstaining from this research. It urges that debates be conducted at appropriate national regulatory levels, enabling expression of a range of views, and whenever possible allowing a consensus to be reached on the limits of the permissible in this important new therapeutic research field. There should be an on-going process of education and information in this area. States should take appropriate measures to initiate an on-going dialogue within society on the ethical issues raised by such research, involving all actors concerned.

B. Whatever form of research involving embryos is allowed, steps should be taken to ensure that such research be carried out within the framework of **a** State-sponsored regulatory system that would give due weight to ethical considerations, and set up appropriate guidelines. When authorisation of donations of supernumerary pre-implantation embryos from IVF treatments for therapeutic embryonic stem cell research is under consideration, particular attention should be given to the dignity and rights of both parental donors of embryos. Thus, it is essential that the donation be made only after the donors should have been given full information as to the implications of the research and have given their prior, free and informed consent. The purposes for which such research is carried out, and the way of its performance, should be subject to assessment by the appropriate ethics committees, which should be independent of the researchers involved. This assessment should include ex post facto ethical evaluation of such research.

C. Alternative new technologies for obtaining human stem cell lines, from genetically compatible sources for transplantation therapeutic research, should be considered. These new technologies include cells taken from an existing adult individual, i.e. adult stem cells, or nuclear transfer. The advantages and risks of these new technologies should be carefully weighed: in this respect, it should be recalled that nuclear transfer should be used only for therapeutic research.

D. Considering the importance and sensitivity of the subject, the IBC will keep this issue under consideration taking into account the discussions and regulations at national, regional and international levels.

E. In all aspects of research involving human embryos, particular importance should be given to respect of human dignity and the principles set out in the Universal Declaration of Human Rights (1948) and the Universal Declaration on the Human Genome and Human Rights (1997).

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http://www.nuffield.org/bioethics/index.html	United Kingdom, Nuffield Council on Bioethics
http://www.oas.org/	Organization of American States
http://www.oau-oua.org/	Organization of African Unity
http://www.palazzochigi.it/bioetica/	Italy, National Bioethics Committee
http://www.senate.be	Belgium, Senate
http://ue.eu.int/df/default.asp?lang=en	European Union, Council of the European Union, Fundamental rights
http://www.unhchr.ch/french/html/intlinst.htm	United Nations, High Commissioner for Human Rights, International Human Rights Instruments

ANNEX

Distribution: limited

COMPOSITION OF THE WORKING GROUP OF THE IBC ON THE ETHICAL ASPECTS OF EMBRYONIC STEM CELL RESEARCH

Chairperson

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Professor, Head of Department of Genetics, Institute of Psychiatry and Neurology

Rapporteurs

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Chairman, Ethics Committee, *British Medical Journal*

REVEL **Prof. (Mr) Michel** (Israel)
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Chief Scientist, *Interpharm*
President of the National Committee for Biotechnology

Members

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