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The European Science Foundation acts as a catalyst for the development of science by bringing together leading scientists and funding agencies to debate, plan and implement pan-European initiatives.

## Foreword

This is the third and final study undertaken for the Biology and Society initiative of the ESF by its High Level Expert Group. It concerns an area of biological research believed to have great promise for the treatment of many serious, chronic medical diseases for which current therapies are inadequate. However, these studies evoke important moral and ethical issues, as well as strong emotions. Therefore, scientific research in this field should be undertaken by simultaneously addressing the ethical issues.

The policy recommendations set out in this briefing paper address both these scientific and ethical concerns. As scientific knowledge about human stem cells is at an early stage, it is recommended that, at this time, it is essential to permit studies of stem cells from embryos, foetal tissues and adults to determine the potential of the different types of stem cells. The European Science Foundation supports this recommendation and urges all European countries to enact legislation to ensure that such research is properly regulated and controlled. This is especially important because the cloning of stem cells is a scientific possibility. The ESF endorses the view that reproductive cloning should not be permitted but that studies involving therapeutic cloning should be allowed, although under tightly controlled regulations. This study by the High Level Expert Group reveals that great differences exist between European countries concerning the state of legislation and control of research into human stem cells and this is a cause of concern. The ESF wishes to see that appropriate measures are put in place as soon as possible. Because research in this area has such great potential but is still in the first development stages, the ESF will continue to play its part by maintaining an overview of scientific progress in the study of human stem cells and its regulation.

I believe that the ESF High Level Expert Group has produced a very important and measured statement on a critical issue in scientific research which I hope will lead to an appropriate framework for research to continue in balance with ethical and moral issues.

**Enric Banda, ESF Secretary General**

## Introduction

There are many chronic, serious and disabling human diseases for which there are currently no effective therapies. The scientific study of stem cells has raised new hopes for their treatment by cell replacement. Animal work has already demonstrated what might be achieved, with the result that a number of scientists are already investigating the properties of human stem cells. This work is at an early stage, but it is creating unease because of the ethical and moral issues involved. The current situation is set out at some length in a number of recent reports<sup>1,2,3</sup>. This paper summarises the scientific and ethical issues and sets out the position of the ESF.

## The biological background and current clinical situation

Stem cells can be derived from different sources: adults, umbilical cord blood or foetal tissues, and from *in vitro* fertilised embryos.

### ● Adult stem cells

These are responsible for cell renewal and tissue growth and repair from early postnatal life to adulthood. Some adult stem cells are multipotent, which means that they can give rise to several cell types in an organ. Blood stem cells, which are encountered in bone marrow, can differentiate to all types of blood cells. Blood stem cell transplantations have been in wide clinical use for more than 20 years. Such cells are derived from bone marrow or from donor blood after growth factor stimulation. Neuronal stem cells were recently found in the human brain (Johansson et al., Kukekov et al.). They can give rise to all the different cell types of the brain.

More differentiated cells, so called progenitor cells, have been identified in at least 20 different human tissues. They give rise to one cell type. Such cells take care of, for instance, the renewal of skin and intestinal mucosa.

<sup>1</sup> *Stem Cell Research: Medical Progress with Responsibility*. A report from Chief Medical Officer's expert group reviewing the potential of developments in stem cell research and cell nuclear replacement to benefit human health, June 2000, Department of Health, UK.

<sup>2</sup> *Ethical Aspects of Human Stem Cell Research and Use*. Opinion of the European group on ethics in science and new technologies to the European Commission. N° 15 (14 November 2000).

<sup>3</sup> Survey on opinions from National Ethics Committees or similar bodies, public debate and national legislation in relation to human embryonic stem cell research and use, June 2002, European Commission, Research Directorate-General

Adult stem cells and progenitor cells are encountered in low numbers, and they are difficult to isolate. For the time being, enhancing their numbers in cell cultures has proven difficult in many cases.

There are ongoing clinical research programmes, in which adult stem cells or progenitor cells are being transplanted to patients. An example is transplantation of pancreatic cell suspensions, obtained from dead donors, to diabetic recipients (Ramiya et al.) to replace the non-functioning insulin-producing cells. Cells from several donors are needed for one recipient. Immunological rejection is a major problem. Immunosuppressive medication is needed for the rest of the life of the recipient.

According to a couple of recent reports, adult stem cells can go backwards in their differentiation, and then be reprogrammed to give origin to another type of stem cell (Björnson et al., Woodbury et al.). Blood cells might be derived from neural stem cells, and neural stem cells from bone marrow stem cells. For the time being, very little is actually known about these mechanisms. Such cells do not appear to work in the organism *in vivo*, at least to any significant extent, because it appears that, if any bone marrow stem cells do spontaneously migrate to the brain as recent reports seem to indicate, they do not succeed in replacing the degenerated dopaminergic cells of individuals suffering from Parkinson's disease sufficiently to demonstrate clinical improvement.

### ● Foetal stem cells

These can be derived from umbilical cord blood after delivery, or from foetal tissues after termination of pregnancy or after spontaneous abortion. Cord blood stem cells are being used in blood cell transplantations. Their small number is a problem. For adult recipients, cord blood from more than one infant is needed. Foetal brain tissue obtained from aborted fetuses contains neural progenitor cells. Such tissue is being used in treatment of Parkinson's disease. More than 200 patients have already been treated in the United States and in Sweden (Björklund & Lindvall). Also in this case, several fetuses are needed to transplant a sufficient number of cells into one patient. Rejection is supposed not to be a problem in the central nervous system, but more data regarding rejection and viability of transplanted cells, especially over long time periods, is still needed.

### ● Embryonic stem cells (ES cells)

These can be derived from 5-6-day old human embryos, which have been obtained by *in vitro* fertilisation. By that time the embryo is called a blastocyst. It consists of a vesicle with a thin wall, the outer cell mass, and some 20-100 cells located inside the vesicle, the inner cell mass. The cells of the inner cell mass give origin to embryonic stem cells, which have the capability to form all the different cell types and organs in the body. They can form cell lines, which can divide and give rise to new cells indefinitely. Theoretically, huge numbers of embryonic stem cells could be derived from one such cell line. These cells can be cryopreserved and cultured again after thawing. There is wide experience from the early eighties as regards culturing of mouse embryonic stem cells. These cells are being used to create transgenic animals. Human ES cell lines have been in culture since 1998 (Thomson et al.). ES cells are pluripotent, i.e. they have a greater potential for differentiation than multipotent adult stem cells, but they are not totipotent. This means that they can specialise to all different tissues, but by themselves they cannot give origin to a new individual.

In human *in vitro* fertilisation treatments, several embryos are normally obtained. One or two are transferred to the uterus of the woman undergoing treatment. The best of the remaining ones, which can be evaluated to survive freezing and thawing, are cryopreserved for infertility treatment in the future. There are often surplus embryos, which could be used in research, after the informed consent of the couple, or have to be discarded. These embryos are a potential source of human ES cells.

Another subject of human embryo research has been the development of preimplantation diagnosis (PGD), which is now practised in many countries, in general in families at genetic risk. PGD is an alternative for prenatal diagnosis. A known genetic abnormality can be diagnosed from two cells taken out of a three-day-old embryo. Embryos lacking the abnormality can be transferred to the woman, and later prenatal diagnosis and possible termination of pregnancy can be avoided. PGD has also been thought to be an effective method in improving the likelihood of pregnancy and diminishing miscarriages, because it is possible to choose a chromosomally normal embryo to be transferred to the uterus.

Hence, to get embryos that are surplus from the treatment of infertility for use in the production of stem cell cultures appears not to be a problem in a technical sense. But there is very little information available as regards the differentiation and properties of human embryonic stem cells. Also questions concerning the best methods of avoiding rejection after cell transplantation remain to be solved. There are several suggested strategies to solve it, but much research is needed before we really know. One option might be to create blastocysts by transferring a somatic cell nucleus from a cell obtained from a potential patient recipient to an unfertilised oocyte, and grow a cell line from such a blastocyst. Another one is to create a large bank, maybe 4000 cell lines derived from donated embryos from *in vitro* fertilisation programmes. A matched cell line could be used for each recipient. The immunological properties of cells might also be modified *in vitro*, but much further research will be required to achieve this.

This summary illustrates the current position in our understanding of human stem cell biology. Whilst recent studies of stem cells from adult sources are interesting and may have real potential, the difficulty of obtaining them in quantity and maintaining them *in vitro* illustrates why parallel work on embryonic cells and attempts to make adult cells revert to an unspecialised state is still necessary. Scientists with experience in this field insist that opponents of embryo research exaggerate the prospects of using adult stem cells. They believe research using stem cells from embryos will be needed in the foreseeable future to determine their value in therapy for human disease and our understanding of stem cell development.

### ● **Stem cell therapy using cell nuclear replacement (CNR): reproductive versus therapeutic cloning**

CNR is the key to reprogramming the adult cell's nucleus. The technique involves replacing an oocyte's nucleus with the nucleus of the adult cell to be cloned and then activating the oocyte's further development artificially without fertilisation. The oocyte genetically reprogrammes the transferred nucleus, enabling it to direct development of a whole new organism, and the information it contains is then copied at each subsequent cell division.

CNR was used to create Dolly the sheep and subsequently other mammalian species. In this research, scientists found a way to genetically 'reprogramme' the nucleus of a fully differentiated adult cell to generate a totipotent cell clone that developed into an identical new copy of the animal from which the adult cell had been taken. This is called **reproductive cloning**.

However, the majority of such embryos did not develop normally, indicating that much work is required before this technique will reliably produce a normal foetus. Nevertheless, recent publicity indicates that some medical experts with experience of assisted human *in vitro* fertilisation may be prepared to use this approach to help otherwise infertile couples have a child. At present, the prevailing European view does not support the use of this technique using human cells, either in fundamental research or as therapy for human infertility.

**Therapeutic cloning** is a stem cell therapy strategy that aims to combine CNR, human stem cell culture and stem cell therapy. Its goal is to remove healthy adult cells from a patient, reprogramme the cell's nuclei by CNR, collect and grow pluripotent embryonic stem cell clones from the resulting blastocyst and then induce these to differentiate into the stem cell or mature cell types required for transplantation to treat disease.

At present, CNR is the only practical means of reversing the differentiation of adult cells to restore their embryonic potential, and of generating tissues which are genetically identical and thus do not induce an immunological response.

Scientists are investigating other ways this might be achieved.

### **Ethical problems**

**No** one objects on ethical grounds to research on stem cells obtained from adult donors. In countries where termination of pregnancy is permitted, it is usually acceptable to undertake research on foetal tissues. However, there are many who object to the use of human embryonic stem cells for research on moral or religious grounds. Such ethical concerns relate to two issues, one the instrumentalisation of human embryos, i.e. the reduction of life to a commodity, and two, deep concern about the

risk of a slide from the cloning of tissues to the cloning of human beings (reproductive cloning).

Some people view embryo research as intrinsically immoral as they believe that from the moment of conception the human embryo has the full status of a human person. Such a viewpoint can not countenance any experimental procedure which entails the destruction of embryos, as the derivation of stem cells must. Another opposing concern is the integrity of individuals and their right not to be treated as a commodity, on the other hand, many people would regard it as morally acceptable to use embryos for purposes which will result in the therapy of major disabling conditions and diseases. On this view, the potential life, which the embryo represents, may be sacrificed for the good of actual persons. This attitude is reinforced by the fact that very many early embryos are lost naturally. Nevertheless, some, who see the embryos as no more than potential human life, still have concerns that the production of stem cells from human embryos may represent a modification of life and so be an affront to human dignity. Such a view favours either an

outright ban on such uses of embryos, or a very strictly controlled experimental setting, in which the derivation of stem cells from embryos is only a stage leading to the application of the techniques developed to adult stem cells, obtained with fully informed consent.

The second concern arising from embryo research is that if cloning of tissues is permitted, this may lead inevitably to the cloning of humans, since the techniques are the same. As with the derivation of stem cells from surplus embryos, the moral debate centres round the question of adequate legislative controls, to draw limits on what is permitted in scientific research in this field. All the work proposed would be on very early embryos *in vitro*, and there is no suggestion that any of these embryos would be implanted. However, it is necessary to have a very robust licensing system for such research and to make any actions which could lead to the implantation of cloned embryos a criminal offence. Without clear and enforceable legislation, there would be nothing to stop the slide to reproductive cloning.

## Statement and recommendations

**There are two major considerations concerning this topic. Firstly, the scientific study of human stem cells is at such an early stage that it is necessary to carry out experiments on cells obtained from embryos and adults in parallel. Secondly, as shown in the accompanying table, the legislative situation governing work in this field differs considerably between countries represented in the ESF. The medical potential of stem cell therapy is obvious. Therapy using stem cells for diseases which involve the degeneration of defined cell types, such as diabetes, Parkinson's disease or Huntington's chorea, could become available within the foreseeable future. Stem cell therapy for diseases that affect whole organs or complex tissues is thought to be possible in the future, but in these cases, the potential is much longer term. Although progress in stem cell biology has been rapid, there are many important scientific questions that need to be addressed.**

1. It is essential to proceed with research on stem cells derived from embryos, foetal tissues and adults, in parallel. Indeed, a key question is to what extent the different types of stem cells in the human embryo, foetus and adult differ. For example, the ease with which they can be made to multiply in culture, their longevity in culture in the laboratory, the range and nature of the mature cell types they can be induced to make, and the molecular signals that bring about these changes.
2. Research is also required to overcome the problem of immunological rejection of cells from donors who are not genetically identical with the recipient.
3. ESF recognises the major ethical concerns that surround this area of research. It recommends that all work on human stem cells should be properly regulated. In many countries the scientific community is engaged pro-actively in ensuring regulation is put in place.

4. There are major differences in the legislative framework between countries concerning human stem cell research. The ESF urges all European countries to introduce legislation and regulation to oversee and control the laboratories concerned, the scientists involved and the experiments that can be performed.
5. When therapies from the study of human stem cells become available, patients from all countries will wish to use these results. The ESF recommends that, in developing their legislative framework for this type of research, European countries take this reality into consideration.
6. Reproductive cloning, that is attempts to create a new human being by any means other than those involving fertilisation of an oocyte by a sperm, is forbidden in most European countries. The ESF and its member organisations endorse this position from the ethical point of view.
7. Therapeutic cloning, in which a nucleus from a somatic cell is transferred into an oocyte from which the nucleus has been removed, has potential for therapy of serious and disabling diseases. For this reason, the ESF suggests that fundamental research involving this technique should be supported, but under strong regulatory control by national bodies.
8. Some scientists wish to study chimaeric embryos, that is embryos created by the fusion of a nucleus from one mammalian species with an oocyte from another species. The ESF suggests that research of this kind should be limited to non-human species when it can be ethically justified, as in the case of endangered species.
9. Much of the research in this area is currently being done in the commercial sector. It is therefore not readily available for the use of nor proper scrutiny by the scientific community. The ESF believes that it is particularly important that adequate funds are made available from public bodies to the scientific community outside the commercial sector to keep pace with those developments. It is essential for public confidence that the views of independent scientists are available for development of national policies.
10. Scientific advance is so rapid in this area that regulation and legislation will need to be kept under continual review. The ESF recognises that the position differs between countries and that there will be continual debates on this sensitive issue. The ESF will ensure that this paper is updated regularly to reflect scientific and regulatory changes in the future.

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## Regulations on the use of human stem cells in research in European countries\*

Country	Reproductive cloning prevented by national law	Research authorised by national law on			Ministries in charge	Specific National Committee(s)	Competences of the Committee members	Communication
		Stem cells	Human embryos	Aborted fetuses				
<b>AUSTRIA</b>	Yes	No law	No law	No law	Justice & Health	No	–	Yes
<b>BELGIUM</b>	No	No law	No law	No law	Public Health & Research (W) Justice & Health (F)	National Committee of Bioethics <sup>1</sup>	Biologists, physicians, ethicists, lawyers, lay persons	Yes
<b>CYPRUS</b> (x)	Yes	No law	No law	No law	Health & Law Office	No	–	No
<b>CZECH REPUBLIC</b> (x)	No	No law	No law	No law	Health	Bioethics Committee of the R&D Council & Ethical Committee of the Ministry of Health <sup>1</sup>	Biologists, physicians, ethicists, theologians, philosophers, lawyers	Yes
<b>DENMARK</b> (x)	Yes	In prep. (end 2002)	In prep. (end 2002)	In prep. (end 2002)	Science, Technology and Innovation	The Central Scientific Ethical Committee <sup>1</sup>	20 members (9 specialists, 11 lay persons)	Yes
<b>FINLAND</b> (x)	Yes	Yes	Yes	Yes	Social Affairs and Health	Sub-committee on Medical Research Ethics of the National Advisory Board on Health Care Ethics <sup>1</sup>	10 members (6 physicians, 2 lawyers, 1 ethicist and 1 representative of patient organisations) and a chair (lawyer)	Yes
<b>FRANCE</b> (x)	Yes	Yes (somatic and foetal stem cells) * No (embryonic stem cells)	No	Yes	Employment and Solidarity	National Consultative Bioethics Committee for Health and Life Sciences <sup>1</sup>	39 members (5 philosophers and theologians, 15 scientists and physicians, 19 lay persons with competence in bioethics)	No
<b>GERMANY</b>	Yes	No (embryonic stem cells) * No law (somatic and foetal stem cells)	No	No law	Federal Ministry of Health	Central Ethics Commission for Stem Cell Research <sup>1</sup>	18 members (biology, ethics, medicine, and theology)	Yes
<b>GREECE</b> (x)	No	No law	No law	No law	Development and Health	No	–	No
<b>HUNGARY</b> (x)	In preparation	Yes	No	No	Health	National Scientific and Ethical Committees <sup>1</sup>	24 members (medical doctors, lawyers, priests, journalists, ethicists, members of the Parliament, representatives of the Ministry of Health) and a chair	Yes
<b>ICELAND</b> (x)	Yes	No	No	No	Health and Social Security	National Bioethics Committee <sup>1</sup>	5 members (health sciences, scientific ethics and human rights)	No
<b>IRELAND</b>	No	No law	No law	No law	Dept of Health and Children	No <sup>1</sup>	–	No
<b>ITALY</b> (x)	Yes	Yes	No	Yes	Health	National Committee of Bioethics <sup>1</sup>	Clinicians, pharmacologists, ethicists, scientists, lawyers, representatives of patient rights	Yes
<b>LUXEMBOURG</b> (x)	In preparation	No law	No law	No law	Health	National Consultative Bioethics Commission for Health and Life Sciences & Committee for Research Ethics (Minis. of Health)	Lawyers, theologians, social workers, teachers, doctors, representatives of social security department	No
<b>NETHERLANDS</b> (x)	Yes	Yes	Yes on left-over embryos	Yes	Health Welfare and Sports	Central Committee on Research involving Human Subjects <sup>1</sup>	Lawyers, physicians, nurses, methodologists, pharmacologists, psychologists, ethicists, & 3 advisors on research on embryos	Yes

Country	Reproductive cloning prevented by national law	Research authorised by national law on			Ministries in charge	Specific National Committee(s)	Competences of the Committee members	Communication
		Stem cells	Human embryos	Aborted fetuses				
<b>NORWAY</b> (x)	Yes	In prep.	No	Yes	Health	National Committee for Research Ethics <sup>1</sup>	At least 9 members (physicians, geneticists, ethicists, lawyers, lay persons)	Yes
<b>POLAND</b> (x)	No	No law	No law	No law	Health and Social Affairs & National Education & Science	No <sup>1</sup>	–	Yes
<b>PORTUGAL</b> (x)	Yes	No law	No law	No law	Health	National Committee for Reproductive Medicine & National Council of Ethics for the Life Sciences <sup>1</sup>	5 members (1 member of Medical Reproduction Society, 1 medical genetics expert, 2 specialised physicians, 1 biologist) & 21 members (Physicians, legal experts, ethicists, philosophers geneticists, 1 theologian)	Yes
<b>SLOVAK REPUBLIC</b> (x)	Yes	No law	'Non-therapeutic', 'interventional' research on living human embryos prohibited	Yes	Health	Central Ethics Committee of the Ministry of Health <sup>1</sup>	Multidisciplinary (experts and lay persons)	Yes
<b>SLOVENIA</b> (x)	Yes	Yes (somatic stem cells and embryonic stem cells from spared embryos)	Yes on embryos which are no longer part of a parental project (14 days)	Yes if authorised by the NMEC	Health	The National Committee for Medically Assisted Reproduction (MAR) & the National Medical Ethics Committee	5 members (1 MAR expert, 1 lawyer, 1 ethicist 1 psychologist and 1 ombudsman's representative) & 13 members (7 physicians, 1 psychologist, 1 social scientist, 1 lawyer, 1 theologian, 1 ethicist, 1 lay person)	Yes
<b>SPAIN</b> (x)	Yes	No law	No	Yes	Health	National Commission for Human Assisted Reproduction <sup>1</sup>	22 members (scientists, lawyers, psychologists, social representatives, members of the Department of Health)	Yes (few)
<b>SWEDEN</b> (x)	Yes	No law	Yes (14 days) <sup>2</sup>	Yes	Health and Social Affairs & Education	No <sup>1</sup>	–	Yes
<b>SWITZERLAND</b> (x)	Yes	No	Yes	No	Federal Office for Public Health & Federal Office for Justice	National Ethical Committee <sup>1</sup>	18 to 25 members (Ethicists, members of the medical profession, scientists, lawyers, lay persons)	Yes
<b>TURKEY</b> (x)	No	No law	No law	No law	Health	Central Ethical Committee <sup>1</sup>	20 members (3 medical pharmacologists, 3 clinicians, 1 pharmaceutical chemist, 1 pharmaceutical technologist, 1 toxicologist, 1 pharmacist, 1 dentist, 4 specialised physicians, 4 representatives of Ministry of Health, 1 lawyer) and a chair (Advisor of the Health Minister)	No
<b>UNITED KINGDOM</b>	Yes	Yes	Yes (14 days) <sup>2</sup>	Yes	Department of Health	Human Fertilisation and Embryo Authority (HFEA) & Human Genetics Commission (HGC) <sup>1</sup>	21 members (1/2 medical and scientific expertise, 1/2 lay expertise) & 22 members (the chair of HFEA, scientists, lawyers, ethicists, members of the medical profession, of industry, a journalist, a member of the National Consumer Council)	Yes

\* The questionnaire was sent to the Heads of ESF Member Organisations. Replies were received from agencies in 25 out of 27 ESF national groups.

(x) Among the 25 respondents' countries, 20 have signed the Convention on Human Rights and Biomedicine (Oviedo, 04/04/97) and the Protocol on the prohibition of cloning human beings. Only 9 have ratified them.

<sup>1</sup> Apart from national committee(s), when existing or not, there are local and/or regional ethical committees.

<sup>2</sup> Research is permitted on human embryos up to 14 days old.

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