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IN BRIEF

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Human Embryo Stem Cell Research

Introduction

Embryos, as well as fetal tissues, have been used for medical research since its beginning. Historically these tissues were obtained through therapeutic, and sometimes spontaneous, abortions. Now, however, with the dawn of artificial conception, embryos are created in the lab and can be used in their very early stages of development for research.

In recent years, a considerable amount of controversy has surrounded the use of human embryos for research now that the possibility of creating embryos solely for the purpose of research has become a reality. This controversy has been most apparent in the United Kingdom and the United States, and has been related to the use of embryonic stem cells for research. For the purposes of this paper, “embryo” refers to those manufactured in the lab and only in their very early stage of development, less than 14 days.

Stem Cells

Stem cells are undifferentiated cells that theoretically have the potential to become any type of cell (pluripotent), for example, nerve cell, blood cell, liver cell. Stem cells removed from embryos are known to be pluripotent whereas stem cells from adults have been considered to only have the potential to become certain cell types. However, recent advances have suggested that adult stem cells may also be successfully “reprogrammed” to grow into any tissue type. The allure of stem cell research is the potential to manipulate these cells to grow into any transplantable tissue or organ.

Embryos used for Research

Discussions of human embryo research usually refer to the use of “spare” embryos, those that were destined only to be discarded after no longer being required for *in vitro* fertilization or other reproductive techniques. Many scientists claim that embryos are never produced specifically for research purposes. This distinction,

however, is suggested by some to be quite artificial. They point out that it is a simple thing to “overproduce” embryos for assisted fertility with the intention of having many remaining for stem cell research.

The Experience in the United Kingdom

In addition to licensing and inspecting all fertility clinics in the United Kingdom, the Human Fertilisation and Embryology Authority (HFEA) also licenses and monitors all embryo research. The HFEA was set up following the enactment of the *Human Fertilisation Act* in 1990. Each research project involving human embryos must be licensed and must meet the criteria for an acceptable purpose of research, and must absolutely require the use of embryos.

The HFEA will license the use of embryos for research into:

- infertility;
- congenital disease;
- miscarriages;
- contraception; and
- the development of pre-implantation genetic diagnoses.

The Act does not prohibit the creation of embryos specifically for research. Embryo research that is prohibited by law includes:

- research on embryos older than 14 days;
- the placement of human embryos in non-human animals;
- one type of cloning (embryonic nuclear transfer); and
- genetic alteration.

The *HFE Act* makes no specific mention of stem cell research using embryos, and there is no other legislation in force in the UK to regulate it. In October 2000, the Stem Cell Research Bill – which would have permitted the use of embryos for this research – was defeated.

The U.S. Experience

Federal legislative initiatives tend to focus on issues driven by the abortion debate, and involve voluntary moratoriums and refusal to fund certain research activities. Embryo research is one such issue. Federally, the current law forbids the use of federal funds to harm a human embryo. The ethical concerns are primarily related to the moral status of the embryo.

In August 2000, the President announced the release of new National Institutes of Health guidelines allowing, for the first time, federal funds to be used for human embryo research. The guidelines allow research on embryonic cells originating from frozen embryos destined to be discarded. The destruction of these embryos will not be permitted to proceed under federally funded research protocols. Instead, the stem cells would have to be extracted from embryos by privately funded researchers who would then pass the cells onto federally supported scientists.

European Experience

In many member states of the Council of Europe, all embryo research is prohibited; in others, it is severely restricted. The European Group on Ethics in Science and New Technologies of the European Commission issued its opinion of the matter in November 2000. The Group believed that a centralized authority should exercise strict public control in those countries that permit embryo research. The Group also indicated that creation of embryos for the purpose of stem cell research is ethically unacceptable.

The Group further declared that therapeutic cloning is unacceptable. They indicated that, although creation of an embryo by nuclear transfer to supply pluripotent stem cells genetically identical to a patient who requires a transplanted organ or tissue may be an effective technique, other sources of stem cells – from the patients themselves – are also promising and not ethically volatile.

The Australian Position

No jurisdiction in Australia prohibits research on embryos. In some of Australia's states (Victoria, Western Australia and South Australia), all destructive embryo research is prohibited.

Canadian Research Practices

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Beings* was produced in 1998 through the cooperation of the Medical Research Council, the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council. The newly formed Canadian Institutes of Health Research have adopted the policy.

This ethical framework for scientific research states that embryos cannot be created for research purposes, that only "surplus" embryos from reproductive techniques can be used. Such embryos can only be used for research within 14 days of their development and must have been obtained with consent from the donors without financial compensation. No genetic alteration of these embryos can be done.

The policy also states that it is not ethically acceptable to undertake research that involves: embryo development outside the womb; the cloning of human beings by any means including somatic cell nuclear transfer; formation of animal/human hybrids; or the transfer of embryos between humans and other species.

This framework does not specifically mention stem cell research but the parameters set out would not preclude it. Like the position of the European Commission, this policy would preclude embryonic stem cell research that includes therapeutic cloning due to the unacceptability of somatic cell nuclear transfer.

Research protocols are approved by the facilities in which they occur such as hospitals and universities. The National Council on Ethics in Human Research (NCEHR) oversees the research ethics boards (REBs) of these facilities that review the protocols. Both the REBs and the NCEHR respect the guidelines set out in the *Tri-Council Policy Statement*.

Conclusion

The use of embryos as a source of pluripotent stem cells has recently become a contentious issue of debate in many countries. It is an emotional issue for those who condemn it as being inextricably linked to the abortion debate. Those who see the therapeutic potential in embryonic stem cells defend the research just as passionately. Ultimately, the debate over the use of embryos as a source of stem cells may prove unnecessary as researchers have shown significant success in demonstrating pluripotency in stem cells originating from adult muscle, brain and blood.