



Australian Academy of Science

A SUBMISSION TO THE
LEGISLATION REVIEW COMMITTEE

Legislation Review of Australia's Prohibition of
Human Cloning Act 2002 and Research Involving Human
Embryos Act 2002

25 July 2005

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The Australian Academy of Science consists of outstanding Australian scientists elected on the basis of excellence in their fields. Fellows are drawn from all areas of the physical and biological sciences, including medicine. Since its foundation over 50 years ago, the Academy has had the privilege of advising successive Governments on national science policy.

Stem cell science was the subject of the Annual International Symposium of the Academy in 2005. The Academy has the knowledge and skills to offer unbiased and accurate advice to the Government on the scientific aspects of stem cell science, and on relevant legislative issues that follow.

Since February 1999, the Australian Academy of Science has adopted as policy the following:

“Human cells, whether derived from cloning techniques, from embryonic stem (ES) cell lines, or from primordial germ cells, should not be precluded from use in approved research activities in cellular and developmental biology.”

“Reproductive cloning to produce human fetuses is unethical and unsafe and should be prohibited.”

The Academy supports a continuation of the 2002 legislation authorising forms of stem cell research that include derivation and studies of embryonic stem cells [*The Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002*]. The present review of the Acts should recommend changes that will strengthen their ethical content by accurately defining reproductive cloning which should be illegal, while permitting research into improving clinical care and human health.

The Academy endorses the decision of the Commonwealth and State Governments to allow the use of an embryo that was created for IVF, but is now either no longer needed or unfit for transfer, even if fertilised after April 2002. Such research must be subject to informed consent of donors and approved by the relevant Human Research Ethics Committee. This could permit research on embryos that are known to have inherited gene mutations that cause diseases such as cystic fibrosis, muscular dystrophy and thalassaemia. It is of great value that researchers should be able to grow ES cell lines with these mutations, to study how to correct the mutations before using the cells (and similar adult stem cells from patients) in therapy. We note that there are only four groups in Australia that are licensed to isolate human ES cell lines at present.

Should the Review Body wish to interview Officers and Fellows of the Australian Academy of Science to discuss this submission, or other relevant matters, we would be pleased to be available at a convenient time in Canberra.

We make the following specific recommendations:

1. Some doctors and scientists have argued that researchers should be allowed to create embryos with specific genetic properties for research using egg and sperm from informed donors. At present the Academy does not support this position and would not allow such research.

At this time, no arguments have been put to us proposing research for which the creation of embryos is necessary. Most researchers agree that "spare embryos" and embryos unfit for transfer meet current and projected needs. The Academy suggests that this issue should be one that is the subject of continuing discussion, perhaps through the Australian Human Genetics Advisory Committee.

2. The present legislation should be amended to provide for a new definition of the illegal act. We suggest that it shall be illegal to implant an embryo (other than one created by the fertilisation of a human egg by a human sperm) in the womb of a woman for the purpose of reproduction. It shall also be illegal to permit the growth of a human embryo in the laboratory, or any other place other than the womb of a woman, past the stage corresponding to development of an embryo for 14 days in vivo.

At present, the "intentional creation of a human embryo clone" is unlawful. A "human embryo clone" is "a human embryo that is a genetic copy of another living or dead human". A human embryo is a "live embryo that has a human genome and that has been developing for less than 8 weeks since ... the initiation of its development ...". The meaning of the law has become progressively less clear as this area of science has developed over the past three years. The present legislation also exempts a "human embryo that is created by the fertilisation of a human egg by human sperm". However, it is now possible to create egg and sperm cells from somatic cells from an adult (see Nature Medicine, May 2005). It could be possible to avoid the law by using these new technologies.

The Academy cannot find any medical or scientific justification for reproduction using technologies other than fertilisation of an egg by a sperm, nor any reason to grow an embryo in vitro to a stage later than implantation (14 days). Reproductive cloning technologies, when applied to animals, are unsuccessful in most cases, and even where successful often lead to serious handicap in any offspring. There are ethical reservations both in the community and among experts about reproduction using cloning techniques. The Academy adds its weight to the views of those who oppose reproductive cloning.

The appropriate legal way to prevent reproductive cloning is to specify carefully the unlawful act that moves from what might be possible in theory into what is performed in reality. There should be nothing unlawful with growing cells that are pluripotent in the laboratory, however derived, provided that no attempt is made to convert these into a viable embryo in utero. The unlawful act should be either placing a cell or cells derived other than by fertilisation in the womb of a woman, or growing an embryo in the laboratory past the stage where the primitive streak has begun to form. The Academy believes that if we legislate in this way we will give reassurance that an ethical way forward will be followed.

3. Cells that are studied entirely *in vitro* in a research context, and are not formed from a fertilised embryo, should not be regarded as embryos. They are cell lines containing the diploid genome of a living person, grown in a laboratory. This includes pluripotent cells derived by nuclear transfer. If an attempt is made to implant such a cell into the womb of a recipient, an offence will be committed under point 1.

Nuclear transfer is often discussed in the context of derivation of cells for cell therapy. However, at least in the foreseeable future, it will almost certainly be used far more extensively to prepare research models of multifactorial diseases. These cannot currently be diagnosed in embryos and hence must use adult donor cells (see the work of the South Korean group, reported in Science, 20/5/05).

The Academy notes that Australia is one of the few developed countries with excellent biomedical research and a growing biotechnology sector that makes “somatic cell nuclear transfer” (so-called “therapeutic cloning”), illegal. It is not illegal in the United States, the United Kingdom, Spain, Singapore, Korea, Brazil or most other countries. We note that Australia has lost some of its biotechnology lead in stem cell science to countries that do not ban nuclear transfer, such as the United States, Singapore and the United Kingdom. The fact that nuclear transfer, regarded as a promising approach to create models of complex disorders such as diabetes and MS, is unlawful in Australia is likely to be a part of the reason.

4. The conditions under which embryos surplus to IVF needs, or unfit for transfer, can be used in research to provide stem cell lines are defined in legislation. The consideration of the ethical issues of each proposal, and of the experimental program, should be delegated to the Australian Health Ethics Committee (AHEC, which shall be responsible for providing guidance and training) and institutional Human Research Ethics Committees (HRECs).

Australia has an ethics system for human experimentation (and for animal experimentation) that has served it well. The guidelines issued by AHEC are admired internationally. The membership of AHEC, and of local HRECs, is regulated and is representative of a wide range of

expertise and viewpoints. Some of the issues with which local HRECs deal, such as clinical trials on infants or on those without capacity, are as contentious as embryo experimentation. It seems unnecessary to introduce a further layer of regulation for this area of research, if the permissible limits of the research are properly defined in the amended legislation. However, guidance and education for members of institutional HRECs should be provided by AHEC.

5. There is a need for an ongoing forum where issues raised by stem cell science and embryo research can be discussed, and where anyone with a question or a point of view can be sure that their opinions will be considered. The Academy believes that public discussion of all aspects of ethics of human stem cell research, whether with adult or embryo stem cells, should fall within the purview of the Human Genetics Advisory Committee. This could be a way to provide factual information to the public to inform opinions in a rapidly moving scientific area.

There have been several surveys of public attitudes to stem cell science, conducted by agencies with policies ranging from support to opposition. All show that the public is hungry for information that offers a realistic appraisal of the potential of these technologies. They also show that the public wishes to engage in the debate, not in the sense of controlling it, but to offer its views on "where the ethical boundaries are to be drawn". The experience of the U.K. Human Genetics Advisory Committee, Chaired by Baroness Helena Kennedy, has shown how valuable such a Committee can be, if it meets in public and focuses on participatory mechanisms.