



Key issues on stem cells

1. Why stem cells are important, the potential they offer in terms of disease control, and realistically when we might expect results
2. What's the difference between embryonic and non-embryonic stem cells?
3. What is somatic cell nuclear transfer (commonly called therapeutic cloning)?
4. When does life begin?
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1. Why stem cells are important, the potential they offer in terms of disease control, and when we might realistically expect results

Because stem cells are differentiated, which means they have the potential to become many different types of cells, they have uses in many different areas of research and medicine:

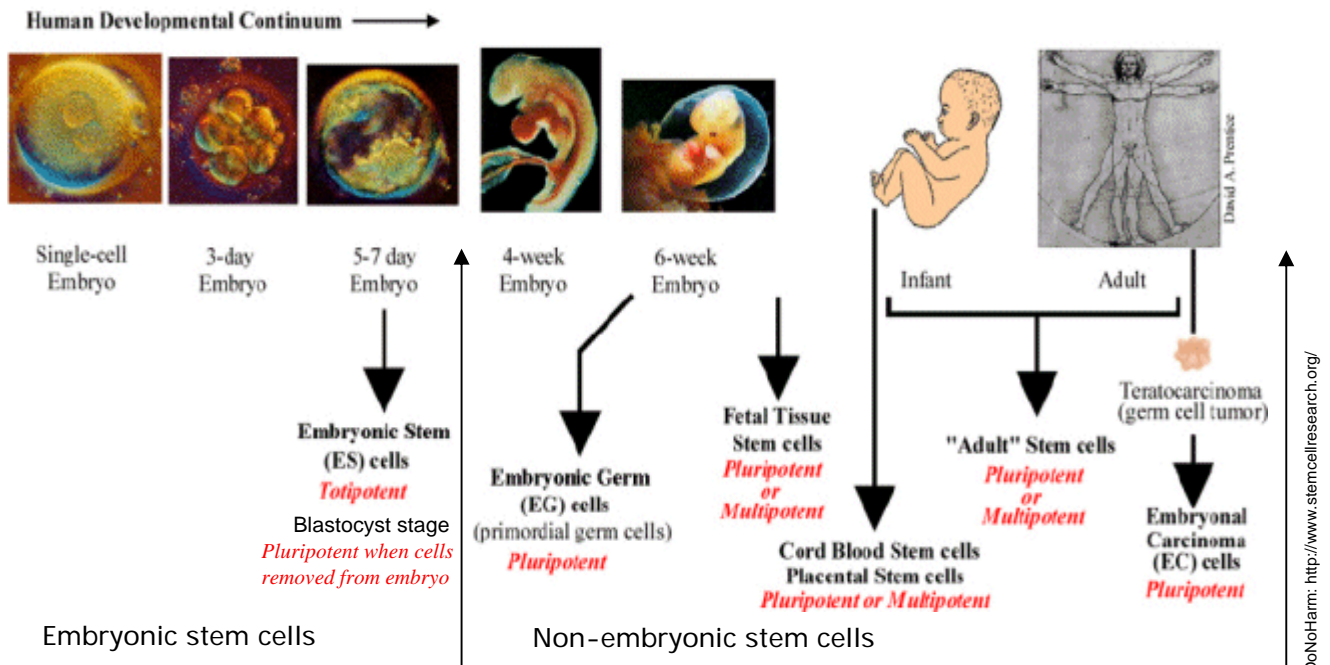
- **Studying human development and disease progression**
Stem cells could be used to study early events in human development, why some cells become cancerous and how some genetic diseases develop, which may lead to clues as to how they may be prevented.
- **Testing of new drugs**
Stem cells grown in the laboratory may be useful for testing drugs and chemicals before they are trialled in people.
- **Screening toxins**
Stem cells may be useful for screening potential toxins in substances such as pesticides before they are released into the environment.
- **Testing gene therapy methods**
Stem cells may prove useful during the development of new methods for gene therapy that may help people suffering from genetic illnesses.
- **Replacing damaged tissue and cells** in the body to potentially treat a range of conditions including heart failure, spinal injuries, diabetes and Parkinson's disease.

Despite community expectations that such treatments may be developed soon, many of these applications based on the pluripotency or multipotency of stem cells may be 10 years or more away.

One possible shorter term use of pluripotent Embryonic Stem Cells may be the development of disease models to study disease progression and to develop and test new drugs.



2. What's the difference between embryonic and non-embryonic stem cells?



- **Embryonic stem cells** come from a five to six-day-old embryo. They have the ability to form virtually any type of cell found in the human body.
- **Embryonic germ cells** are derived from the part of a human embryo or foetus that will ultimately produce eggs or sperm (gametes).
- **Adult stem cells** are undifferentiated cells found among specialised (differentiated) cells in a tissue or organ after birth. Based on current research they appear to have a more restricted ability to produce different cell types and to self-renew.

In addition, umbilical cord blood stem cells are currently being used to treat a range of blood disorders and immune system conditions.

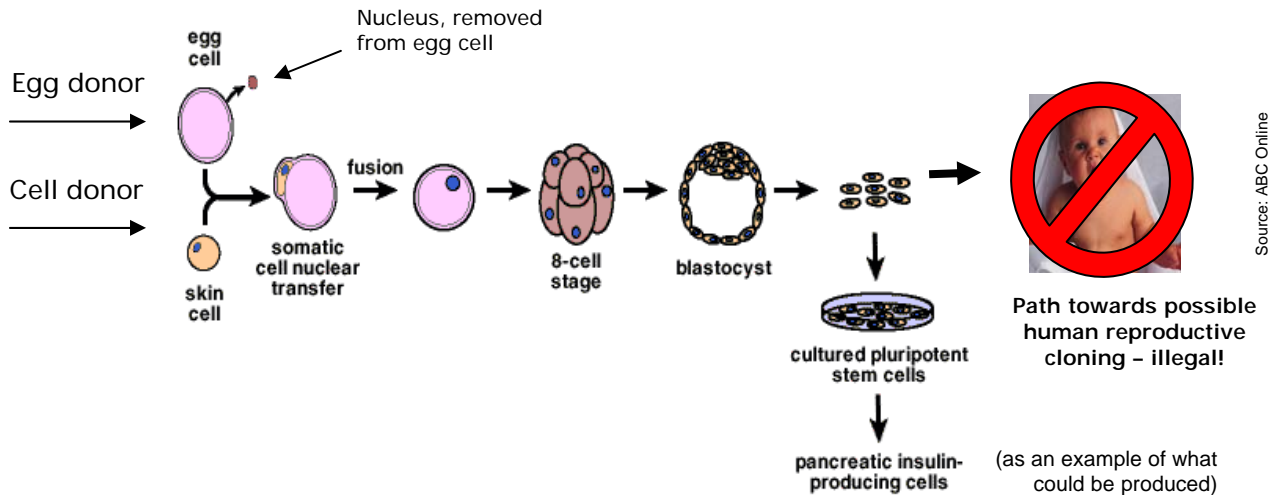
Stem cells that have the potential to develop into any of the cell types found in an adult organism are called *pluripotent*. Embryonic stem cells are pluripotent.

Stems cells that only have the potential to make a few cell types in the body are called *multipotent*. Adult stem cells are considered multipotent.

Cells that are capable of forming a completely new embryo that can develop into a new organism are called *totipotent*. A fertilised egg is totipotent. None of the stem cells used in current research, as they are removed from a blastocyst or embryo, appear to have this capacity.



3. What is somatic cell nuclear transfer (commonly called therapeutic cloning)?



A major problem with the use of embryonic stem cells to generate tissue for transplant would be the immune system of the patient detecting these cells as foreign and attacking them. Immune rejection is a major problem in all transplant therapies.

One strategy for overcoming this could involve the use of somatic cell nuclear transfer technology (which used to be called *therapeutic cloning*, but scientists no longer use the term as it is misleading).

This would involve replacing the nucleus of an egg cell with that from a cell from the patient's body and allowing it to develop to form a blastocyst. Embryonic stem cells from the inner mass cells of the blastocyst would then be harvested and used to establish an embryonic stem cell line that has the same genetic makeup as the patient.

These cells would then be directed to develop into the tissue needed for transplant, and would not likely be rejected. **Somatic cell nuclear transfer technology is not legal in Australia.**

Opposition to somatic cell nuclear transfer technology has been based on two key issues:

1. As any embryo would be a genetic clone of the patient, the technology could, in theory, be used to generate a new human. Reproductive cloning is regarded as unethical by the medical and scientific community, and is not legal in Australia.
2. Somatic cell nuclear transfer technology involves the generation of embryos specifically for research and results in the destruction of the embryo, which some consider unethical.



4. When does life begin?

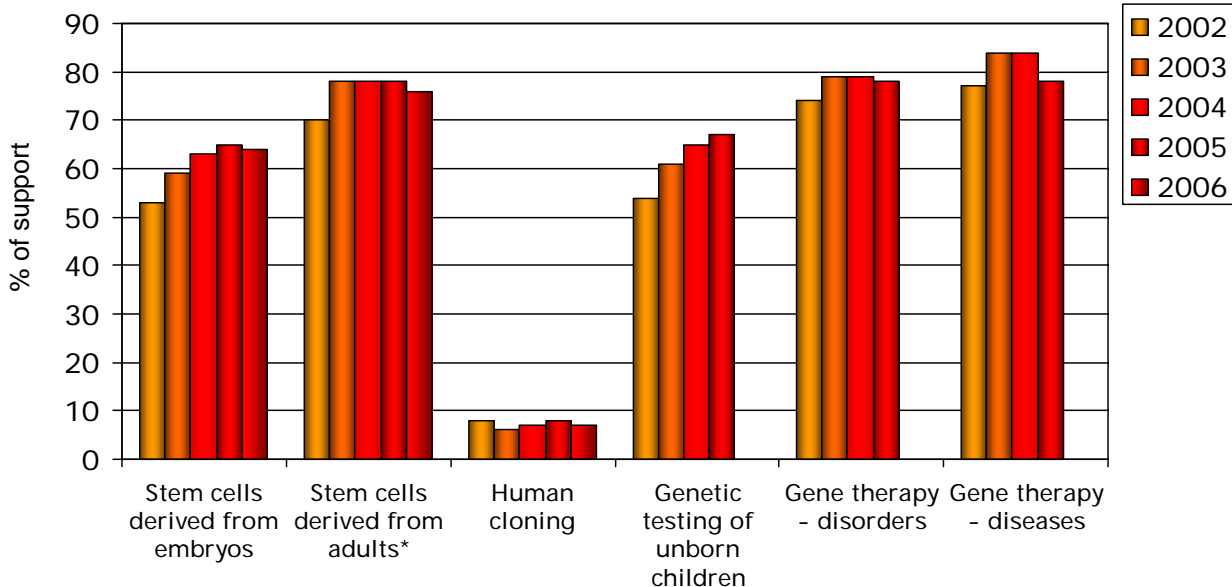
The overwhelming objection to embryonic stem cell research is that it involves the destruction of an embryo. For some this constitutes destruction of a potential human, and conflicts with religious and moral views held in our society. For others, the potential for embryonic stem cell research to provide treatments and possibly cures for debilitating illnesses that have no cure and significantly impact on our way of life overrides this concern. Central to different attitudes to the use of embryonic stem cells is the question of what actually constitutes the beginning of life for a human. There is a range of views on this both within and across the different religions. The listing below provides a brief indication of the range of views among some of the major religions:

- The **Christian perspective** is pluralistic and there is not a single view. Amongst the main Christian religions, the **Catholic view** is that a human person comes into existence at the time of fertilisation, and an embryo is therefore considered as a full human individual having the right to its own life. While many in the **Anglican Church** hold the same view as that of the Catholic church, there is also a view that an embryo is accorded the status of an individual human after 14 days after fertilization ie. following implantation. Several other **Protestant views** do not regard the earliest stages of the embryo as being a full human.
- **Jewish Law** holds that human status is acquired progressively during embryonic development only and not at fertilisation. The foetus becomes a full human only at birth, however, foetuses after the first four weeks still have a 'potentiality for life'.
- In **Islam** the use of embryos for therapeutic or research purposes may be acceptable provided that it occurs before the point at which the embryo is ensouled, i.e., from the 120th day after fertilisation.
- In the **Buddhist view**, there is no single point at which the soul takes residence in the human form. Rather, this process occurs gradually and is not complete until some time after birth.
- In classical **Hindu teaching** the transmigration of the soul occurs at conception, however life does not begin until the moment of birth.

[References: 'Embryos, Cells and God', *Science and Society*, European Molecular Biology Organization, Vol 5. No 6. 2004; *Evangelium Vitae*, 1995; Philosophy Department and Centre for Buddhist Studies, Chulalongkorn University, Thailand; Archbishop Peter Carnley, quoted in the *Anglican Journal*, May 2002; The Islamic Institute, Washington DC.]



5. What are public attitudes towards stem cell uses?



Acceptability depends on use and context

- Uses to treat injury and disease are generally supported, particularly if a matter of life and death.

There is a range of level of understanding

- Many have not thought about the origin of stem cells.
- Many are unaware of the distinction between embryonic and non-embryonic cells, either in general or in specific terms (eg origins).
- There is some familiarity with the term *embryonic stem cells*, but fewer are familiar with the term or concept of *non-embryonic stem cells*.
- There is confusion between an embryo and a foetus.
- Well over 70 per cent of the public have either never heard of 'Therapeutic Cloning' or 'Somatic Cell Nuclear Transfer', or don't know enough about them to make a judgement.

For any given purpose, acceptance of use of embryonic stem cells appears to depend upon:

- Perceived origin (i.e. embryo vs foetus vs umbilicus/placenta).
- Understanding of what is meant by an embryo (the 'age' of an embryo, distinction between a lump of cells and a baby).
- Social trust in the institution undertaking the research.
- Religious values.
- Intention in creating the embryo and benefit for society from the use of embryonic stem cells.

*[Corrected data for 2003 from that released earlier]

Source: Public attitude research commissioned by Biotechnology Australia. More information at www.biotechnology.gov.au



6. What is the current Australian legislation?

Originally, research involving human embryos fell under the National Health and Medical Research Council's Ethical Guidelines on Assisted Reproductive Technology (1996). Under the Guidelines research on human embryos was permitted only under exceptional circumstances, and embryos could only be created as part of an approved IVF treatment program.

The House of Representatives Standing Committee on Legal and Constitutional Affairs (the Andrews Committee) tabled a report relating to the Scientific, Ethical and Regulatory Considerations Relevant to the Cloning of Human Beings on 20 September 2001, recommending that regulated stem cell research continue.

The Australian Government passed legislation to provide for a nationally consistent regulatory scheme for human embryo research. The framework was embodied in two pieces of Commonwealth legislation:

- *The Prohibition of Human Cloning Act 2002*, which bans all forms of human cloning, including reproductive cloning and somatic cell nuclear transfer (has also been referred to as therapeutic cloning). *The Research Involving Human Embryos Act 2002*, which establishes a licensing system for the use of excess embryos from assisted reproductive technologies.

Licences to carry out work using embryos, including research, is administered by the Embryo Research Licensing Committee, a new Principal Committee of the National Health and Medical Research Council (NHMRC).

The first licenses were granted in April 2004: four companies were given approval, two in Sydney and two in Melbourne. Australia's first human embryonic stem cell line was created in June 2004 from five blastocysts.

Australian, State and Territory Governments have enacted complementary legislation to ensure the national consistency of the regulatory system.

In 2005 the moratorium on use of spare fertilised eggs from 5 April 2002 ended. A Review of the *Acts* (the "Lockhart Review"), was undertaken by a committee chaired by late Federal Court Judge Justice John Lockhart, and the report on the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* was tabled in Parliament in December 2005.



7. What is happening overseas?

EU

Production of new hESC lines: Permitted from unused IVF embryos where legal in member nations

Somatic Cell Nuclear Transfer (SCNT): Prohibited

Funding: \$170m on stem cells over the past three years (only \$650,000 for hESC research)

Status in some member nations:

France: Creation of hESC lines from IVF embryos legal as of October 2004; public funding is \$4m

Germany: Only work on hESC lines predating 2002 is legal; public funding is \$4m

Finland: Permits research with IVF embryos; public funding is \$5m

Italy: June 12 referendum will consider permitting IVF embryo research; public funding is \$6m

(EU will not increase funding for hESC projects despite a doubling of the total research budget.)

SWEDEN

Number of published hESC lines: 8

Production of new lines: Legal

SCNT : Legal as of April 2005

Number of researchers: 400

Government funding: \$10m-\$15m

Private funding: Cellartis and NeuroNova, the two largest stem cell research companies in Sweden, contribute the bulk of the \$35m spent annually there

(Cellartis, the single largest source of defined hESC lines in the world, maintains more than 30-two of which are approved by the US National Institutes of Health.)

UK

Number of published hESC lines: 3

Production of new lines: Legal

SCNT: Legal

Government funding: About \$225.5m 2006-08 Private funding: \$15m-\$20m

(The Wellcome Trust alone has spent \$12m annually since 2002. First licence for human ES cell research was granted in 1996. The Human Fertilisation and Embryology Act of 1990 allows the UK to fund hESC research flexibly. The UK's first licence for human cloning research granted in 2004. Its recipients in May announced the country's first cloned human embryo but have not published in a scientific journal. The Government announced £100 million funding for stem cell research 2006-08)

USA

Number of published hESC lines: 46

Production of new lines: Legal, but prohibited with federal funds

SCNT: Legality varies from state to state

Federal government funding: About \$550m for all stem cell research (\$24m for hESC)

Private funding: About \$200m

Public funding at state level:

California: \$3bn over 10 years (blocked by legal dispute)

New Jersey: \$11.5m (another \$380m proposed)

Wisconsin: \$375m proposed

Illinois: \$1bn proposed

Connecticut: \$20m proposed

(Federal government allows its funds to be used only on the 22 available hESC lines created before August 2001. Pending legislation would relax some of these federal restrictions.)



An Australian Government Initiative

BRAZIL

Production of new hESC lines: As of March, legal from IVF embryos at least 3 years old

SCNT: Banned

Government funding: \$4.5m annually planned, allocated by the Health Ministry and the Science and Technology Ministry

SOUTH KOREA

Number of published hESC lines: unclear

Production of new lines: Permitted with case approval from Ministry of Health

SCNT: Permitted with case approval from Ministry of Health

Number of researchers: 300-400

Government funding: About \$10m

Private funding: About \$50m

(Some fraudulent research has thrown doubts over the validity of Korean stem cell research and its future.)

SINGAPORE

Number of published hESC lines: 6

Production of new lines: Legal, if embryos are destroyed within 14 days

SCNT: Legal, as above

Number of researchers: About 150, in industrial and academic settings

Academic spending: About \$10m, from public and private sources

Industrial spending: About \$10

(A pending government proposal would spend \$60m over the next four years. A UK Government report estimates current spending of \$11 million public and \$20 million private. Source: <http://www.advisorybodies.doh.gov.uk/uksci/global/singapore.htm>)

ISRAEL

Number of published hESC lines: 1

Production of new lines: Legal

SCNT: Legal

Government spending: About \$5m

Private spending: \$15m-\$30m

(Israeli scientists led one of the research teams that first isolated hES cells. They were also the first to show that hES cells could be changed into heart cells, and to show that hES cells can integrate with tissues.)

CHINA

Number of published hESC lines: 2

Production of new hESC lines: Legal

SCNT: Legal

Number of researchers: 300-400

Public and private funding: About \$40m

(The journal Nature reports that "China has probably the most liberal environment for embryo research in the world", with little public opposition to such studies. No laws govern stem cell research, but the recommendations of the Ministry of Health endorse it.)

TURKEY

Number of published hESC lines: 7

Production of new lines: no specific legislation

SCNT: no specific legislation

Government spending: NA

Private spending: NA

(Turkey has no specific regulations and guidelines have so far been defined by legal or governmental institutions for human embryonic stem cell research.) Source: Reproductive Biomedicine Online Volume 10, No 5 May 2005

AUSTRALIA

Number of published hESC lines: 3

Production of new lines: Conditionally legal

SCNT: Banned

Number of researchers: 200-250

Government funding: The Australian Stem Cell Centre is funded by total government funding of \$104.05 million through to 2011.

(Source: Scientific American June 2005)



8. Lockhart Review summary

What are some of the Lockhart Review's key points?

The Lockhart Review Committee made 54 recommendations addressing issues including:

- Maintenance of the prohibition on reproductive cloning and on the implantation into a woman of a human embryo created by any means other than fertilisation of a human egg by human sperm.
- Continued licensed use of excess assisted reproductive technology embryos in research, including for the production of human embryonic stem cells, subject to regulation.
- Amending the definition of 'human embryo' to more closely reflect the stage at which a new genetic entity is formed. This is a slightly later stage in the fertilisation process than under current legislation.
- Amending legislation to allow human somatic cell nuclear transfer, under licence, for research, training and potential clinical applications, including the production of human embryonic stem cells, but not for implantation into a woman.
- Amending legislation to permit research on embryos created through processes other than the fertilisation of a human egg with human sperm, while maintaining the prohibition on their implantation into a woman. These embryos could be used for training, research or improvements in assisted reproductive technologies, for example to test sperm viability.
- Establishment of a national stem cell bank, possibly at the Australian Stem Cell Centre.

Rationale for the recommendations

The Committee considered that Australian society is made up of diverse 'communities' with different perspectives, interests and values. Furthermore, an individual may be the member of multiple communities, each with divergent perspectives, or 'standards', and these standards vary between and within communities and over time.

Because of these divergent values and interests represented within Australian society, the Committee has accepted that some disagreement will remain, whether or not any changes are made to the two Acts.



However, certain moral values are held in common by all communities, such as commitment to social justice and equity and to the care of vulnerable people. This is reflected in broad community support for medical research aimed at understanding, preventing or treating disease, and for research and clinical practice aimed at assisting people to have children (including a general acceptance that this process may involve the 'wastage' of some embryos).

Therefore, in considering whether certain activities should be made illegal, the social and moral value that some communities attach to the human embryo needs to be balanced against the social and moral value that other communities attach to the treatment of disease and to helping people to have a family.

In framing the recommendations for these reviews, the Committee considered that the higher the potential benefits of an activity, the greater the need for ethical objections to be of a high level and widely accepted in order to prevent that activity. Conversely, where benefits are not yet established, or where there is widespread and deeply held community objection, then total prohibition through the legal system may be justified. In addition, even though some people think that an activity is unethical, it does not necessarily follow that that activity should be made illegal. Furthermore, the wider the range of ethical views on a particular activity, the weaker becomes the case for declaring that activity to be illegal, with all the attendant consequences of criminal conduct.

However, despite the divergent views received by the Committee during the reviews, both proponents and opponents of embryo research agreed that the current system of legislation is valuable. Therefore, the Committee recommended a continuation of national legislation imposing prohibitions on human reproductive cloning and some other ART practices, as well as strict control and monitoring, under licence, of human embryo research.

The 54 recommendations of the Lockhart Review follow. The full text of the review is available at <http://www.lockhartreview.com.au/>



Recommendations

National legislation

- 1 Clinical practice and scientific research involving assisted reproductive technologies (ART) and the creation and use of human embryos for research purposes should continue to be subject to specific national legislation.

Reproductive cloning

- 2 Reproductive cloning should continue to be prohibited.

Prohibitions on developing and implanting embryos

- 3 Implantation into the reproductive tract of a woman of a human embryo created by any means other than fertilisation of an egg by a sperm should continue to be prohibited.
- 4 Development of a human embryo created by any means beyond 14 days gestation in any external culture or device should continue to be prohibited.
- 5 Implantation into the reproductive tract of a woman of a human–animal hybrid or chimeric embryo should continue to be prohibited.
- 6 Development of a human–animal hybrid or chimeric embryo should continue to be prohibited, except as indicated in Recommendation 17.
- 7 Placing a human embryo into an animal or into the body of a human apart from into a woman's reproductive tract, or placing an animal embryo into the body of a human, for any period of gestation, should all remain prohibited.
- 8 Implantation into the reproductive tract of a woman of an embryo created with genetic material provided by more than two people should continue to be prohibited.
- 9 Implantation into the reproductive tract of a woman of an embryo created using precursor cells from a human embryo or a human fetus should continue to be prohibited.
- 10 Implantation into the reproductive tract of a woman of an embryo carrying heritable alterations to the genome should continue to be prohibited.
- 11 Collection of a viable human embryo from the body of a woman should continue to be prohibited.

Creation of human embryos by fertilisation

- 12 Creation of human embryos by fertilisation of human eggs by human sperm should remain restricted to ART treatment for the purposes of reproduction.
- 13 Creation of human embryos by fertilisation of human eggs by human sperm to create embryos for the purposes of research should continue to be prohibited except in the situation described in Recommendation 15.

Use of excess ART embryos in research

- 14 Use of excess ART embryos in research should continue to be permitted, under licence, as under current legislation.



ART clinical practice and ART research

- 15 Research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division should be permitted for research, training and improvements in clinical practice of ART.
- 16 Testing of human oocytes for maturity by fertilisation up to, but not including, the first cell division or by parthenogenetic activation should be permitted for research, training and improvements in clinical practice of ART.
- 17 Certain interspecies fertilisation and development up to, but not including, the first cell division should be permitted for testing gamete viability to assist ART training and practice.
- 18 The Licensing Committee should develop a simple proforma application for licences to undertake training and quality assurance activities for ART clinics.
- 19 Consideration should be given to the use of cytoplasmic transfer (including transfer of mitochondrial DNA), under licence, for research on mitochondrial disease and other uses to improve ART treatment.

Use of fresh ART embryos

- 20 An expert body should formulate objective criteria to define those embryos that are unsuitable for implantation.
- 21 Fresh ART embryos that are unsuitable for implantation, as defined by the objective criteria, should be permitted to be used, under licence, for research, training and improvements in clinical practice.
- 22 Fresh ART embryos that are diagnosed by preimplantation genetic diagnosis (according to the ART guidelines) as being unsuitable for implantation should be permitted to be used, under licence, for research, training and improvements in clinical practice.

Use of human embryos created by somatic cell nuclear transfer

- 23 Human somatic cell nuclear transfer should be permitted, under licence, to create and use human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.
- 24 In order to reduce the need for human oocytes, transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

Use of human embryos created by activation methods not involving fertilisation of a human egg by a human sperm or somatic cell nuclear transfer

- 25 Creation of human embryos and human embryo clones by means other than fertilisation of an egg by a sperm (such as nuclear or pronuclear transfer and parthenogenesis) should be permitted, under licence, for research, training and clinical applications, including production



of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

- 26 Creation of human embryos using the genetic material from more than two people, or including heritable genetic alterations, should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.
- 27 Creation of embryos using precursor cells from a human embryo or a human fetus should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

Definition of a human embryo

- 28 The definition of a ‘human embryo’ in both Acts should be changed to:

‘A human embryo is a discrete living entity that has a human genome or an altered human genome and that has arisen from either:

- (i) the first mitotic cell division when fertilisation of a human oocyte by a human sperm is complete; or
- (ii) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, 14 days

and has not yet reached eight weeks of development.’

Consent arrangements for the donation of embryos

- 29 The National Health and Medical Research Council (NHMRC) should review its guidelines in relation to consent to research on excess ART embryos, in order to clarify the consent process in relation to the following issues:
- the circumstances, if any, where those who choose to donate excess ART embryos to research may be able to choose not to be contacted at some later stage to give consent to a particular research proposal
 - the circumstances, if any, where a human research ethics committee can determine that the researcher need not ask for further consent to use embryos already declared ‘excess’
 - the development of an appropriate form of consent that could be completed by the responsible persons for excess ART embryos shortly after the declaration that the embryos are excess
 - the manner in which those who donate embryos or gametes for the creation of ART embryos may express any preference for the type of research for which the tissue will be used, once the embryo is declared excess.
- 30 The NHMRC should develop ethical guidelines for the use of embryos that are unsuitable for implantation for research, training and improvements in clinical practice (see Recommendations 20–22).



Egg donation

- 31 The current principles of consent for participation in medical research must apply to sperm, egg and embryo donors, so as to ensure that decisions are freely made.
- 32 The NHMRC should develop guidelines for egg donation.
- 33 The present prohibition of the sale of sperm, eggs and embryos should continue, but the reimbursement of reasonable expenses should continue to be permitted.

Licensing arrangements

- 34 The Embryo Research Licensing Committee of the NHMRC (the Licensing Committee) should continue to be the regulatory body responsible for assessing licence applications, issuing licences and monitoring compliance, as under current arrangements.
- 35 The role of the Licensing Committee should be extended to include assessment of licensing applications and issuing licences for any additional activities permitted, under licence (see Recommendations 14–27).
- 36 The Australian Parliament and the Council of Australian Governments should give urgent attention to the problem of delays in the filling of vacancies on the Licensing Committee.
- 37 There should be no attempt to recover the cost of administration, licensing, monitoring and inspection activities associated with the legislation from researchers at this point in time.

Monitoring powers

- 38 The Licensing Committee should continue to perform its functions in relation to licences and databases for research permitted by licences under the Research Involving Human Embryos Act.
- 39 Licensing Committee inspectors should be given powers, under the Prohibition of Human Cloning Act and the Research Involving Human Embryos Act, of entry, inspection and enforcement in relation to non-licensed facilities in the same manner and by the observance of the same procedures as applicable to search warrants under Commonwealth legislation, if such powers do not clearly exist.

Oversight of ART clinical practice and research

- 40 There should be a continuation of the role of the Reproductive Technology Accreditation Committee in the regulation of ART.

Import and export of human reproductive materials for personal use

- 41 The import or export of a patient's reproductive material, including ART embryos, for the purpose of that person's ongoing ART treatment should not require any regulation other than that required under existing quarantine regulation.

Trade and international exchange of human reproductive materials and stem cells

- 42 The import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority.



- 43 The existing requirements for the import and export of human biological materials are satisfactory and, for ethically derived human embryonic stem cells, no further restrictions are necessary.

Biotechnology and commercialisation

- 44 Trade in human gametes or embryos, or any commodification of these items, should continue to be prohibited.
- 45 Donors of tissue that is going to result in an immortal stem cell line should be informed by means of processes monitored by human research ethics committees about the potential use of that stem cell line, including the potential for commercial gain and the fact that they may not have any rights in potential stem cell developments.
- 46 The development of biotechnology and pharmaceutical products arising from stem cell research should be supported.

National stem cell bank

- 47 A national stem cell bank should be established.
- 48 Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem cell bank.
- 49 A national register of donated excess ART embryos should be established.

Regulatory approach to legislation

- 50 The Licensing Committee should be authorised under the Prohibition of Human Cloning Act to give binding rulings on the interpretation of that Act, or the regulations made under that Act, on condition that it reports immediately and in detail to the NHMRC and to parliament on such rulings.
- 51 The Licensing Committee should be authorised by the Research Involving Human Embryos Act to give binding rulings and to grant licences on the basis of those rulings for research that is not within the literal wording of the Act, or the regulations made under the Act, but is within their tenor, on condition that the Committee reports immediately and in detail to the NHMRC and to parliament on any rulings it gives, or any licences it grants, in that way.
- 52 A researcher who conducts research on the basis of a ruling or a licence should be protected from liability under the legislation, provided that they act in accordance with the relevant ruling or licence.
- 53 In view of the fast-moving developments in the field, and the range of amendments proposed herein, the two Acts should be subject to a further review either six years after royal assent of the current Acts or three years after royal assent to any amended legislation.

Public education

- 54 There should be ongoing public education and consultation programs in the areas of science that are relevant to the Acts.



9. Glossary

Adult stem cell: An undifferentiated cell found in a differentiated tissue that can renew itself and (with certain limitations) differentiate to yield all the specialised cell types of the tissue from which it originated. Adult stem cells are multipotent.

Astrocyte: One of the large neuroglia cells of neural tissues.

Blastocoel: The cavity in the blastula of the developing embryo.

Blastocyst: A preimplantation embryo of about 150 cells. The blastocyst consists of a sphere made up of an outer layer of cells (the trophoctoderm), a fluid-filled cavity (the blastocoel), and a cluster of cells on the interior (the inner cell mass).

Bone marrow stromal cells: A stem cell found in bone marrow that generates bone, cartilage, fat, and fibrous connective tissue.

Cell division: Method by which a single cell divides to create two cells. This continuous process allows a population of cells to increase in number or maintain its numbers.

Cell-based therapies: treatment in which stem cells are induced to differentiate into the specific cell type required to repair damaged or depleted adult cell populations or tissues.

Cell culture: Growth of cells *in vitro* on an artificial medium for experimental research.

Clone: A line of cells that is genetically identical to the originating cell; in this case, a stem cell.

Culture medium: The broth that covers cells in a culture dish, which contains nutrients to feed the cells as well as other growth factors that may be added to direct desired changes in the cells.

Differentiation: The process whereby an unspecialised early embryonic cell acquires the features of a specialized cell such as a heart, liver, or muscle cell.

Directed differentiation: Manipulating stem cell culture conditions to induce differentiation into a particular cell type.

DNA: Deoxyribonucleic acid, a chemical found primarily in the nucleus of cells. DNA carries the instructions for making all the structures and materials the body needs to function.

Ectoderm: Upper, outermost layer of a group of cells derived from the inner cell mass of the blastocyst; it gives rise to skin nerves and brain.

Embryo: In humans, the developing organism from the time of fertilisation until the end of the eighth week of gestation, when it becomes known as a foetus.

Embryoid bodies: Clumps of cellular structures that arise when embryonic stem cells are cultured.

Embryonic germ cells: Cells found in a specific part of the embryo/foetus called the gonadal ridge that normally develop into mature gametes.

Embryonic stem cells: Primitive (undifferentiated) cells from the embryo that have the potential to become a wide variety of specialised cell types.



Embryonic stem cell line: Embryonic stem cells, which have been cultured under *in vitro* conditions that allow proliferation without differentiation for months to years.

Endoderm: Lower layer of a group of cells derived from the inner cell mass of the blastocyst; it gives rise to lungs and digestive organs.

Feeder layer: Cells used in co-culture to maintain pluripotent stem cells. Cells usually consist of mouse embryonic fibroblasts.

Fertilisation: The process whereby male and female gametes unite.

Foetus: A developing human from usually two months after conception to birth.

Gamete - An ovum (egg) or sperm.

Gene: A functional unit of heredity that is a segment of DNA located in a specific site on a chromosome. A gene directs the formation of an enzyme or other protein.

Haematopoietic stem cell: A stem cell from which all red and white blood cells develop.

Human embryonic stem cell: A type of pluripotent stem cell derived from the inner cell mass of the blastocyst.

***In vitro*:** Literally, "in glass"; in a laboratory dish or test tube; an artificial environment.

***In vitro* fertilization:** An assisted reproduction technique in which fertilisation is accomplished outside the body.

Inner cell mass: The cluster of cells inside the blastocyst. These cells give rise to the embryonic disk of the later embryo and, ultimately, the foetus.

Long-term self-renewal: The ability of stem cells to renew themselves by dividing into the same non-specialised cell type over long periods (many months to years) depending on the specific type of stem cell.

Mesenchymal stem cells: Cells from the immature embryonic connective tissue. A number of cell types come from mesenchymal stem cells, including chondrocytes, which produce cartilage.

Mesoderm: Middle layer of a group of cells derived from the inner cell mass of the blastocyst; it gives rise to bone, muscle, and connective tissue.

Microenvironment: The molecules and compounds such as nutrients and growth factors in the fluid surrounding a cell in an organism or in the laboratory, which are important in determining the characteristics of the cell.

Multipotent: The ability of a single stem cell to generate several different cell types of the body. For example, some bone marrow stem cells can give rise to all types of the cells in the blood but not other types of cells.

Neural stem cell: A stem cell found in adult neural tissue that can give rise to neurons, astrocytes, and oligodendrocytes.

Neurons: Nerve cells, the structural and functional unit of the nervous system. A neuron consists of a cell body and its processes, an axon, and one or more dendrites. Neurons function by the initiation and conduction of impulses and transmit impulses to other neurons or cells by releasing neurotransmitters at synapses.

Oligodendrocyte: A cell that provides insulation to nerve cells by forming a myelin sheath around axons.



Plasticity: The ability of stem cells from one adult tissue to generate the differentiated cell types of another tissue.

Pluripotent: Ability of a single stem cell to develop into many different cell types of the body.

Proliferation: Expansion of a population of cells by the continuous division of single cells into two identical daughter cells.

Regenerative or reparative medicine: A treatment in which stem cells are induced to differentiate into the specific cell type required to repair damaged or depleted adult cell populations or tissues.

Signals: Internal and external factors that control changes in cell structure and function.

Somatic stem cells: Another name for adult stem cells.

Stem cells: Cells with the ability to divide for indefinite periods in culture and to give rise to specialised cells.

Stromal cells: Non-blood cells derived from blood organs, such as bone marrow or foetal liver, which are capable of supporting growth of blood cells *in vitro*. Stromal cells that make this matrix within the bone marrow are also derived from mesenchymal stem cells.

Subculturing: The process of growing and replating cells in tissue culture for many months.

Surface markers: Surface proteins that are unique to certain cell types, which are visualized using antibodies or other detection methods.

Teratoma: A tumour composed of tissues from the three embryonic germ layers. Usually found in ovary and testis. Produced experimentally in animals by injecting pluripotent stem cells, in order to determine the stem cells' abilities to differentiate into various types of tissues.

Totipotent: A cell that has the capacity to give rise to all tissue types, including placental and other extra-embryonic tissues.

Transdifferentiation: The observation that stem cells from one tissue may be able to differentiate into cells of another tissue (see plasticity).

Trophoblast: The extraembryonic tissue responsible for implantation, developing into the placenta, and controlling the exchange of oxygen and metabolites between mother and embryo.

Undifferentiated: Not having changed to become a specialised cell type.