The Parliament of the Commonwealth of Australia

Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research

House of Representatives
Standing Committee on Legal and Constitutional Affairs

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Foreword

In February 1997, the world awoke to the news that seven months earlier scientists in Edinburgh, Scotland had created a sheep known as 'Dolly' by the technique of somatic cell nuclear transfer, commonly referred to as cloning. The news of Dolly's birth generated vast publicity, including suggestions that humans might also be replicated in a similar manner.

A year later, scientists in the US state of Wisconsin isolated stem cells from 14 embryos surplus to an IVF program. Grown in a special culture, these cells have demonstrated the capacity to develop into a wide range of specialised cell lines, raising the possibility that many diseases and disabilities might be cured in the future.

Elsewhere, scientists have discovered adult stem cells, and heralded the use of these cells for the repair of human disease.

In many nations, legislators and ethicists have been struggling for an appropriate response to these developments.

The Australian House of Representatives Legal and Constitutional Affairs Committee was asked in 1999 to review the report of the Australian Health Ethics Committee on Human Cloning. It has been examining the many complex issues surrounding human cloning and stem cell research for the past two years.

During this time the Committee has heard from many people. Scientists have shared their excitement about the discovery of techniques that could open future possibilities of cures for life threatening conditions. Families of people with disabilities have welcomed the prospect that some day relatives with Parkinson's or Alzheimer's disease might be restored to health. Yet researchers have cautioned also that such treatments remain speculative, and warned against raising hopes prematurely. In the case of Alzheimer's, the disease process has not even been identified.

At the same time many ethicists have gently, but firmly reminded us that where this research involves human embryos, the harvesting of embryonic stem cells for continued experimentation involves the destruction of the embryo.

Lawyers and regulators have indicated that three states (New South Wales, Queensland and Tasmania) and the territories have failed to properly regulate or legislate in this area, despite repeated urgings from the Australian Health Ethics Committee, and that the legislation elsewhere may not adequately cover new developments.

And many people have written urging a ban on human cloning.

CENTRAL QUESTIONS

At the centre of the Committee's deliberations is the question: is there any benefit in conducting this research or in the application of cloning technologies to human beings? If there is, what use of cloning techniques is permissible to achieve the benefits? For what purposes would such use be permitted? At the heart of these questions is whether it is ethical to conduct research involving cloning techniques which destroy embryos, and, if so, to what degree.

These questions involve consideration of respect for human life, the appropriate limits of science, and the need for transparency and accountability in any system of regulation.

There is also a need for clear language in our public discussions. Expressions like 'therapeutic' and 'reproductive' cloning can be misleading and disguise the actual techniques involved. Even the expression 'cloning' includes a wide range of techniques that attract different ethical considerations. We have attempted in this report to clearly describe what is involved in the research.

CLONING FOR REPRODUCTIVE PURPOSES

Almost universal opposition was expressed to the Committee about the use of cloning techniques for the purpose of creating, implanting and bringing to birth a human being— a human 'Dolly'.

The clear evidence is that it would be unsafe, remembering that 'Dolly' was produced only after 276 attempts, many of which resulted in miscarriages, deformities, and still births. More importantly, the notion of 'photocopying' a human being is contrary to human dignity, confuses family and personal relationships and offends many of the deepest understandings of our unique identity and individuality.

The Committee concludes that there should be a national legislative ban on cloning for reproductive purposes.

THE USE OF ADULT STEM CELLS

Conversely, there was universal support for cloning techniques involving adult stem cells. Research in Australia and elsewhere has isolated stem cells in adult tissue. There is a growing appreciation that these cells may provide the key to future advances in medicine without the ethical problems associated with embryonic stem cells.

The Committee supports continued research involving adult and placental stem cells and encourages funding and resources for this work.

THE USE OF EMBRYONIC STEM CELLS

Great contention surrounds the use and destruction of embryos for the purposes of obtaining stem cells. Sincerely held arguments were presented to us both in favour of and against permitting these procedures.

A number of possible outcomes open to Australian governments were considered by the Committee:

- all destructive experimentation on human embryos and the use of embryonic stem cell lines could be prohibited;
- existing human embryonic stem cell lines could be permitted to be used, but all further destructive experimentation prohibited;
- research on embryos surplus to assisted reproductive technology programs, (which destroys these embryos) could be permitted in defined limited circumstances but otherwise the creation of human embryos for research be prohibited;
- human embryos produced by somatic cell nuclear transfer be permitted in order to obtain embryonic stem cells for research provided they are destroyed before they pass the stage of formation of a blastocyst;
- the creation of human embryos could be permitted for any destructive experimentation.

It is not surprising that the diversity of opinion in the community over the use of embryos in cloning research for the derivation of stem cells is reflected among Committee members.

All Committee members call for a ban on the deliberate creation of embryos for experimentation. They also support a moratorium on the creation of embryos by means of somatic cell nuclear transfer techniques for three years at which point the issue can be re-examined.

For reasons set out in the report, six members of the Committee support research, in defined limited circumstances, on embryos surplus to assisted reproductive technology programs. They also support research on existing stem cell lines and any stem cell lines newly created from surplus embryos within the defined parameters.

Four other members would restrict research to existing human embryonic stem cell lines, provided these stem cells cannot develop into an embryo. If these stem cells could develop into embryos, they would want a prohibition on all destructive experimentation on embryos, including the continued use of existing embryonic stem cell lines.

A SYSTEM OF REGULATION

All members recognise, however, that the final decision about cloning in Australia will be made by Commonwealth, State and Territory Parliaments. If Australian Governments and Parliaments decide to permit human cloning involving stem cells derived from embryos surplus to assisted reproductive technology programs, all Committee members agree upon a system of regulation outlined in the report.

This regulatory framework includes the following features:

- a national uniform legislative approach;
- a ban on cloning for producing children;
- one system of regulation for privately and publicly funded research;
- legislation regulating human cloning and stem cell research separate from that governing artificial reproductive technologies;
- any attempt to undertake reproductive cloning subject to criminal penalty and the withdrawal of a licence to undertake research in this area;
- research using cloning techniques subject to clear legislative parameters, including (subject to a moratorium on somatic cell nuclear transfer) a complete ban on the deliberate creation of embryos for research purposes;
- a national licensing body established to regulate human cloning and research using cloning techniques;
- individual researchers licensed for each research project that involves the use of an embryo;

- the import and export of embryonic stem cells permitted within the framework of principles outlined in the report, but a ban on the import and export of embryos; and
- a regulatory framework that is transparent, accountable and responsive.

The Committee proposes that the role of the Australian Health Ethics Committee be enhanced to consult and involve the public in consideration of ongoing issues raised by human cloning and stem cell research. We also propose an independent review of the Institutional Ethics Committee system in Australia.

CONCLUSION

These are not matters to be decided behind closed doors by scientists or lawyers, however expert and sincere, without widespread community consultation. Nor are they matters that can be resolved by doing nothing.

As a society we are confronted with profound issues that require ongoing attention and discussion.

We believe this report contributes to this end.

Kevin Andrews MP
Chair

Membership of the Committee

Chair	Mr Kevin Andrews MP	
Deputy Chair	Ms Nicola Roxon MP	
Members	Mr Bruce Billson MP (from 17/02/2000)	Hon Michael Ronaldson MP (until 17/02/2000)
	Ms Julie Bishop MP	
	Hon Alan Cadman MP	
	Hon Duncan Kerr MP	
	Mr Alan Griffin MP (from 31/08/2000)	Ms Kirsten Livermore MP (until 31/08/2000)
	Mr John Murphy MP (from 01/09/1999)	Mr Frank Mossfield MP (until 01/09/99)
	Mr Stuart St Clair MP	
	Mrs Danna Vale MP	

Committee Secretariat

Secretary	Claressa Surtees (until February 2000)
Acting Secretary	Catherine Cornish (from February 2000)
Inquiry Secretary	Deborah Nance (from July 2000) Marie Kawaja (until July 2000)
Research Officer	Deborah Nance (from January 2000) Dr Barbara Eckersley (from March 2001)
Scientific Adviser	Professor John Hearn
Administrative Officer	Frances Wilson

Terms of reference

On 10 August 1999, the Minister for Health, the Hon Dr Michael Wooldridge MP, asked the House of Representatives Standing Committee on Legal and Constitutional Affairs to review the report of the Australian Health Ethics Committee of the National Health and Medical Research Council, *Scientific, Ethical and Regulatory Considerations relevant to Cloning of Human Beings* (16 December 1998).

List of abbreviations

AAS	Australian Academy of Science
AHEC	Australian Health Ethics Committee
AQIS	Australian Quarantine and Inspection Service
ARC	Australian Research Council
CEO	Chief Executive Officer
COAG	Council of Australian Governments
ES Cells	Embryonic Stem Cells
FDA	Food and Drug Administration
GIFT	Gamete Intra-Fallopian Transfer
HFEA	Human Fertilisation and Embryology Authority
HGAC	Human Genetics Advisory Commission
IEC	Institutional Ethics Committee
IP	Intellectual property
IPP	Information Privacy Principles
IVF	*In vitro* fertilisation
NBAC	National Bioethics Advisory Commission

NHMRC	National Health and Medical Research Council
NIH	National Institutes of Health
NRC	National Regulatory Committee
RTAC	Reproductive Technology Accreditation Committee
UNESCO	United Nations Educational, Scientific and Cultural Organisation

List of recommendations

Proposed regulation of human cloning

Recommendation 1

The Committee recommends the enactment of legislation by the Commonwealth to regulate human cloning and stem cell research.

Recommendation 2

The Committee recommends that legislation regulating human cloning and stem cell research cover all research in this area, both publicly and privately funded.

Recommendation 3

The Committee recommends that the regulation of research involving the use of cloning technologies should be separate from that governing assisted reproductive technologies.

Recommendation 4

The Committee recommends that the legislation regulating human cloning and stem cell research contain a ban on cloning for reproductive purposes. Any attempt to undertake cloning for reproductive purposes should result in a criminal penalty and the withdrawal of a licence to undertake research in this area for the individual concerned.

Recommendation 5

The Committee recommends that the Commonwealth regulate human cloning and stem cell research within the strict parameters outlined in paragraphs 12.41-12.43.

Recommendation 6

The Committee recommends that a national licensing body be established to regulate any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 7

The Committee recommends that a licence issued by the national licensing body should be required to undertake any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 8

The Committee recommends that the national licensing body have the responsibilities listed in paragraph 12.55.

Recommendation 9

The Committee recommends that the Australian Health Ethics Committee (AHEC) be responsible for monitoring scientific developments in this area, analysing their potential impact and providing advice to Commonwealth, State and Territory governments on these matters.

Recommendation 10

The Committee recommends that individuals and organisations be licensed for each research activity involving the isolation, creation and use of embryonic stem cells they intend to undertake.

Recommendation 11

The Committee recommends that the matters listed in paragraph 12.63 be prohibited. Such a prohibition would mean that the licensing body would not have the authority to issue a licence for research involving any of the items listed in paragraph 12.63.

Recommendation 12

The Committee recommends that research using cloning technologies and involving the use of embryos may only be undertaken pursuant to a licence.

Recommendation 13

The Committee recommends that a licence for research using cloning technologies and involving the use of embryos only be granted if the licensing body is satisfied of the matters listed in paragraph 12.43 and that informed consent has been granted by all relevant persons.

Recommendation 14

The Committee recommends that the licensing body develop detailed guidelines specifying the requirements for informed consent and take into account the matters discussed in paragraphs 12.69-12.77 in developing these guidelines.

Recommendation 15

The Committee recommends that the Government establish an independent review of the institutional ethics committee system in Australia.

Recommendation 16

The Committee recommends that all Commonwealth Departments refer to the licensing body for guidance where a matter arises that involves the use of human reproductive material, embryonic stem cell research or cloning research.

Executive summary

INTRODUCTION

E1 The terms of reference for the inquiry were for the House of Representatives Standing Committee on Legal and Constitutional Affairs (the Committee) to review the report of the Australian Health Ethics Committee (AHEC) entitled *Scientific, Ethical and Regulatory Considerations Relevant to cloning of Human Beings.* The report was presented on 16 December 1998. The Committee considered the AHEC report and its recommendations carefully and found that it provided a thorough scientific review of developments prior to its completion and a useful summary of the ethical issues as they were perceived at the time.

E2 Since AHEC reported a great deal of scientific progress has been made. The Committee outlines this progress and has built on AHEC's report in developing its own recommendations. It hopes that this report will inform the public and contribute to development of the community debate on these issues. The Committee recommends a regulatory mechanism within which the research can progress in an appropriate way.

SCIENTIFIC ISSUES

E3 Chapters 2, 3 and 4 summarise the scientific principles, processes and issues related to cloning and stem cell technologies. Chapter 2 provides an outline of human reproductive processes and assisted reproductive technologies, and the research techniques relevant to the cloning of human tissues, organs or whole individuals. The AHEC report defines cloning as 'asexual propagation without altering the nuclear genome' and distinguishes between procedures for the cloning of a whole human being and the copying of the component parts of a human (such as DNA and cells). The Academy of Science developed the following definitions which recognise the different purposes for cloning and distinguish between the cloning of a whole human individual and cloning of cells and tissues:

- the production of a cell or organism with the same nuclear genome as another cell or organism;

- reproductive cloning: to produce a human foetus by nuclear replacement
- therapeutic cloning: to produce human stem cells, tissues and organs.

E4 The Committee acknowledges that the existing definitions of cloning are confusing and notes that cloning does not necessarily mean the replication of a whole individual. Many natural clones exist in the plant and animal kingdoms, including identical twins in humans. Cloning techniques may be used to duplicate DNA, cells, organs or whole individuals.

E5 The principal research techniques described are somatic cell nuclear transfer, the procedure that resulted in the birth of Dolly; the derivation of embryonic stem cells and embryonic germ cells; and current developments with adult stem cells. Somatic cell nuclear transfer involves the fusion (using an electric pulse) of a somatic cell from an 'adult' (foetal, juvenile or adult) animal with an unfertilised enucleated egg. The resulting 'embryo' is transferred to the uterus of a surrogate mother for development. The failure rate of this technique is currently very high.

E6 Embryonic stem cells are removed from the inner cell mass of a 6-7 day old embryo (blastocyst). They can replicate in culture indefinitely and can differentiate into a wide range of specialised cells.

E7 Adult stem cells, found in organs and tissues of the body throughout life, are difficult to identify, isolate and grow in culture. They are thought to be less flexible than embryonic stem cells, capable of differentiating into a more restricted range of specialised cells. An attraction of adult stem cells is that their isolation does not involve the destruction of an embryo.

E8 Brief reference is made to other technologies such as embryo splitting, cross species cell transfer and ooplasmic transfer. In considering the advantages and challenges of these procedures, the Committee noted the rapid pace of research in cell and developmental biology that will produce greater understanding and an appreciation of potential applications in the next few years. The Committee proposes that the field be monitored closely as new discoveries may have repercussions on the related ethical and regulatory dimensions.

Scientific conclusions by Australian Health Ethics Committee

E9 Chapter 3 presents the scientific conclusions from the AHEC report, and the recommendations of the Australian Academy of Science resulting from a review of the status and future directions of cloning and stem cell technologies. This chapter reports the evidence presented to the Committee on the scientific aspects of cloning for reproductive purposes and cloning for therapeutic purposes. The Committee notes that Australian scientists do not approve of the use of cloning

technologies to create a whole human being or wish to be involved in such work. The evidence presented raised concerns about the current high failure rate and risks of abnormalities caused by present reproductive cloning techniques.

E10 Scientists and members of the general public presenting evidence recognised the potential importance of 'therapeutic cloning' to medicine including the supply of tissue for transplantation, research into early human development and the discovery of factors which direct cell differentiation and tissue regeneration. However, a more cautious view expressed by some of the researchers in the field is that therapeutic cloning may prove too inefficient and expensive to become a routine clinical procedure. The potential applications of embryonic and adult stem cell research are considered, together with those of the cell signals that influence cell lineage development, currently the focus of much research.

E11 Evidence on the relative advantages and disadvantages of embryonic and adult stem cells is considered and it is noted that for the moment, embryos are required for the derivation of embryonic stem cells. Many scientists both in Australia and internationally dispute the assertion that adult stem cells will soon replace embryonic stem cells in their importance for basic or applied research, and believe that for the foreseeable future the study of embryonic stem cells derived from embryos is crucial to progress.

E12 Transdifferentiation or dedifferentiation of somatic cells is a fast emerging priority for research, as understanding cell flexibility may hold the potential for more specifically designed therapies for individual persons and diseases, while avoiding the need for embryos.

International and Australian scientific research

E13 Chapter 4 provides a few examples of the research being conducted in the United Kingdom, America and elsewhere. It notes the evidence from Australian scientists on Australia's international standing in the field and gives some examples of current Australian research. It looks briefly at funding of stem cell research in Australia and the predicted timeframes for results. Although it is difficult to predict, a 5–10 year projection for clinical trials of therapies was made by some of the scientists involved. The intellectual property and potential commercial applications from the field could hold significant advantage for Australia.

E14 The AHEC report suggested that existing non-human primate research facilities in Australia might be expanded, or a facility for developmental biology or embryology might be established. The Committee considered evidence presented on the need for basic research, including that on primates. While the Committee supports the need for more basic research including that in animals, it does not

support the establishment of a separate primate facility in Australia for cloning and stem cell research. Current priorities are to focus on human cell differentiation.

E15 In supporting the need for research towards new cell therapies, the Committee also notes the concern expressed in some submissions that 'state of the art' research such as therapeutic cloning should not diminish the importance of less expensive, lower technology research that may also deliver results.

ETHICAL ISSUES

E16 Chapters 5, 6 and 7 discuss the ethical issues raised by human cloning and related research. Chapter 5 provides an introduction by outlining, and commenting on, the discussion of ethical issues in the AHEC report.

E17 Chapter 6 considers the issue of 'reproductive cloning', that is, the use of cloning techniques for reproductive purposes in order to produce a whole human being. There has been almost total condemnation of the proposition that a whole human being might be replicated. The Committee agrees and totally rejects the use of cloning techniques for reproductive purposes, that is, to produce a child. The Committee believes that cloning for reproductive purposes is unacceptable. While the Committee holds this view unanimously, individual members reached this conclusion for a variety of reasons encompassing ethical, medical, legal and/or social considerations. The Committee emphasises that its conclusions are equally applicable to the use of any future technologies for the purpose of the artificial creation of whole human beings.

E18 The use of cloning technology for the purpose of the implantation, gestation and birth of a whole human being is not the only aspect of cloning related research that aroused passionate interest and comment during the inquiry. Ethical issues have also arisen in relation to more general research involving cloning techniques and the possible application of these techniques to treat illness. Chapter 7 considers the ethical issues in relation to the use of stem cells (including embryonic stem cells) and embryos in research. 'Embryos' in this context may include embryos that are surplus to assisted reproductive technology programs and embryos created by somatic cell nuclear transfer techniques.

E19 Chapter 7 considers the key issue of whether there are benefits to be obtained from applying cloning techniques to human beings. Having concluded that there are potential benefits to be gained, the Committee considers whether research involving the use of stem cells, embryos and cloning technologies should be permitted in order to realise those potential benefits and, if so, within what parameters. Members of the Committee hold different views on some of these matters but agreed on the parameters within which research involving the use of

embryonic stem cells and embryos surplus to assisted reproductive technology programs should be permitted.

REGULATORY ISSUES

E20 Regulatory issues relevant to human cloning and its related research are discussed in Chapters 8-12. Chapters 8 and 9 provide an outline of the legislative and non-legislative framework that currently regulates human cloning and research involving embryos in Australia. As a result of its review of this framework the Committee considers the current regulatory framework governing these matters is unsatisfactory and outdated. In addition to legislative regulation in three States there is a system of self-regulation coupled with non-legislative national guidelines applied by individual institutional ethics committees. The system is complicated, confused, inconsistent and ad hoc. It is difficult for the public to understand and lacking in transparency and accountability. One of the greatest inadequacies of the current regulatory framework is its differing application to the public and private sectors in many States and Territories. This does not assist researchers, businesses, investors or citizens who must try to navigate their way through this intricate array of regulatory arrangements. It is also unfair that such different regulations apply to citizens living in different States and Territories.

E21 The Committee asserts that consistent regulation must be applied to both publicly and privately funded research and that the current regulatory framework should not continue. The questions raised by human cloning and research involving the use of embryos are social questions and should not be left to ethics committees to decide. Nor should the answer to such fundamental questions depend on geography or source of funding. It is vital to ensure public knowledge of, and confidence in, the regulatory processes in place.

E22 A number of inquiries and consultation exercises have been conducted in various countries addressing the potential benefits and difficulties posed by human cloning and its related research and assessing the potential ethical and regulatory implications of the research. Some recent initiatives in the regulation of human cloning and research involving the use of embryos in the international sphere are outlined in Chapter 10. It has not been possible to outline comprehensively all international developments. Multilateral instruments developed by the Council of Europe and the United Nations Educational, Scientific and Cultural Organisation (UNESCO) are canvassed as well as recent significant regulatory developments in the United States of America and the United Kingdom. Several factors emerged relevant to Australia's consideration of the issues arising from human cloning and related research emerged as a result of this overview. These included the consistent condemnation of cloning for

reproductive purposes, the attempts to balance the harnessing of the potential of stem cell research with the protection of the human embryo, and the problems created by distinguishing between publicly and privately funded research for the purposes of regulation.

E23 In Chapter 11 the Committee responds to the recommendations made by AHEC and considers options for the regulation of human cloning and its related research. Chapter 12 outlines the Committee's proposed framework to regulate human cloning and related research in Australia. This report is advisory; if Australian governments and parliaments decide to regulate human cloning involving stem cells derived from embryos surplus to assisted reproductive technology programs, all Committee members agree on the proposed system of regulation outlined in Chapter 12 of the report. Those members who believe the use of embryos in research is unethical agree that if such research is permitted that it be undertaken within clear parameters. In summary, the Committee's proposed regulatory framework would have the following features:

- a national uniform legislative approach;
- a ban on cloning for reproductive purposes;
- one system of regulation for privately and publicly funded research**;**
- legislation regulating human cloning and stem cell research to be separate from that governing artificial reproductive technologies (ART);
- any attempt to undertake cloning for reproductive purposes to be subject to criminal penalty and the withdrawal of a licence to undertake research in this area;
- research using cloning techniques be subject to clear legislative parameters, including (subject to the moratorium referred to in paragraph 12.42) a complete ban on the deliberate creation of embryos for research purposes;
- a national licensing body be established to regulate human cloning and research using cloning techniques;
- individual researchers to be licensed for each research project that involves the use of an embryo;
- the import and export of embryonic stem cells should be permitted within the framework of principles outlined in this report, that is, it should be permissible to import or export embryonic stem cell lines that are already in existence or have been created using embryos that are surplus to the requirements of assisted reproductive technology programs. The import or export of embryos for the purposes of cloning related research need not

occur. As there is no evidence to suggest that this is required, the Committee is not convinced that it is appropriate or necessary; and

- the regulatory framework must be transparent, accountable and responsive.

E24 The legislation should permit the licensing body to issue a licence for a person to use a surplus embryo from an assisted reproductive technology program for research or therapy that damages or destroys the embryo where that project has the approval of both an institutional ethics committee (IEC) established, composed and conducted in accordance with NHMRC guidelines and the national licensing body proposed in this report, and that the approval is given on the basis that:

- there is a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed procedure;
- the significant advance in knowledge or improvement in technologies could not reasonably be achieved by other means;
- the procedure involves a restricted number of embryos and a separate account of the use of each embryo is provided to the IEC and the national licensing body (as is the case with animal research);
- all tissue and gamete providers involved and their spouses or domestic partners, if any, have consented to the specific form of research for each embryo used;
- no animal tissue or animal gametes are used to form a human-animal hybrid embryo;
- no embryo that has been the subject of cloning technology, or produced other than by fertilisation of a human ovum by a human sperm is ever transferred to the body of a woman or otherwise allowed to survive beyond the stage at which a blastocyst forms or the age by which a blastocyst would normally have formed;
- no human embryo is ever allowed to be transferred to the body of an animal or to be artificially gestated;
- no attempt is made to form embryos using stem cells or stem cell cultures; and
- a licence has been granted for the use of the embryo.

SUMMARY OF RECOMMENDATIONS

If Australian governments and parliaments decide to regulate human cloning involving existing stem cell lines derived from embryos surplus to assisted reproductive technology programs, all Committee members agree on the

proposed system of regulation outlined in Chapter 12. Those members of the Committee who believe the use of embryos in research is unethical agree, however, that if such research is permitted it should be undertaken within clear parameters.

Recommendation 1: the enactment of legislation by the Commonwealth to regulate human cloning and stem cell research.

Recommendation 2: that legislation regulating human cloning and stem cell research cover all research in this area, both publicly and privately funded.

Recommendation 3: that the regulation of research involving the use of cloning technology should be separate from that governing assisted reproductive technologies.

Recommendation 4: that the legislation regulating human cloning and stem cell research contain a ban on cloning for reproductive purposes. Any attempt to undertake cloning for reproductive purposes should result in a criminal penalty and the withdrawal of a licence to undertake research in this area for the individual concerned.

Recommendation 5: that the Commonwealth regulate human cloning and stem cell research within the strict parameters outlined in paragraphs 12.41-12.43.

Recommendation 6: that a national licensing body be established to regulate any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 7: that a licence issued by the national licensing body should be required to undertake any research involving the isolation, creation and use of embryonic stem cells.

Recommendation 8: that the national licensing body have the responsibilities listed in paragraph 12.55.

Recommendation 9: that AHEC be responsible for monitoring scientific developments in this area, analysing their potential impact and providing advice to Commonwealth, State and Territory governments on these matters.

Recommendation 10: that individuals and organisations be licensed for each research activity involving the isolation, creation and use of embryonic stem cells they intend to undertake.

Recommendation 11: that the matters listed in paragraph 12.63 be prohibited. Such a prohibition would mean that the licensing body would not have the authority to issue a licence for research involving any of the items listed in paragraph 12.63.

Recommendation 12: that research using cloning technologies and involving the use of embryos may only be undertaken pursuant to a licence.

Recommendation 13: that a licence for research using cloning technologies and involving the use of embryos only be granted if the licensing body is satisfied of the matters listed in paragraph 12.43 and that informed consent has been granted by all relevant persons.

Recommendation 14: that the licensing body develop detailed guidelines specifying the requirements for informed consent and take into account the matters discussed in paragraphs 12.69-12.77 in developing these guidelines.

Recommendation 15: that the government establish an independent review of the institutional ethics committee system in Australia.

Recommendation 16: that all Commonwealth departments refer to the licensing body for guidance where a matter arises that involves the use of human reproductive material, embryonic stem cell research or cloning research.