Submission to
Lockhart Review Committee

Prohibition of Human Cloning Act 2002

and

Research Involving Human Embryos Act 2002

September 2005

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Abbreviations

Centre	Australian Stem Cell Centre
NH&MRC	National Health & Medical Research Council
SCNT	Somatic cell nuclear transfer
IVF	*In vitro* fertilisation

Overview

The Australian Stem Cell Centre was established in May 2002 as the first Australian Biotechnology Centre of Excellence, with the principal goal of integrating a national multi-institutional research program involving stem cells and related technologies to ultimately develop treatments for human diseases.

The existing legislation, namely the ***Prohibition of Human Cloning Act 2002*** and the ***Research Involving Human Embryos Act 2002,*** has effectively provided a national functional framework that has enabled the Centre to take the first important steps toward achieving its goal.

The Centre believes the development and adoption of national legislation, complemented by state legislation regulating embryo research, has contributed to this country's current high standards and scientific position as leaders in quality human embryonic stem cell research. Therefore, the Centre fully supports the maintenance of national legislation to ensure the regulation and continued advancement of ethical, high quality and competitive human embryonic and adult stem cell research in Australia.

Adoption of the suggestions and recommendations set out in this submission would not only further assist the Centre in achieving its goals, but would also considerably enhance Australia's international competitiveness in stem cell research.

On 30 May 2002, the Prime Minister announced the successful applicant for Australia's first Biotechnology Centre of Excellence: the Centre for Stem Cells and Tissue Repair, now known as the Australian Stem Cell Centre Limited. The Prime Minister's comments[1] when making the announcement remain relevant to the Lockhart Committee's review of the legislation, as they help set this whole review into a proper context. The Prime Minister noted

> *"... This centre … will ... provide the vehicle for Australia to compete in the rapidly growing area of tissue regeneration and cell therapies. A key area of research will be the potential application of both adult and embryonic stem cells in the treatment of diabetes, vascular, bone and nerve damage, kidney disease and diseases of the blood and the skin. The centre will be truly national with its headquarters in Victoria and nodes in South Australia, New South Wales, Queensland and the Australian Capital Territory, providing a valuable boost to the Australian biotechnology industry. … I hope that the centre will attract the world's best researchers to Australia, especially many of our best and brightest who are currently working overseas.*
>
> *"This is a very exciting day for Australian research, it really is. One of the goals of Backing Australia's Ability was to put Australia's name up in lights in two specific areas by establishing centres of excellence. You have to specialise, you have to carve out some organisations and units that are better than any others and you've got to give them the financial support to achieve their goals. … and I think there'll be great excitement in the Australian research community because the potential, particularly in the area of biotechnology and stem cell research, is quite literally unlimited. And I want as Prime Minister, I want Australia to be up there with more than a reasonable slice of the action."*

The Commonwealth legislation under review, when coupled with mirror State legislation, has provided a useful national framework. However, the legislative framework in its current form will not enable the Centre to fully achieve the goals set for it when it was chosen as Australia's first Biotechnology Centre of Excellence in 2002. Unless the legislative framework is modified, the Centre will not be able to:

1 http://www.pm.gov.au/news/speeches/2002/speech1675.htm

1. fully undertake leading research in a key identified area, namely human embryonic stem cell research;
2. retain and attract the best researchers to Australia in this area of research;
3. specialise, and make proper use of significant taxpayer funding, to explore the *full extent* of the potential in stem cell research;
4. establish important scientific collaborations with highly regarded research groups in jurisdictions that allow activities that are not currently allowed in Australia under Australian law; and
5. ensure that Australia is "up there with more than a reasonable slice of the action".

The submissions below, if accepted by the Committee and ultimately acted upon by all relevant Governments, would not only positively assist the Centre in achieving its goals and enable the Centre to be an active collaborator on a global scale, but would also enhance Australia's international reputation for ground-breaking stem cell research conducted in a legal, ethical and socially responsible manner.

Summary of Recommendations

The Centre supports:

- a continued ban on human reproductive cloning;
- the continuation of a national co-ordinated approach, including legislative and licensing framework, to ensure that Australia's position in ethical human stem cell research, embryo and adult, is enhanced;
- continued ethical access to excess ART embryos for deriving new human embryonic stem cell lines for research purposes;
- the use of somatic cell nuclear transfer (SCNT) as a means of deriving disease specific stem cells for research purposes under an ethical license regime; and
- an amendment to existing Australian Customs Regulations to allow the import and export of SCNT derived cell lines, either generally or from nominated Centres.

Scope of Submission

The intent of this submission is for the Centre, in accordance with its obligations to the Commonwealth, to take a leadership role in the development of Australia's research expertise in the biotechnology sector and to propose changes which will enable Australian researchers to remain part of, and so reap benefit from, the exciting advances in medical research that are occurring in stem cell research.

Our submission describes and discusses scientific matters relevant to the Lockhart Review Committee's investigation only insofar as such scientific matters pertain to stem cell research and related technologies. We have deliberately excluded from our discussion implications for research relating to assisted reproductive technology (ie ART, meaning all fertility treatments in which eggs or sperm are manipulated), save for where those factors may impinge upon the development of stem cell research.

In preparing this submission, the Centre has consulted widely with its stakeholders and collaborators, as described in the Consultation Process on page 15.

While the Centre necessarily presents a single point of view on a number of issues, which represents a consensus, we acknowledge that this may not in every instance be exactly aligned with the views of individual stakeholders, employees or funded researchers represented by the Centre in this document.

Recommendations

1. **The Centre supports a ban on human reproductive cloning.**

   The Centre fully supports a continued ban on human reproductive cloning. There is no equivocation on the part of the Centre with respect to its view on this matter. This recommendation is supported unanimously.

2. **The Centre supports the continuation of a national co-ordinated approach to ensure that Australia's position in ethical human stem cell research, embryo and adult, is not compromised.**

   The business plan of the Centre is commercial in confidence. However, it is publicly known that the Centre is focussing not just on stem cells (adult and embryo), not just on tissue repair and not just on immune modulation. The Centre is taking a coordinated approach to maximise the potential benefit from one research program to enhance the outcomes and advance research in another. This approach is a deliberate strategy of the Centre because, as was said in a recent editorial in *Nature Biotechnology* "it is too early too leap to grand conclusions about which types of cells – whether embryonic or adult stem cells – will prove more useful. It is also too early to know which approaches will work in which conditions."[2] At this stage, the preponderance of scientific evidence would suggest there will probably be an ongoing role for both embryonic and adult stem cell research.

   To ensure that Australia does not to waste its resources - financial, intellectual capital and social even-handedness - it is vital that the State, Territory and Commonwealth Governments work together to ensure a consistent legislative framework is in place. The inherent strength of the Centre's design, in being a national and multi-nodal centre, will ultimately be sub-optimal if the Centre is not able to fully access stem cell resources and draw on and deploy the broad spectrum of research expertise available to it throughout Australia and the rest of the world.

[2] Nat. Biotechnol. **23**, 763 (2005)

3. The Centre supports continued ethical access to excess ART embryos for deriving new human embryonic stem cell lines for research purposes.

Between 5 April 2002 and 5 April 2005, Australian researchers could obtain a license authorising the use of an excess ART embryos that had been created before 5 April 2002 and donated with consent to research. The moratorium was lifted by operation of section 46 of the *Research Involving Human Embryos Act 2002 (Cth)* in April this year. Any change to the present ability of researchers to access excess ART embryos, and in particular any reinstatement of the moratorium, would seriously hinder research in Australia. Australian researchers would be required to undertake research on a diminishing pool of embryos of variable quality that have spent an ever-increasing time in a frozen state and are therefore not optimal for research purposes. Australian researchers would be required to formulate leading edge research projects with this restricted pool of aged embryos which may compromise the quality of the research itself.

There is a strong case for the continuing effort to derive new human embryonic stem cell lines, particularly since this is a rapidly developing technology with constant improvements in the derivation and propagation of human embryonic stem cells, human feeder layers and improved media, coming to light. Importantly, as well as compromising the quality of the research, many of these older existing cell lines may present a potential safety hazard as they have been developed in vitro using animal products and therefore may cause problems such as the raising of unwanted antibodies. In addition, many of these lines are exhibiting genetic instability, and so their potential use in therapeutic applications has been called into question.[3]

Although many more cell lines have been reported in the literature since 2002, many of these are not well described and most are not in widespread circulation. Many existing cell lines have significant limitations, including derivation under sub-optimal conditions and commercial restrictions that may restrict their use in certain projects. There is an inadequate understanding of how the properties of various existing cell lines derived and propagated under a variety of conditions compare with one another. There may well be certain desirable or less desirable features associated with particular cell lines which are a function of the particular growth conditions (which may/may not have been properly documented). To remedy some of these limitations on a global scale, there is an established co-ordinated analysis underway via the International Stem Cell Initiative to evaluate and standardise all human embryonic stem cell lines. Professor Martin Pera, Embryonic Stem Cell Program Director at the Centre, is one of four primary participating members worldwide.[4] Professor Pera and a number of other Australian scientists are embarking on their own derivation projects to yield at least another twenty six stem cell lines within the next two years. While controls and standardisation can be applied to the derivation of embryonic stem cell lines going forward, it is clearly impossible to correct the inadequacies of processes previously used to develop embryonic cell lines and accordingly, reliance exclusively on these old cell lines for research purposes must necessarily be similarly inadequate.

A further issue is to ensure that IVF couples will continue to have the option of donating to research the unused embryos that would otherwise be destroyed in the IVF process. It is important to note that the scientists interviewed for this submission are not arguing for indefinite or unlimited access to embryos for research for any purpose. Fundamentally, they and the Centre believe that donors should be given an informed opportunity to consider a variety of options with respect to their excess embryos:

1. donation to another couple for the purpose of achieving a pregnancy;

2. donation to dedicated embryo research for the improvement of IVF techniques or training;

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[3] Nature Genetics paper from the Johns Hopkins group: Anirban Maitra et al. Genomic alterations in cultured human embryonic stem cells; Published online: 4 September 2005; | doi:10.1038/ng1631

[4] Andrews PW *et al.* 2005. The International Stem Cell Initiative: toward benchmarks for human embryonic stem cell research. *NatBiotech* 23(7):795-97

3. donation to embryonic stem cell research; or

4. destruction of their spare embryos according to their wishes.

At present it appears that a reasonable number of Australian donors are prepared to commit their excess embryos to research which has, to date, provided an adequate pool of embryos available to research projects under license.

A second issue relates to the sourcing of defective embryos which would be useful to scientists wishing to understand and address these defects. Unfortunately, under current Australian law, these embryos are not available to scientists. Therefore it is common practice during pre-implantation genetic diagnosis in IVF clinics to destroy, rather than donate to research, all embryos that have been identified as having genetic defects or disease. The potential benefits for the study of disease by developing disease-affected stem cell lines are self-evident, but unfortunately at this stage, not possible.

4. The Centre supports a provision to allow the use of somatic cell nuclear transfer (SCNT) as a means of deriving new disease specific stem cell lines.

The Centre is mindful of the intense ethical debate in this area. The Issues Paper describes the debate as being polarised. Longitudinal perception research conducted by Biotechnology Australia[5] suggests that perhaps the debate in Australia is in fact not evenly polarised into two opposite points of view. There appears to be a clear majority of community support for stem cells being derived from excess human embryos which would otherwise be discarded. In the last four years, a steady and perceptible increase in community support for deriving stem cells from excess embryos is evident. This majority approval is mirrored in other countries such as the United States, as revealed recently in a poll conducted by Research America.[6]

If, as appears to be the case, the underlying concern about SCNT is that an embryo is created only to be destroyed once the stem cells have been taken, then it is noteworthy that the present regulatory regime in Australia prevents any alternative models for SCNT being investigated and developed. Any investigation of an alternative model potentially raising fewer ethical concerns is precluded by the terms of the *Prohibition of Human Cloning Act 2002* and in particular Section 12.

SCNT should be viewed as an important tool for reprogramming an adult cell genome in an experimental environment and not as a procedure related to reproductive biology. Understanding the reprogramming of an adult cell nucleus to achieve a pluripotent state would have far-reaching beneficial implications for biology and medicine. Ultimately, such an understanding might eventually obviate the need to use eggs or produce embryos at all, because it could be applied directly to the reprogramming of adult cells. In addition, understanding reprogramming would also increase our knowledge of tissue stem cell plasticity (the conversion of one type of tissue stem cell into cells of another tissue). This important area of SCNT is currently entirely closed to Australian researchers.

SCNT offers a unique approach to the study of both multigenic and single gene disorders in humans. The availability of such cell lines would enable the study of the cellular basis of disease susceptibility and the testing of hypotheses concerning the involvement of specific genes for patients suffering from a number of serious diseases.

Stem cell lines can be created by using SCNT technology from individuals with a known genetic predisposition to a particular disease. These cell lines would be models for investigation of the cell biology and genetic basis of the given disease or disorder. Research into the reprogramming of human

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[5] Biotechnology Australia. www.biotechnologyaustralia.gov.au

[6] Research America. www.researchamerica.org

cells will yield new information into the human condition that is not available from the study of animal cells.

Without the ability to perform SCNT, elite researchers remaining in Australia will always be behind the lead of the top researchers in the United Kingdom and other countries where SCNT is lawful. Inevitably, without the ability to perform SCNT and collaborate on SCNT projects, the strategy and outlook for the Centre will also be hindered. Our attempts to fulfil and exceed the expectations of the broad Australian community, as expressed through the comments by the Prime Minister quoted at the start of this submission and reflected in recent research by Biotechnology Australia, will be stifled.

Put quite simply, if SCNT is not allowed in Australia then the potential for stem cell research, and resulting expected benefits for Australian's suffering from certain diseases, is limited. The unlimited potential of stem cells of which the Prime Minister spoke will remain but it will be fully explored, fully understood and fully harnessed outside Australia. In such circumstances, Australia is likely to see the defection of some of its most valuable and highly regarded human capital and may well become a consumer at the behest of the producer.

5. The Centre supports an amendment to existing Australian Customs Regulations to allow the import and export of SCNT derived cell lines

The Centre supports an amendment to the Customs (Prohibited Imports) Regulations 1956 to allow Australian researchers access to stem cells and stem cell lines derived from SCNT embryos developed overseas. If SCNT becomes lawful in Australia as a result of this review, co-extensive amendments must be made to allow importation of SCNT-derived cell lines in order for researchers in Australia to effectively use this technology. The amendments become even more critical to the survival of Australian stem cell research if, the Committee is of the view that Australian researchers may use SCNT-derived cell lines but should not be entitled to undertake SCNT experiments in Australia.

At present under those Regulations:

- **human embryo clone** has the meaning given by section 8 of the *Prohibition of Human Cloning Act 2002*;
- **viable material** means living tissue and cells;
- under regulation 3 (1), the importation of goods specified in Schedule 1 is prohibited absolutely; and
- item 27 in Schedule 1 of the Regulations is "viable material derived from human embryo clones".

Under the *Prohibition of Human Cloning Act 2002*, **human embryo clone** means a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilization of a human egg by human sperm.

Under this provision of the Act, an embryo created through SCNT would, by default, be captured within the definition of human embryo clone. Stem cells taken from such an embryo's blastocyst would also fall within the definition of viable material and so could not be imported.

There are a number of factors in support of a limited amendment of the Customs Regulations.

First, by allowing Australian researchers access in Australia to stem cell lines derived from an SCNT embryo originating in an overseas laboratory (rather than performing SCNT in Australia), the total number of SCNT-derived embryos created worldwide will be less than would otherwise be required. With the present degree of international collaboration amongst stem cell scientists, it is a reasonable assumption that groups would collaborate freely in developing a collection of unique SCNT derived cell lines amidst an intricately woven fabric of co-operation.

Second, by allowing Australian researchers access to stem cell lines derived from overseas, research can be conducted in Australia specifically to Australia's benefit. Australian scientists would have the freedom to collaborate on more equal terms. This amendment would also contribute significantly to the creation of a more attractive location for collaborative agreements with Australian groups and independent investment vital to the field.

Third, this amendment should enable the Australian public to be informed about the precise ethical and regulatory framework within which each particular SCNT embryo was derived and the controls employed by like-minded ethical institutes and organisations in other countries with similar licensing systems. Should it be considered necessary, we would not oppose an Australian licensing system which reviews and qualifies specific institutions seeking to import or export SCNT-derived cell lines.

Fourth, by importing stem cells from overseas the best use is made of resources (both the technical resources in performing SCNT and also the product resource) rather than each and every laboratory creating their own stem cell lines. We would therefore be minimising duplication and fostering a deeper spirit of co-operation.

The Centre believes that an appropriate licensing framework could either be accommodated through the present licensing framework within the NH&MRC or alternatively made in conjunction with the oversight function of an Australian Stem Cell Bank.

It is the belief of the Centre that Australian Customs Regulations regarding the import and export of embryos should remain unchanged.

The Committee's Issues Paper

The Lockhart Review Committee has produced a detailed and informative Issues Paper. The following addresses a number of specific issues and questions raised in the document, to the extent not already covered in our submission.

Definitions and Terminology

Save as discussed, the Centre has not been made aware of any problems in interpreting or applying any of the definitions or terminology in either Act. The Centre does have a few recommendations that may assist in clarifying a few terms to ensure a more accurate understanding of the terminology and associated technology.

The use of the term 'human cloning' in the *Issues* box, page 15 of the Issues Paper is probably intended to cover both reproductive cloning and the technique of SCNT. It perpetuates an unfortunate joining of two very distinct and technically very different technologies. One technology (reproductive cloning) is held in nearly universal ill-regard in Australia and most of the rest of the world. The other technology (SCNT) is viewed as having immense promise and benefit owing to its ability to generate specific cell lines and assist in the understanding of human disease, possibly enabling the development of advanced therapies not otherwise attainable. It should be noted that the SCNT procedure in and of itself is not therapeutic, it is a research procedure with research objectives. Its purpose is not the producing or enabling the production of a human being. Any attempt to use it for such purposes is not only ethically unacceptable, but scientifically totally unjustifiable.

Rather than use the term 'human embryo clone' for an embryo derived through SCNT technology, a more apt descriptive term may be 'SCNT embryo' or 'human nuclear transfer embryo', thereby clearly identifying its lineage and method of being brought into existence. The term 'human embryo clone' may suggest to some a misleading, implied purpose, being to give rise to a cloned human.

The Prohibition of Human Cloning Act 2002 should include the term 'somatic cell nuclear transfer' (SCNT) or 'cell nuclear replacement' (CNR) as in the legislation in the United Kingdom. This term should be described as the technique used to create an embryo from the nucleus of a cell, typically an adult somatic cell. The resulting 'nuclear transfer embryo' should be for research purposes only and should be explicitly banned from any use for the purpose of reproduction. If SCNT is allowed, the legislation should prohibit the implantation of the 'nuclear transfer embryo' into the body of a woman.

The question as to future problems arising regarding definitions and terminology emphasises the great unknown of regulating science generally, let alone in such a fast moving field as stem cell research.

Prohibited Embryos and Practices

It is evident from our submissions above that the current legislative framework has affected research in Australia in two ways: directly, because we are not allowed to conduct SCNT derived research; and indirectly, because we are not allowed to import cell lines derived from SCNT research and work on those cells. The consequence of each is that Australian researchers and institutions like the Centre are currently shackled in their ability to make collaborations with leading overseas institutions and researchers.

Without access to cell lines derived from SCNT research, Australia will inevitably doom itself to a secondary role in this area of research. With a continuing restrictive environment, other places such as the United Kingdom and the United States (with private funding only) which allow cutting edge research to be performed using this technology, will take the lead. Australia will not be in a position to retain, let alone attract, the required intellectual capital in the form of elite researchers; and similarly will not attract the financial investment required to support world class Australian stem cell research.

Certain overseas research institutions are rapidly gaining momentum in the area of SCNT research, however it is not too late to allow Australian researchers to begin utilising SCNT in Australia. Giving them access to SCNT cell lines will enable them to once again take the lead in this important area of stem cell research.

Use of Excess ART Embryos

We have previously described in this submission the clear need of the Australian Stem Cell Centre for continued access to ART embryos. The need for the derivation of new stem cell lines must not be underestimated. The research strategy and output of the Centre will be adversely affected by the inability to access excess ART embryos or the reinstatement of a "sunset clause" in the legislation which has the effect of delaying such access.

Licensing and Statutory Arrangements

The Centre is not a party to any of the embryo research licenses, but is, or will be, a collaborator with a number of license holders.

The provisions of the *Research Involving Human Embryos Act 2002 (Cth)* appear sufficient to ensure a complete separation of the production and clinical use of IVF embryos on the one hand, and proper consent regarding the donation of spare embryos to research on the other.

Importantly, there must be a strong scientific case made before a license is issued by the NH&MRC Licensing Committee. In issuing a license, the Committee restricts the number of excess ART embryos that may be used and takes into account the likelihood that the licensed project will contribute significant new knowledge to the field. However, two of the factors to be taken into account, section 21 (4) (a) and (b) are problematic because no objective measures exist for determining how many embryos will be needed for a research project or the significance of the outcome of that project.

Further, the Centre believes that the ability of researchers to plan their activities is hampered by the existing open-ended decision making process of the licensing system. The Centre acknowledges that due care is vital when evaluating an application and that some extra time to do so was required in the 'start-up' phase of the licensing system. However, now that the system is established and protocols are in place, a reasonable maximum response time should be stated as a matter of natural justice.

Finally, the jurisdiction of the NH&MRC Licensing Committee after the embryonic stem cell line has been derived requires clarification, and has a bearing on the assessment by that Committee of the scientific purpose of the project. An application to create new human embryonic stem cell lines is necessarily unable to include details of how those cells will be used by the applicant or third parties. The Centre believes it is neither feasible nor practical for the jurisdiction of the Licensing Committee to extend beyond the step whereby the derivation of the cell lines is complete (and no longer considered reproductive tissue). The existing regulatory framework provides adequate oversight to monitor the use of human cells for research purposes and assure that they are used in a responsible and ethical manner.

International Exchanges of Embryos and Stem Cell lines

As discussed previously, the Centre believes that the Australian Customs Regulations should be amended to allow for the import and export of cell lines derived from SCNT technology under a licensing protocol. Cell lines, regardless of the technology employed to derive the lines, should be seen as 'human tissue' not unlike human organs which are donated for research or transplanted, or human blood which is analysed or transfused.

The prohibition of payment for gametes and embryos has not adversely affected research in Australia. The Centre supports the ongoing prohibition of payment. Under the present system, it appears that there is no immediate danger of a shortage of donated embryos which could be made available for research purposes. Though the donation rate to stem cell research is relatively small, it is at present sufficient to provide an adequate pool of embryos for research purposes in this country.

National Stem Cell Bank

The Australian Stem Cell Centre has established a complementary Major National Research Facility (MNRF). The MNRF facility, based in Melbourne, has received support funding from both the Victorian and Australian Governments. The Australian Stem Cell Centre, supported by the MNRF, is the logical organisation to oversee a national stem cell bank. Presently the MNRF facility offers Mel 1 and Mel 2 cell lines for distribution to researchers free of encumbrances. To develop the Major National Research Facility's capacity to also become a national stem cell bank for the region would require additional funding and infrastructure. The Major National Research Facility has an existing Access Committee, with an independent chairman, that determines policies and structure regarding access by scientific groups around the country to use the facilities in Melbourne.

The formal implementation of an Australian stem cell bank would enhance Australia's reputation as a leading producer of high quality cell lines. A national stem cell bank would have many positive features including:

1. ensuring regulatory and ethical compliance of all cell lines deposited;
2. standardizing the quality of all cell lines;
3. providing consistent complementary information and service advice with all cell lines;
4. conserving embryos; the Bank would reduce duplication of research to produce specific cell lines;
5. being a national (and eventually international) resource by requiring compulsory deposition of all Australian derived cell lines;
6. providing an independent assessment of the quality and standard of cell lines;
7. being a database of historical records of production and distribution of all cell lines;

8. monitoring the import and export of cell lines; and

9. providing a central body for the independent reporting requirement to licensing bodies.

The development of a national stem cell bank, when coupled with the implementation of the Centre's other submissions – principally, allowing SCNT technology in Australia and also amending Customs Regulations – would have great practical benefit for Australia and would greatly enhance Australia's reputation as a leader in stem cell research and development.

For example, SCNT was originally proposed as an effective means of producing patient-specific stem cell lines to be used to treat the patient by cell transplant while avoiding the risk of immune rejection. Although proof-of-concept has often been demonstrated for this use of SCNT, there remain practical obstacles to its application in the clinic. Despite such difficulties, it may be possible to use SCNT for the creation of banks of stem cell lines possessing specific genes (the so-called 'histocompatibility loci') that determine the compatibility of tissues. A bank of such stem cell lines specific for each locus could provide an effective tissue cell match for a significant proportion of the population.

Research Developments

Recent advances in knowledge from stem cell research have exceeded expectations in some areas of research and been disappointingly slow in others. The development of knowledge regarding the potential of adult stem cells and embryonic stem cells is evident by the wide number of excellent articles published in prestigious journals over the past three years.

Some notable advances would include both the initial proof-of-concept of human SCNT and a subsequent greatly enhanced efficiency of SCNT by Professor Woo Suk Hwang from Korea.[7]. At the time of the previous legislative debate, human SCNT had not been achieved and there was some controversy in the field as to whether it was in fact possible.

Within the last three years, Professor Hwang has shown that it is indeed possible and, in his recent paper in the journal *Science*, he has shown that it can be performed with a level of efficiency that greatly increases its potential therapeutic application. Thus, this technique is no longer theoretical; it has been proven, optimised, and is being performed in laboratories throughout the world.

Internationally, there has been the establishment of the International Society for Stem Cell Research (ISSCR), a collaborative membership of stem cell scientists from around the world (www.isscr.gov.org). The prestigious ISSCR Board includes a number of Australian representatives. The Australian Stem Cell Centre has sponsored and secured a bid to host the 2007 ISSCR meeting to be held in Cairns; the first time it will be hosted outside North America.

Nationally, an Australian Stem Cell Society has been established with representation from every State in Australia and growing interest from our Asia-Pacific neighbours. In November, the Centre's 3rd Annual Stem Cell Congress will be held in Queensland. It is predicted to attract more than a dozen international guests and approximately 300 stem cell scientists from around the region.

The International Stem Cell Forum (www.stemcellforum.org.uk) was established in January 2003. The aim was to bring together nine international funding agencies that were united in the belief that bilateral collaboration and information-sharing, thereby accelerating scientific progress and global practices in stem cell research. The Australian NH&MRC is a member of the Forum. A year later, membership has increased from nine to fourteen organisations.

[7] Woo Suk Hwang et al. *Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts* Science Jun 17, 2005. Vol. 308, Iss. 5729; p. 1777-1784.

The International Consortium of Stem Cell Networks was established in November 2004 in Montreal at the International Stem Cell Forum. Several countries had taken steps to create national stem cell research centres or networks. Network representatives met and agreed to form a collaborative group to create a research fabric that will bring together the world's best stem cell biologists, bioengineers, clinical practitioners, ethical and legal scholars to ensure the most efficient path to the development and execution of stem cell therapeutics. The International Consortium is a complementary vehicle of the Forum. Professor Stephen Livesey, Chief Scientific Officer of the Australian Stem Cell Centre, is co-Director of the International Consortium. The Victorian Government recently announced a two year funding grant to the Australian Stem Cell Centre to establish a secretariat for the International Consortium at the Centre's office in Melbourne.

In the past three years Stem Cell Ethics Australia, an independent organisation that aims to stimulate discussion on issues of ethics concerning stem cell research, has been established in Melbourne. It is representative of a broad range of views with members drawn from a range of disciplines and backgrounds.

The Australian Stem Cell Centre was established three years ago, at around the same time that the current legislation was enacted. The progress made by the Centre in developing a broad national approach toward the progress of stem cell research and regenerative medicine has been very successful. The four major platform technologies have numerous associated statements of work from scientific groups from around the country that are rigorously and systematically monitored and refined to achieve the most useful and valuable results. The Australian Stem Cell Centre is unquestionably one of the most ambitious and progressive partnerships between the Commonwealth, the scientific community and academia. The Centre believes one of the key future critical success factors in this research field is the investment in building highly trained human capital and intellectual assets. The Centre has committed approximately $400,000 in support of eight PhD students in the field of stem cell science and philosophy, with four more planned to enter the scholarship program next year.

Commercially, since its inception three years ago, the Centre has filed an impressive number of patents and created a valuable portfolio of intellectual property derived from the world-class scientific research undertaken by researchers funded by the Centre. We believe this portfolio will deliver significant benefits to all stakeholders, which ultimately includes the Australian community as well as individuals suffering from disease around the world.

This Legislative Review is timely. The community continues to support stem cells derived from embryos, as evident by Biotechnology Australia's perception and awareness research (www.biotechnology.gov.au). The proposed changes to allow SCNT and the amendment of Australian Customs Regulations pertaining to stem cell lines are in accordance with scientific advances recently reported in the scientific press and in Australia. We believe these legislative changes are imperative; they will enable the Australian Stem Cell Centre to fulfil the expectations of the Prime Minister and the public by exploring the potential of stem cells to its greatest extent with the goal of providing improved treatments for people suffering from disease.

Australian Stem Cell Centre
September 2005

Consultation Process for the Preparation of Position Paper

The Australian Stem Cell Centre is, by deliberate design, a collaborative environment that encourages consultation. At every level the Centre invites independent review of its procedures and processes to ensure the outcomes are consistent and unbiased. This process is vital to the identification and advancement of high quality science: it is also critical to the spirit of collaboration in general and the essence of the Australian Stem Cell Centre.

This submission has been a collaborative effort bringing together the thoughts and opinions of more than 60 scientists, biotechnology executives, board members and administrators, all with a common goal to ensure Australia's position at the frontline of research.

Inevitably this paper cannot precisely represent the specific views of each person associated with the Centre. The Centre's stakeholders and wider scientific community each hold their own independent view of the legislation, each view is different from the next and falls within a broad spectrum of beliefs. The Centre's role is to reasonably represent all of its stakeholders; therefore this submission endeavours to reflect the majority view. The Centre respects the views of individuals.

To accurately and equitably capture the diversity of views from the scientific community in which the Centre operates, this paper was initially drafted after interviews with scientists and executives including; Dr Hugh Niall, Professor Stephen Livesey, Dr Dianna DeVore, Professor Alan Trounson, Professor Martin Pera, Professor Peter Rathjen, Associate Professor Melissa Little and Professor Richard Harvey.

Once the initial draft was complete the paper was then reviewed by a representative group of senior scientists and the executive management group.

The final draft of this submission, incorporating all of the comments, discussion, suggestions and recommendations was finally presented to the Board of the Australian Stem Cell Centre for comment and approval. Once approval was granted, the paper was cleared for public distribution.

The distribution of this submission includes:

- the Lockhart Review Committee;
- all stakeholders of the Australian Stem Cell Centre;
- all scientists and employees of the Australian Stem Cell Centre;
- the Australian stem cell community and industry, and
- the general public via the Australian Stem Cell Centre website (www.stemcellcentre.edu.au).