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VICTORIAN PARLIAMENTARY INTERNSHIP
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PUBLIC ACCOUNTABILITY FOR TAX PAYERS' FUNDING OF STEM CELL RESEARCH

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TABLE OF CONTENTS

| | |
|---|-----------|
| EXECUTIVE SUMMARY..... | 4 |
| 1.0 INTRODUCTION..... | 6 |
| 1.1 Terms of reference..... | 6 |
| 1.2 Objectives of report..... | 7 |
| 1.3 Report methodology..... | 7 |
| 2.0 POLICY FRAMEWORK: SCIENCE, TECHNOLOGY AND INNOVATION | 8 |
| 2.1 Creating a ‘Culture of Innovation’..... | 8 |
| 2.2 State Policy Framework..... | 8 |
| 2.2.1 Victorians. Bright Ideas. Brilliant Future..... | 9 |
| 2.2.2 Biotechnology Strategic Development Plan..... | 10 |
| 2.2.3 Healthy Futures: Delivering better health, research & jobs for Victorians.... | 10 |
| 2.2.4 Leveraged Funding..... | 10 |
| 2.3 National Policy Framework..... | 12 |
| 2.3.1 Backing Australia’s Ability I and II..... | 12 |
| 2.3.2 The Biotechnology Centre of Excellence..... | 12 |
| 2.4 Conclusion..... | 12 |
| 3.0 FUNDING FRAMEWORK: THE AUSTRALIAN STEM CELL CENTRE..... | 13 |
| 3.1 ASCC Funding Sources..... | 13 |
| 3.2.1 Federal Government Funding..... | 13 |
| 3.2.2 State Government Funding..... | 13 |
| 3.2.3 Other revenue sources..... | 14 |
| 3.3 ASCC Funding Distribution..... | 14 |
| 3.4 Conclusions..... | 14 |
| 4.0 GOVERNANCE: THE AUSTRALIAN STEM CELL CENTRE..... | 16 |
| 4.1 ‘Good corporate governance’: a general definition..... | 16 |
| 4.2 ‘Good corporate governance’: a specific definition..... | 16 |
| 4.2.1 Statement of Ethical Principles for Biotechnology in Victoria..... | 16 |
| 4.3 Prima Facie Conclusions..... | 17 |
| 4.3.1 Principles of the Biotechnology Strategic Development Plan..... | 17 |

| | | |
|------------|---|-----------|
| 4.3.2 | Principles espoused by the ASCC..... | 18 |
| 4.4 | A Systematic Evaluation..... | 18 |
| 5.0 | TENDER AND SELECTION: THE AUSTRALIAN STEM CELL CENTRE..... | 19 |
| 5.1 | The process..... | 19 |
| 5.2 | Integrity of the process..... | 20 |
| 5.2.1 | <i>The Allen Report</i> | 21 |
| 5.3 | Conclusions..... | 21 |
| 6.0 | CURRENT FRAMEWORK AND PROCEDURES: THE AUSTRALIAN STEM CELL CENTRE..... | 22 |
| 6.1 | Current framework..... | 22 |
| 6.1.1 | Internal procedures..... | 22 |
| 6.1.2 | External procedures..... | 23 |
| 6.1.3 | Independent review..... | 24 |
| 6.2 | Funding and governance documentation..... | 24 |
| 6.2.1 | Problems with the corporatisation model..... | 26 |
| 6.2.2 | Areas for Improvement..... | 27 |
| 6.3 | Conclusions..... | 28 |
| 6.4 | Ethical Evaluations..... | 28 |
| 6.4.1 | Internal Ethics Committee..... | 28 |
| 6.4.2 | External Ethics Committees..... | 29 |
| 6.5 | Conclusions..... | 31 |
| 7.0 | FUTURE DIRECTIONS AND VIABILITY: THE AUSTRALIAN STEM CELL CENTRE..... | 33 |
| 7.1 | Future directions and viability..... | 33 |
| 7.1.1 | A strategic sustainability plan..... | 33 |
| 7.1.2 | Commercialisation of the science: stakeholders and intellectual property..... | 34 |
| 7.2 | Conclusions..... | 34 |
| 8.0 | CONCLUSION..... | 36 |
| | BIBLIOGRAPHY..... | 37 |
| | APPENDICES..... | 42 |

Executive Summary

Since coming to office in October 1999, the Victorian Government has invested more resources in Science, Technology and Innovation (STI) than any other Australian State. In what many predict will be the 'biotechnology age', this investment is positioning Victoria to become one of the top five biotechnology locations in the world by 2010.

However, whilst biotechnology has the potential to bring great benefits, it could also lead to adverse impacts. Therefore, it is imperative that governments ensure research and development in this area is underpinned by sound public policy. Governance and regulatory arrangements must ensure that ethical and safety standards are met, and that the community is well informed and confident about the direction of the biotechnology industry.

This is particularly important in highly sensitive and ethically contentious research areas such as stem cell research. There is an obligation on government to satisfy legitimate community concern in the allocation of significant public funds for this research.

This report examines the operation of the Australian Stem Cell Centre (ASCC), as an example of the extent to which the aforementioned imperatives can be said to be met.

The objectives of this report are to:

- Examine State and Federal Government STI policies
- Examine the ASCC as a key component of State and Federal Government STI policies
- Assess the governance arrangements that exist between the ASCC and State and Federal Governments
- Identify key areas in which governance arrangements between the ASCC and State and Federal Governments can be improved

This report considers these objectives by analysing the ASCC and its interaction with Government through three main phases of operation: tender and selection, working framework and procedures, and future directions and viability.

Research has indicated the following conclusions:

- The Victorian Government has spent an unprecedented amount on STI: \$1.6 billion from 1999-2006, compared to \$310 million from 1992-1999
- This expenditure has leveraged significant private and public sector contribution to research projects and developments within Victoria
- The ASCC is a key component of joint Federal and State innovation initiatives
- The ASCC has governance and funding arrangements with both State and Federal Governments to administer the practice of stem cell research

The ASCC operates in a highly complex legal, political and social environment. Its research relies heavily on public funding, and its practices are sensitive and sometimes controversial. Within this environment, good governance is especially important.

Although this report acknowledges the existence of some very sound governance structures, its overarching philosophy is that critical assessment is always a useful mechanism for improvement. This report identifies key areas for improvement.

These include:

- Ensuring that grant evaluation and selection is conducted with integrity, by constantly reviewing tender and selection processes
- Providing public access to higher level research strategies, objectives and target outcomes
- Assessing public interest versus commercial interest objectives, so as to ensure that one is not unreasonably subordinated to the other
- Ensuring that ethical evaluations are conducted by a truly external, independent, and sufficiently involved ethics committee
- Preparing a strategic continuity plan, involving detailed financial forecasting and modelling based on a variety of possible scenarios affecting future viability

1.0 Introduction

Since coming to office in October 1999, the Victorian Government has invested more resources in Science, Technology and Innovation (STI) than any other Australian State.¹ Its total \$1.6 billion investment has positioned Victoria to become one of the top five biotechnology locations in the world by 2010.²

Biotechnology is regarded as a research area, which will have profound affects on the future health and quality of our lives.³ Victoria (and indeed Australia) has demonstrated a sustained commitment to capitalising on what many predict will be the ‘biotechnology age’.⁴ It is expected that biotechnology will generate strong economic growth, retain and develop leading skills, and improve the wealth and future of our State.⁵

However, whilst biotechnology is recognised as a field with significant potential, it is not a practice without ethical or financial concern.⁶ Many facets of biotechnology research operate in complex scientific, social, environmental and political surrounds. Thus, it is important that the research is properly governed by both the responsible research institution and Government.

1.1 Terms of Reference

This report was commissioned to assess the governance structures that exist between the Australian Stem Cell Centre (ASCC) and the Victorian and Federal Governments. This example was selected to illustrate both general and case-specific issues of what constitutes

¹ Victorian Department of Innovation, Industry and Regional Development, *Victoria. Bright Ideas. Brilliant Future* (2002), p 4.

² Victorian Department of Innovation, Industry and Regional Development, *Revised Strategic Development Plan* (2004), p 7.

³ Victorian Department of Innovation, Industry and Regional Development, *Healthy Futures Statement* (2006), p 7.

⁴ Victorian Department of Innovation, Industry and Regional Development, *Revised Strategic Development Plan* (2004), p 5.

⁵ Victorian Department of Innovation, Industry and Regional Development, *Victoria. Bright Ideas. Brilliant Future* (2002), p 6.

⁶ Victorian Department of Innovation, Industry and Regional Development, *Revised Strategic Development Plan* (2004), p 9.

‘good governance,’ and includes a consideration of compliance with key performance indicators and the comprehensiveness of project evaluations.

Most of the existing literature on stem cell research (particularly embryonic stem cell research) is concerned with the ethics of the process and whether it should or should not take place. The terms of this report are somewhat unique because the report is not concerned with whether the research is ‘ethically’ or ‘morally’ justified, but rather, how well governed the process is.

1.2 Objectives of Report

The objectives of this report are to:

- Examine State and Federal Government STI policies
- Examine the ASCC as a key component of State and Federal Government STI policies
- Assess the governance arrangements that exist between the ASCC and State and Federal Governments
- Identify key areas in which governance arrangements between the ASCC and State and Federal Governments can be improved

1.3 Report methodology

This report considers these objectives by analysing the ASCC and its interaction with Government through three main phases of operation

- Tender and selection;
- Working framework and procedures; and
- Future directions and viability.

Analyses of both primary and secondary resources were used in the development of this report.

Recommendations are made accordingly.

2.0 Policy Framework: Science, Technology and Innovation (STI)

2.1 Creating a ‘Culture of Innovation’

The current Victorian and Commonwealth Governments, view innovation and commercialisation of science as a key driver for economic growth and international competitiveness. Through their respective STI policies, they strive to build world class infrastructure, attract, develop and retain leading skills, and create wealth and high value jobs through investment in the knowledge base.

2.2 State Policy Framework

Victorian Government expenditure on STI has increased approximately 500% since it came to power in 1999: from 1992-1999 the Liberal Party spent \$310 million on STI, compared to the record \$1.6 billion spent by the Labor Party from 1999-2006.⁷ Victoria has now made the largest commitment to innovation of any Australian State.⁸

Figure 2a:

| Victorian Government Investment in Science, Technology and Innovation since 1999 | |
|---|-------------------------|
| STI Initiative (including ASCC funding) | \$620 million |
| Medical Research Institute Support | \$330 million |
| Biotechnology Strategic Development Plan | \$34.5 million |
| Other ICT & Innovation Projects | \$618 million |
| National Biosecurity Centre | \$6 million |
| TOTAL | \$1.6085 billion |

Source: Victorian Department of Innovation, Industry and Regional Development, *Healthy Futures Statement* (2006)

⁷ Victorian Department of Innovation, Industry and Regional Development, *Healthy Futures Statement* (2006), p 13.

⁸ Victorian Department of Innovation, Industry and Regional Development, *Victoria. Bright Ideas. Brilliant Future* (2002), p 4.

In recognising the importance of a coordinated innovation effort, the Victorian Government created a new Ministerial Portfolio for Innovation, in February 2002.⁹ The Hon. John Brumby, Treasurer and Minister for State and Regional Development, was appointed Minister for Innovation. This appointment reflects the important role attributed to innovation in the economic development of the state. With his Treasury hat on, the Hon. John Brumby has been described as a ‘critical driver’ in the development of the Government’s innovation agenda.¹⁰

A number of policy documents have been produced to promote this agenda.

2.2.1 Victorians. Bright Ideas. Brilliant Future

In October 2002, the Victorian Government announced its Innovation Economy Policy in the Innovation Statement, *Victorians. Bright Ideas. Brilliant Future*.¹¹ At its centerpiece, was the declaration of a *Second Generation STI Initiative*, worth \$310 million. This built on the \$310 million already allocated under the *First Generation STI initiative* in 1999.¹²

The Innovation Statement identified six key performance areas:

- Building an educated and highly skilled workforce;
- Becoming a leader in knowledge creation and innovation;
- Developing linkages, clusters and networks to become a more integrated and networked local economy;
- Fostering high levels of enterprise formation and business growth;
- Becoming a globally focused and internationally integrated economy; and
- Creating a business environment and infrastructure base that facilitates business success.¹³

⁹ Victorian Department of Innovation, Industry and Regional Development, *Victoria. Bright Ideas. Brilliant Future* (2002), p 11.

¹⁰ Corrina Richards, Personal Interview conducted on 25 September, 2006. Corrina Richards is the General Manager Biotechnology Policy and Projects, Office of Science and Technology, Department of Innovation, Industry and Regional Development.

¹¹ Victorian Department of Innovation, Industry and Regional Development, *Victoria. Bright Ideas. Brilliant Future* (2002).

¹² Ibid.

¹³ Ibid.

Through the *STI Initiative*, the Victorian Government has already provided support for several major physical infrastructure projects including:

- A \$100 million commitment to building Australia's first Synchrotron;
- Support for the ASCC and Bio21 Institute projects; and
- Developing six key biotechnology research precincts.

Within this Innovation strategy, biotechnology is explicitly identified as a key strategic priority.¹⁴

2.2.2 *Biotechnology Strategic Development Plan*

This strong biotechnology focus is clarified in the Victorian Government's *Biotechnology Strategic Development Plan* (2001, 2004).¹⁵ This plan retains the central vision of Victoria becoming one of the top five biotechnology locations in the world by 2010.¹⁶ Victoria is already home to 40% of Australia's core and diversified biotechnology companies¹⁷ and 45% of Australia's biotechnology employees.¹⁸

2.2.3 *Healthy Futures: Delivering better health, research and jobs for Victorians*

*Healthy Futures: Delivering better health, research and jobs for Victorians*¹⁹ is the most recent statement of the Victorian Government's commitment to delivering strong support for life sciences, particularly medical research. Announced in 2006, a further \$230 million is to be invested in innovation initiatives.²⁰

2.2.4 Leveraged Funding

The *STI Initiative* has been highly successful in leveraging private and public sector investment. Under *STI First Generation*, for every \$1 of Victorian Government funds, on

¹⁴ Ibid, p 4.

¹⁵ Victorian Department of Innovation, Industry and Regional Development, Revised *Strategic Development Plan* (2004)

¹⁶ Ibid, p 7.

¹⁷ Ibid, p 14.

¹⁸ Ibid, p 15.

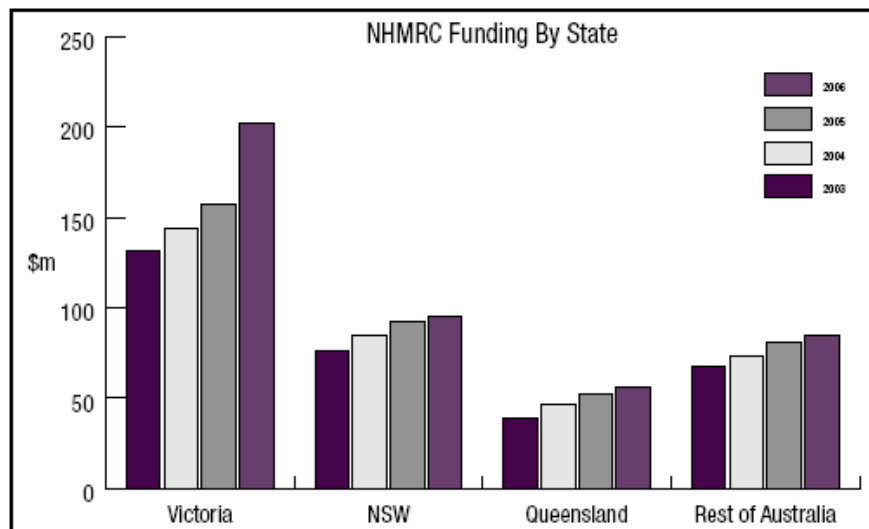
¹⁹ Victorian Department of Innovation, Industry and Regional Development, *Healthy Futures* Statement (2006).

²⁰ Ibid, p 4.

average, \$5 was leveraged from other sources.²¹ Under the *Healthy Futures* package, it is estimated that the \$230 million investment will trigger \$713 million in leveraged funds.²²

Commonwealth support for Victorian innovation initiatives is the largest of any other State, with Victoria now receiving 46% of National Health and Medical Research Centre (NHMRC) grants.²³

Figure 2b:



Source: Victorian Department of Innovation, Industry and Regional Development, *Healthy Futures* Statement (2006)

The Victorian Life Sciences Industry Update, prepared by Blake Industry and Market Analysis, shows that Victoria’s publicly listed life sciences sector is valued at \$16.4 billion, a 50% increase on 2004-05 figures.²⁴ Further, corporate R&D expenditure in 2004-05 was \$413 million, a 30% rise on 2003-04 figures.²⁵

²¹ The Allen Consulting Group, Report to the Department of Innovation, Industry and Regional Development, *Outcome Review of the STI Initiative* (November 2003)

²² Minister for Innovation, ‘Victoria’s success in commercialising medical research soars’, Thursday 6 April, 2006.

²³ Victorian Department of Innovation, Industry and Regional Development, *Healthy Futures* Statement (2006), p 17.

²⁴ Blake Industry and Market Analysis Pty Ltd, *Victorian Life Sciences Industry Update* (March 2006).

²⁵ Ibid.

2.3 National Policy Framework

The Commonwealth Government has also made a significant contribution to the development of STI in its own right.

2.3.1 *Backing Australia's Ability I and II*

In 2001, the Prime Minister announced *Backing Australia's Ability*²⁶, a \$3 billion innovation package over five years to 2005-06. In May 2004, the Prime Minister built on this initial investment through *Backing Australia's Ability – Building our Future through Science and Innovation*.²⁷ Under this second installment, \$5.3 billion was to be invested over seven years from 2004-05.²⁸ Together, these packages constitute a ten year, \$8.3 billion funding commitment, and are representative of a strong commitment to pursue excellence in research, science and technology.

2.3.2 *The Biotechnology Centre of Excellence*

A key initiative of the Federal Government's *Backing Australia's Ability* policy was the creation of a Biotechnology Centre of Excellence program. On 30 May 2002, the ASCC was selected as the first Biotechnology Centre of Excellence.²⁹ This initiative has been strongly supported by the State Government of Victoria through its *STI Initiative*.

2.4 Conclusion

The development of the ASCC constitutes a clear example of an overarching State and Federal Biotechnology policy focus.

²⁶ Commonwealth Department of Industry, Tourism and Resources, *Backing Australia's Ability* (2001).

²⁷ Commonwealth Department of Industry, *Backing Australia's Ability – Building our Future through Science and Innovation* (2004).

²⁸ Ibid.

²⁹ Department of Education, Science and Training, *Backing Australia's Ability: an Australian government initiative*, <<http://backingaus.innovation.gov.au/2001/research/biocentre2001.htm>> Accessed 14 August 2006.

3.0 Funding Framework: The Australian Stem Cell Centre

3.1 ASCC Funding Sources

The ASCC is funded by both the Commonwealth and Victorian governments. In total, the Federal Government has granted \$104.05 million in funding, and the State Government has granted \$11.375 million.

3.2.1 Federal Government Funding

In 2002, \$43.55 million was set aside under the Federal Government's *Backing Australia's Ability*, Biotechnology Centre for Excellence Program.³⁰ This was jointly administered and granted to the ASCC by the Department of Industry Tourism and Resources (DITR) and the Australian Research Council (ARC).

In May 2004, a further \$55 million was granted under *Backing Australia's Ability II* for the period 2006-2011.³¹

\$5.5 million was also granted by the Department of Education, Science and Training (DEST) for the ASCC Major National Research Facilities program.³²

3.2.2 State Government Funding

To supplement this Commonwealth expenditure, the Victorian Government Department of Industry, Innovation and Regional Development (DIIRD) contributed \$10 million to support infrastructural elements of the ASCC, and a further \$1.375 million to support infrastructural elements of the Major National Research Facility located at the ASCC.³³

³⁰ Commonwealth Department of Industry, Tourism and Resources, *Backing Australia's Ability* (2001).

³¹ Commonwealth Department of Industry, *Backing Australia's Ability – Building our Future through Science and Innovation* (2004).

³² Australian Stem Cell Centre (ASCC) website < http://www.stemcellcentre.edu.au/centre_funding.aspx > Accessed 28 August 2006.

³³ Ibid.

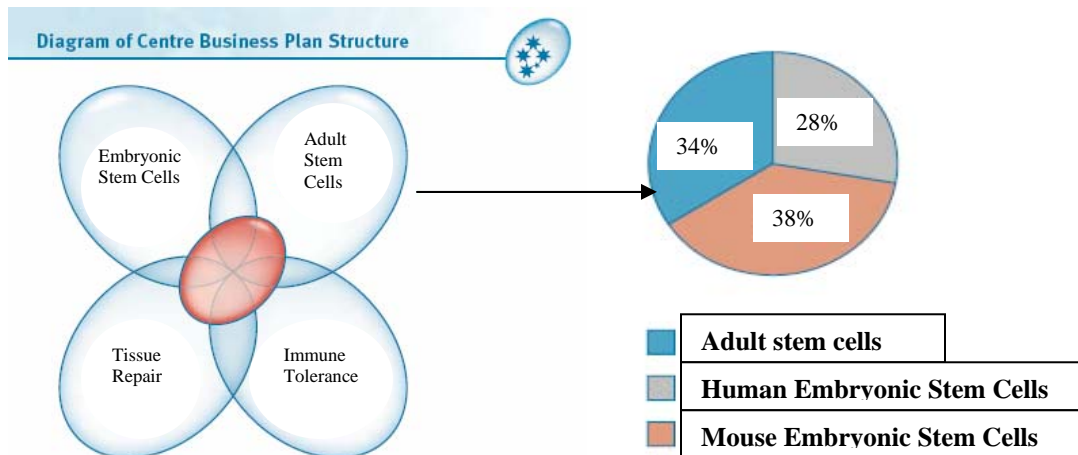
3.2.3 Other revenue sources

Monash University and other ASCC Stakeholders also provide “in kind” contributions, as decided within their own internal organisations.³⁴

3.3 ASCC Funding Distribution

The ASCC has used these funds to develop four core platform technologies: embryonic stem cell research, adult stem cell research, tissue repair and immune tolerance.³⁵ Of the research on stem cells, 38% of research is conducted on mouse embryonic stem cells, 34% on human embryonic stem cells and 28% on adult stem cells.³⁶

Figure 3b:



Source: Australian Stem Cell Centre, *Annual Report* (2005)

3.4 Conclusion

Total government expenditure of \$115.425 million on the ASCC is not an insignificant amount. Moreover, the nature of the research, particularly embryonic stem cell research, is of

³⁴ Michelle Goldsmith, Personal Interview conducted on 25 September, 2006. Michelle Goldsmith is the Director of Legal Services, Australian Stem Cell Centre.

³⁵ Australian Stem Cell Centre, *Annual Report* (2005), p 17.

³⁶ Ibid, p 12.

a sensitive and contentious kind. The ASCC operates in a complex scientific, technical, regulatory and political environment. As a predominately publicly funded project, tax payers have a right to know whether there is accountability for such expenditure and research. This can be determined by an examination of the corporate governance structures that exist between Government and the ASCC.

4.0 Governance: The Australian Stem Cell Centre

Prior to examining whether the ASCC is well governed, it is important to define what constitutes ‘good corporate governance.’

4.1 ‘Good corporate governance’: a general definition

The better practice guide, developed by the Australian National Audit Office, measures governance in terms of five key principles: accountability; transparency and openness; integrity; stewardship; and leadership.³⁷ Assessment on the basis of these principles has been endorsed by the Public Accounts and Estimates Committee’s, *Report on Corporate Governance in the Victorian Public Sector*, which was prepared by Members representing both Houses of Parliament and all political parties.³⁸

4.2 ‘Good corporate governance’: a specific definition

There are also specifically developed principles governing all actions associated with Biotechnology in Victoria.

4.2.1 *Statement of Ethical Principles for Biotechnology in Victoria*

In December 2005, the Victorian Government endorsed a *Statement of Ethical Principles for Biotechnology in Victoria*,³⁹ which is designed to guide the activities of individuals and institutions involved in biotechnology developments in Victoria. This statement was developed by the Victorian Biotechnology Ethics Advisory Committee (VBEAC) (see appendix one). Some of the key principles of this statement include, respect for the public good, probity and accountability.⁴⁰

³⁷ Australian National Audit Office, *Public Sector Governance Better Practice Guide: Framework, Processes and Practices*, July 2003, p 8.

³⁸ Public Accounts and Estimates Committee Report, *Corporate Governance in the Victorian Public Sector* (2006).

³⁹ Victorian Department of Human Services, Public Health Group, Rural and Regional Health & Aged Care Services Division, *Statement of Ethical Principles for Biotechnology in Victoria* (January 2006).

⁴⁰ *Ibid*, p 6.

According to the VBEAC statement, some of the guiding questions to be asked when considering these principles are as follows:

Respect for public good

- Is balanced information available to the public?
- Is proposed research activity of sufficient scientific merit that it does not produce results of questionable validity?

Probity

- Are activities conducted honestly, truthfully, lawfully, impartially, competently and with considered regard for transparency of process?
- Are responses to requests for information from the community met promptly and accurately, subject to specific privacy or commercial-in-confidence restrictions?
- Are there processes in place to monitor compliance with Statements, and mechanisms for dealing with conflicts of interest?

Accountability

- Are activities carried out in a transparent and open way with public scrutiny as far as possible given the constraints of commercial-in-confidence requirements?
- Are institutions adopting Statements and putting in place transparent processes that report on compliance with these Statements?⁴¹

4.3 Prima Facie Conclusions

Prima facie, Government and the ASCC do acknowledge the importance of good governance.

4.3.1 Principles of the *Biotechnology Strategic Development Plan*

Embodied within the Victorian *Biotechnology Strategic Development Plan* are five broad principles which are said to guide the Government's Biotechnology policies and actions, and build upon Biotechnology Ethics and Safety.

⁴¹ Ibid, p 8-10.

These are:

- Optimize the economic, environmental, and social benefits available through biotechnology; and
- Protect and promote the health of the Victorian community; and
- Require that all actions are undertaken within an ethical framework; and
- Assure environmental safety and accountability; and
- Ensure there is full consultation, communication, transparency, monitoring and accountability.⁴²

4.3.2 Principles espoused by the ASCC

The ASCC also claims to aspire to the highest standards of corporate governance, operating in an ethical and transparent manner.⁴³ It states that government is not simply considered a source of funding but their oversight provides an intrinsic and highly necessary soundboard for planning, reporting and monitoring of ASCC activities.⁴⁴ Further, in its Annual Report, it states that ‘the ASCC management believes there is a responsibility to report to the public on the activities the organisation undertakes throughout the year, to keep the public informed on the exciting progress [of] the ASCC.’⁴⁵

4.4 A Systematic Evaluation

This report evaluates the extent to which these claims can be said to be upheld, and how well governed the process really is. The report contextualises these issues through an examination of the ASCC tender and selection process, current framework and procedures, and future directions and viability.

⁴² Victorian Department of Innovation, Industry and Regional Development, Revised *Strategic Development Plan* (2004), p 31.

⁴³ Australian Stem Cell Centre, *Annual Report* (2004), p 2.

⁴⁴ Australian Stem Cell Centre, *Annual Report* (2005), p 11.

⁴⁵ *Ibid*, p 3.

5.0 Tender and Selection: The Australian Stem Cell Centre

5.1 The Process

In August 2001, a substantial discussion paper was issued to seek public input on the selection of a Biotechnology Centre of Excellence.⁴⁶ At around the same time, calls for expressions of interest were made. Approximately 28 expressions of interest were made, which culminated in 11 applications.⁴⁷ A Panel of 12 scientific and commercial experts (selected by Ministers) was created to assess the applications (see appendix two) on the basis of quality of research, governance, management and business and international linkages.⁴⁸ The Panel met 11 times in total, and short-listed four applications for rigorous interviewing.⁴⁹

- In-person meeting - 9.30am to 4.00pm, 25 July 2001;
- In-person meeting - 4.00pm to 7.30pm, 27 August 2001;
- Teleconference - 9.00am to 11.00am, 13 September 2001;
- Teleconference - 10.00am to 12.00pm, 24 October 2001;
- In-person meeting - 2.00pm to 7.30pm, 15 November 2001;
- Centre of Excellence Workshop - 16 & 17 November 2001;
- Teleconference - 10.00am to 12.00 noon, 28 November 2001;
- In-person meeting - 11.00am to 4.00pm, 20 February 2002;
- In-person meeting - 10.00am to 5.00pm, 8 April 2002;
- Interviews with short-listed applicants - 9.00am to 5.00pm, 22 and 24 April 2002; and
- In-person meeting - 8.30am to 12.00 noon, 25 April 2002.

Source: The Allen Consulting Group, Report to the Prime Minister, *Review of the National Biotechnology Centre of Excellence Selection Process* (December 2002)

⁴⁶ The Allen Consulting Group, Report to the Prime Minister, *Review of the National Biotechnology Centre of Excellence Selection Process* (December 2002), p 8.

⁴⁷ Ibid.

⁴⁸ Ibid, p 9.

⁴⁹ Ibid.

In May 2002, the ASCC was unanimously chosen to be the Biotechnology Centre of Excellence.⁵⁰

5.2 Integrity of the Process

Concerns were raised by the integrity of the process, which resulted in the National Stem Cell Centre (now the ASCC) being selected as the Biotechnology Centre of Excellence. In response to these concerns, an independent report by The Allen Consulting Group was commissioned to assess issues of probity, conflict of interest and the adequacy of arrangements for assessing the veracity of claims made on scientific matters.⁵¹ Negotiations with the ASCC to establish a “Deed of Agreement” were suspended pending the review and report on whether the selection should stand.⁵²

In my inquiries, I made a direct request to the ASCC for a copy of the ASCC’s full funding submission application. However, Michelle Goldsmith, ASCC Director of Legal Services informed me that the *‘the submission is definitely commercial-in-confidence. Commercial-in-confidence is probably the wrong word, but there is a lot of commercially sensitive information in there.’*⁵³ All she could tell me was that the funding submission was several hundred pages long, and prepared by Professor Alan Trounson, along with other leading commercial and scientific experts.⁵⁴

The application manager, Professor Alan Trounson had previously agreed to the application being made publicly available, and a copy was provided during the Budget Estimates hearing on 3 June 2002, and another forwarded to the Secretary of the Senate Economics Legislation Committee after the hearing.

Without my own access to the submission, I could only draw inferences from the conclusions of *The Allen Report*, which was tabled in Parliament on 5 March 2003.

⁵⁰ Ibid.

⁵¹ Ibid, p 1.

⁵² Ibid.

⁵³ Michelle Goldsmith, Personal Interview conducted on 25 September, 2006. Michelle Goldsmith is the Director of Legal Services, Australian Stem Cell Centre.

⁵⁴ Ibid.

5.2.1 *The Allen Report*

Overall, the report deemed the selection process to have been conducted with ‘high levels of integrity and thoroughness, leaving no serious issues of concern.’⁵⁵

However, it did note that conflicts of interest can be complex in an environment where there is a relatively small community of expertise in each area of specialisation globally.⁵⁶ As the trend for creating a small concentration of highly specialized experts continues, institutional and personal interconnectedness will increase.⁵⁷ This is clearly an issue for peer reviewed grant evaluation and grant making, and will continue to challenge policy makers, as they develop their innovation policies.⁵⁸ *The Allen Report* observes that as interdependence intensifies, the processes used in the selection of the ASCC are likely to represent the minimum requirement.⁵⁹

5.3 Conclusions

Problem:

- **As the trend for a small concentration of highly specialised experts increases, *independent* grant evaluation and decision-making will become increasingly problematic**

Evaluation:

- **The processes utilised in the selection of the ASCC as the Biotechnology Centre of Excellence are likely to represent the *minimum* requirement in the near future**

Recommendation:

- **As policy makers develop their innovation policies, it is important that they review selection processes constantly to ensure integrity of process**

⁵⁵ The Allen Consulting Group, Report to the Prime Minister, *Review of the National Biotechnology Centre of Excellence Selection Process* (December 2002) (Letter to the Hon John Howard).

⁵⁶ Ibid, p 2.

⁵⁷ Ibid, p 29.

⁵⁸ Ibid.

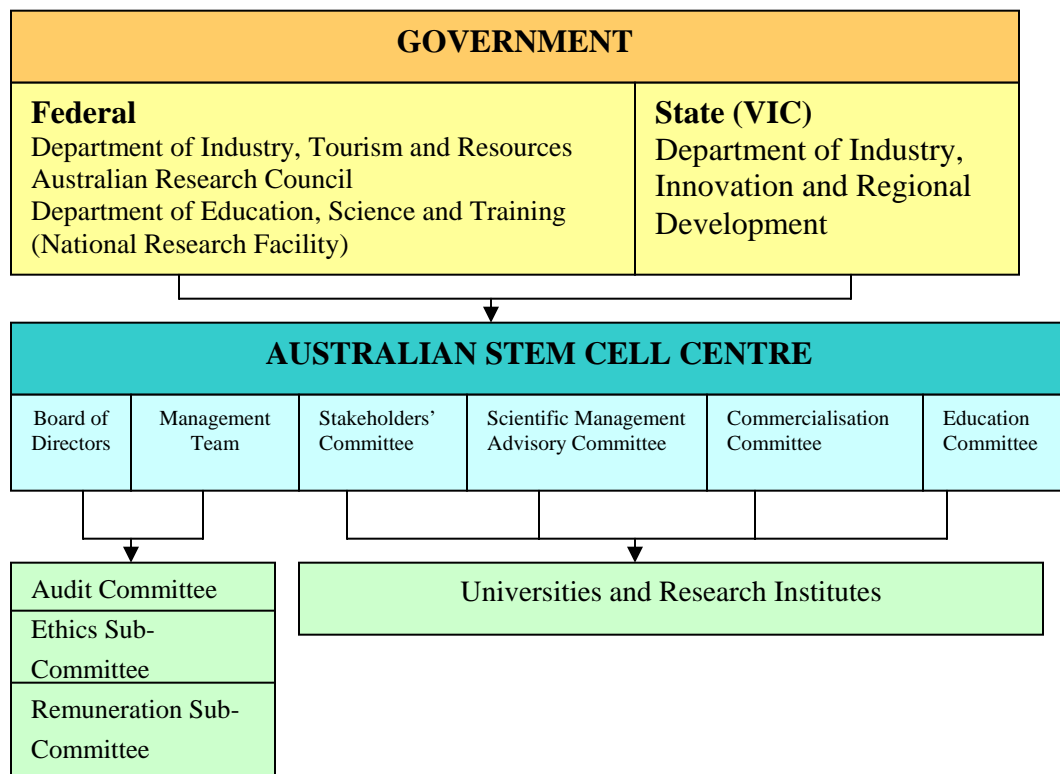
⁵⁹ Ibid.

6.0 Current Framework and Procedures: The Australian Stem Cell Centre

6.1 Current Framework

The ASCC is subject to both internal and external governance processes. Externally, it is governed by Federal and State Government Departments. Internally, it is governed by a Board of Directors and Senior Management, with a series of Advisory Committees, which form part of the overall framework.

Figure 6a:



Source: Australian Stem Cell Centre website <http://www.stemcellcentre.edu.au/centre_org-structure.aspx>

6.1.1 Internal procedures

Internally, the ASCC maintains a commitment to best practice corporate governance, through its comprehensive risk management program.

Conflicts of Interest are managed under external conflicts advisor, Sir Ninian Stephen (former Governor-General and High Court Judge) upon request by the ASCC.⁶⁰ A Code of Conduct for conflicts of interest is formalised under the Commonwealth Deed of Agreement.⁶¹

The ASCC is also governed by an official constitution, and complies broadly with Australian Stock Exchange and Australian Institute of Company Directors guidelines.⁶² The ASCC has also developed its own *Principles of Good Corporate Governance*.⁶³ A series of Advisory Committees provide support to the Board (See Figure 6a).

6.1.2 External procedures

Externally, State and Federal Governments require the ASCC to fulfill certain obligations.

For example, prior to any payments being released under the Deeds of Agreement, Key Performance Indicators (KPIs) and Milestones must be met. Compliance is assessed by Client Managers who then make recommendations to the Executive as to whether payment should be made.⁶⁴

Each year, the ASCC is required to lodge a Business Plan with State and Federal Government, and must consult with Government if there is any deviation from that Plan.⁶⁵

The ASCC is also required to lodge quarterly, mid-year and annual reports, and although the State Government Grant has now been fully paid out, ongoing reporting is required.⁶⁶

Although these provisions are said to exist, they could not be verified for confidentiality reasons.

⁶⁰ Australian Stem Cell Centre, *Annual Report (2005)*, p 40.

⁶¹ Michelle Goldsmith, Personal Interview conducted on 25 September, 2006. Michelle Goldsmith is the Director of Legal Services, Australian Stem Cell Centre.

⁶² Ibid.

⁶³ National Stem Cell Centre Ltd (now Australian Stem Cell Centre), *Principles and Policies of Good Corporate Governance* (16 September 2003).

⁶⁴ Corrina Richards, Personal Interview conducted on 25 September, 2006. Corrina Richards is the General Manager Biotechnology Policy and Projects, Office of Science and Technology, Department of Innovation, Industry and Regional Development.

⁶⁵ Michelle Goldsmith, Personal Interview conducted on 25 September, 2006. Michelle Goldsmith is the Director of Legal Services, Australian Stem Cell Centre.

⁶⁶ Ibid.

6.1.3 Independent review

In 2005, the Commonwealth Government, with the assistance of the Victorian Government, commissioned a review of the ASCC. The purpose of this review was to assess the ASCC's compliance with the Biotechnology Centre of Excellence Deed of Agreement. Independent Consulting Group, *Growing Your Knowledge*, completed this audit over a period of nine months and conducted more than ten interviews with the ASCC.⁶⁷ Only a summary of the review is available for public viewing. This summary observes that:

In a number of respects, through its commitment to achieve 'best practice' governance, the ASCC has considerably exceeded the requirements specified in funding deeds....notwithstanding the above statement, there are a number of improvements which could be implemented.

Growing Your Knowledge

Review of the Australian Stem Cell Centre: Review Summary

February 2006

6.2. Funding and governance documentation

One of the key ways I had planned to assess the potential for improvement to current governance structures was by an examination of the Commonwealth Deed of Agreement (signed 30 May 2003), the Victorian State Grant Agreement and the Stakeholders Agreement. Such agreements typically provide a description of targets and objectives, key performance indicators (KPIs), mechanisms for monitoring and reporting expenditure, and measures to ensure compliance. Performance is commonly assessed in periodic reports to Government.

However, requests of Federal Government for the Commonwealth Deed of Agreement and other relevant funding and governance documentation were met with the following responses:

As we discussed, unfortunately we cannot provide you with the material you have requested. The Deed between the Commonwealth and the ASCC, as well as other documents pertaining to the funding and governance of the ASCC are Commercial in Confidence. All I can suggest is that you examine the ASCC's annual report, which is on their website.

⁶⁷ Ibid.

Alistair Taylor
Assistant Manager
Biotechnology Development, Innovation Division
Department of Industry, Tourism and Resources

Unfortunately, the terms of the Deed of Agreement between the ASCC and the Commonwealth, as represented by DEST, are confidential to those parties and a copy of the agreement cannot be provided to you

Dr Jade Sharples
Adviser to the Hon Julie Bishop MP
Department of Education, Science and Training

A request of the ASCC for the Commonwealth Deed of Agreement, State Grant Agreement, Stakeholders Agreement, and quarterly, mid-year and annual reports to Government was met with the following response:

The ASCC is unable to provide copies of the Grant Agreements, the Stakeholders Agreement and reports to Government, due to the confidential information they contain both about the ASCC and about collaborators and stakeholders of the ASCC.

Michelle Goldsmith
Director of Legal Services
Australian Stem Cell Centre

Finally, a separate request of the State Government of Victoria for the State Grant Agreement and ASCC quarterly, mid-year and annual reports was met with the following response:

I understand that Michelle Goldsmith (ASCC Director of Legal Services) has addressed your query below. I trust that you now have sufficient information for the purposes of your report.

Corrina Richards
General Manager Biotechnology Policy & Projects
Office of Science and Technology
Department of Innovation, Industry and Regional Development

I had not been privy to this internal correspondence between the ASCC and the Department of Innovation Industry and Regional Development (DIIRD). Again, I sought an independent statement from the DIIRD, and was provided with the following response:

The documents contain commercial-in-confidence information. As the property of the ASCC, it is within their discretion to withhold information considered to be confidential to the ASCC or its stakeholders.

Corrina Richards
General Manager Biotechnology Policy & Projects
Office of Science and Technology
Department of Innovation, Industry and Regional Development

In a joint meeting with Corrina Richards and Michelle Goldsmith, I made a request for access to those parts of the Agreements, which do not contain commercial-in-confidence information. However, I was informed that the Agreements contain specific confidentiality clauses which apply to the document as a whole. As such, no part of the documents can be publicly accessed.⁶⁸

6.2.1 Problems with the corporatisation model

This refusal to grant access to key governance documentation is indicative of the inherent tensions that exist within the corporatisation model. As an incorporated company limited by guarantee, ASCC Ltd operates as if it were a private sector business. It is governed by an independent Board of Directors and managed by a team of Executives. Although this structure may enhance the ASCC's prospects of becoming financially independent, this model creates accountability and public interest concerns. Non-commercial imperatives of good governance and public interest must compete against the commercial imperatives of capitalisation. Without sound governance structures and openness and transparency of operation, it is impossible to ensure that both these interests are being given appropriate weight. This is particularly important where the line of research is of serious concern to many in the community and surrounded by significant ethical sensitivities. Development of a Biotechnology sector with wide public acceptability requires broad public engagement rather than 'top down' decision-making by experts & bureaucrats.

⁶⁸ Ibid.

This spending of public money in the absence of accountability is likely to be a more general governance problem, but one that is related to the particular structures associated with the corporatisation model.

6.2.2 Areas for improvement

What this ASCC example illustrates, is that there is a greater need for transparency of objectives that are both commercial and public interest based. Whilst there may be legitimate concerns about providing strategic business directions, higher level objectives should be made public. General strengthening of accountability could be achieved by requiring public availability of Statements of Corporate Intent that express objectives as target outcomes. The Auditor General has recommended that agencies like the ASCC table such plans, including KPIs and targets, in Parliament.⁶⁹

Although the ASCC produces an annual report available to the public, it lacks detail. The *Growing Your Knowledge* independent review of the ASCC's compliance with the Commonwealth Deed of Agreement, completed in 2006, specifically advised that the annual reports should contain more information on operational performance as against the funding Deeds' objectives.⁷⁰

Government also shares this responsibility in being accountable to the public tax payer. It was disconcerting to discover that the second tranche of Federal Government funding for the ASCC was granted without evaluation of the operation or success of the centre, without recommendation from a funding committee, and without request from the ASCC itself.⁷¹ It was inexcusable for the government to allocate \$55 million to the ASCC, without prior justification being provided. Provision for its spending has only been incorporated into the Commonwealth Deed of Agreement in hindsight.⁷²

⁶⁹ Public Accounts and Estimates Committee Report, *Corporate Governance in the Victorian Public Sector* (2006), p 176.

⁷⁰ *Growing Your Knowledge, Review of the Australian Stem Cell Centre: Review Summary* (1 February 2006), p 10.

⁷¹ Michelle Goldsmith, Personal Interview conducted on 25 September, 2006. Michelle Goldsmith is the Director of Legal Services, Australian Stem Cell Centre.

⁷² *Ibid.*

6.3 Conclusions

Problem:

- **Allocation of significant amounts of money to sensitive and ethically contentious issues without public accountability**

Evaluation:

- **It should be a corollary of accepting public money that expenditure will be accountable to the public**
- **The Minister and the ASCC both have an obligation to satisfy legitimate public concern in the allocation of public money**

Recommendation:

- **Higher level objectives (including key performance indicators and target outcomes) should be made public**
- **ASCC annual reports should contain more information on operational performance as against Deed objectives**
- **There should be stronger requirements to explain why material is deemed to be ‘commercial-in-confidence’ and not publicly released**
- **Funding should not be granted in absence of performance evaluation and funding committee recommendation**

6.4 Ethical Evaluations

Another area in which it is imperative that processes are sound, is in the ethical evaluation of potential projects for research development. According to the ASCC website, ethical issues relating to the Centre’s operations ‘are reviewed both internally and externally.’⁷³

6.4.1 Internal Ethics Committee

Within the ASCC internal structure exists an ethics sub-committee, which is comprised of members of the Board of Directors.⁷⁴ This committee, chaired by Barry Jones, is

⁷³ Australian Stem Cell Centre website <http://www.stemcellcentre.edu.au/centre_commitees.aspx> Accessed 6 September 2006.

commissioned to ensure that the Centre's activities strictly comply with relevant standards and procedures. All projects are subject to ethics scrutiny at the institution where the research takes place, and then, by the ASCC ethics sub-committee (see appendix three).⁷⁵ However, there is no charter and performance assessment process for the internal ethics committee.⁷⁶ Moreover, independence may be compromised by fact that the Ethics Committee is a subset of the Board (see figure 6a) and ethical overview is performed by internal institutions of what aims to be a commercially profitable company.

6.4.2 External Ethics Committee

In addition to the internal ethics review process described above, the ASCC also has an external ethics committee.

In 2003, an Independent Ethics Advisory Committee, Stem Cell Ethics Australia (SCEA), was created to examine the legal, ethical and social issues surrounding the research.⁷⁷ SCEA's membership was to represent a diverse range of views on the use of adult and embryonic stem cells, from individuals of ethical, medical, legal, religious and scientific backgrounds⁷⁸ (see appendix four). However, SCEA's independence was questionable from its inception.

SCEA was established with seed funding from the ASCC.⁷⁹ It was also supported by The Lion Fund and the Murdoch Children's Research Institute.⁸⁰ Cassy Harris from The Lion Fund, and Professor Bob Williamson, Carolyn Cameron, and Professor Julian Savulescu from the Murdoch Children's Research Institute, subsequently became members of SCEA. The Murdoch Children's Research Institute joined the ASCC as a founding stakeholder (see appendix four).

⁷⁴ Australian Stem Cell Centre, *Annual Report (2005)*, p 30.

⁷⁵ Michelle Goldsmith, Personal Interview conducted on 25 September, 2006. Michelle Goldsmith is the Director of Legal Services, Australian Stem Cell Centre.

⁷⁶ Growing Your Knowledge, Review of the Australian Stem Cell Centre: Review Summary (1 February 2006), p 4.

⁷⁷ Professor Bob Williamson FRS, AO, Telephone Interview conducted on 9 October, 2006. Professor Williamson is a Former Director, Murdoch Children's Research Institute, and a Co-founder and Former Member, Stem Cell Ethics Australia.

⁷⁸ Ibid. See also Australian Stem Cell Centre, *Annual Report (2005)*, p 30.

⁷⁹ Ibid.

⁸⁰ Ibid.

SCEA's contribution to balanced debate must be viewed in light of its submission to the *Lockhart Report*: 11 out of 12 members made a joint submission in favour of *expanding* embryonic stem cell research to include the use of somatic cell nuclear transfer technology.⁸¹ This included the Chair of the Committee, Reverend Colin Honey.

I attempted to contact SCEA via details provided on the ASCC website. Sarah Chan was listed as the appropriate contact for SCEA and her details were included. However, upon calling Ms Chan, I was informed that she had gone overseas 12 months ago and was no longer involved with the Committee. The website has been updated since my inquiry, and no longer includes any contact details for SCEA. It simply states that the Ethics Sub-committee will interact with the Independent Stem Cell Ethics Advisory Committee. The Chair of SCEA, Reverend Colin Honey, was unavailable for discussion.

According to SCEA member, Reverend Dr Norman Ford, SBD, SCEA may have in fact dissolved.⁸² Dr Ford did not receive any notice of a meeting in 2006 and does not know if any meetings have been held in 2006.⁸³ He described any previous interaction with the Chair of the ASCC Ethics Sub-committee as minimal.⁸⁴ SCEA did not get down to any 'nitty-gritty' issues internal to the ASCC.⁸⁵ SCEA was kept quite independent of the ASCC's ethics procedures.⁸⁶

Professor Bob Williamson, former member and founder of SCEA, confirmed that the committee has not met in the past six to nine months.⁸⁷ He considers that SCEA no longer has the same drive as it originally did, and has since fallen away.⁸⁸ His perception is that as

⁸¹ More commonly referred to as 'therapeutic cloning', this term is used to describe cloning to generate embryonic stem cells.

⁸² Rev Dr Norman Ford SBD, Telephone Interview conducted on 19 September, 2006. Reverend Norman Ford is Director, Caroline Chisolm Centre for Health Ethics, and a Member, Stem Cell Ethics Australia.

⁸³ Ibid.

⁸⁴ Ibid.

⁸⁵ Ibid.

⁸⁶ Ibid.

⁸⁷ Professor Bob Williamson FRS, AO, Telephone Interview conducted on 9 October, 2006. Professor Williamson is a Former Director, Murdoch Children's Research Institute, and a Co-founder and Former Member, Stem Cell Ethics Australia.

⁸⁸ Ibid.

SCEA became less active, the ASCC did not see it as being, or becoming an important player in discussions on ethics.⁸⁹

In any case, Professor Williamson described SCEA as ‘more of a talking shop’ than an ethics committee.⁹⁰ It prepared a few fact sheets for the ASCC but never went into the specific details of ASCC projects.⁹¹ From its initial constitution, SCEA never thought of itself as having the power of a formal committee.⁹²

Perhaps this can be attributed to SCEA’s initial terms of reference. It was set up to interact with the ASCC, and produce discussion papers and recommendations ‘where appropriate.’⁹³ Its role was not to assess and give ethics approval to specific research project proposals.⁹⁴ There was no mandate on the ASCC to interact with SCEA.

Even if SCEA was only ever meant to be discretionary, it is disappointing to see that the committee no longer convenes. An examination of SCEA demonstrates the need for more comprehensive independent ethics review processes.

6.5 Conclusions

Problem:

- **The lack of financial and association independence of SCEA**
- **The lack of diversity of views represented by SCEA**
- **The minimal powers/responsibilities given to SCEA under its Terms of Reference**
- **The dissolution of SCEA**

⁸⁹ Ibid.

⁹⁰ Ibid.

⁹¹ Ibid.

⁹² Ibid.

⁹³ Australian Stem Cell Centre website <http://www.stemcellcentre.edu.au/centre_committees.aspx> Accessed 6 September 2006.

⁹⁴ Australian Stem Cell Centre, *Annual Report* (2004), p 2.

Evaluation:

- **An external ethics committee can only be considered ‘external’ where it is completely *independent* of the ASCC**
- **An external ethics committee can only be considered a formal ‘ethics committee’ if it is properly constituted and involved in ethical evaluations**
- **An external ethics committee is not effective if it does not convene**

Recommendation:

- **There should be regular review of areas selected for development using independent experts**
- **Committees like SCEA should be properly constituted**
- **The ASCC should actively work to ensure that committees like SCEA do not simply dissolve**

7.0 Future Directions and Viability: The Australian Stem Cell Centre

7.1 Future directions and viability

Three years after commencing operations, the ASCC remains a not-for-profit organisation.⁹⁵ The minimal capital it has generated has been re-invested into its research.⁹⁶ However, the ASCC has a secured government funding source until at least 2011.

7.1.1 A strategic sustainability plan

According to Michelle Goldsmith (ASCC Director of Legal Services) the ASCC has provisions in place to deal with the possibility that it may receive no funding beyond 2011. She assured me that a major focus of the ASCC is sustainability, and that this is considered in detail in the ASCC Business Plan.⁹⁷

However, according to the *Growing Your Knowledge* independent review, the ASCC needs to establish a sound financial continuity plan for future viability when funding expires. This needs to involve detailed financial forecasting and modelling based on a variety of possible scenarios.⁹⁸

The *Growing Your Knowledge* Report has also recommended that the ASCC conduct a formal benchmarking process with a comparable organisation.⁹⁹

The ASCC should assess these recommendations as well as the views and recommendations espoused by this report, and provide an appropriate response within their Future Business Plan.

⁹⁵ Michelle Goldsmith, Personal Interview conducted on 25 September, 2006. Michelle Goldsmith is the Director of Legal Services, Australian Stem Cell Centre.

⁹⁶ Ibid.

⁹⁷ Ibid.

⁹⁸ *Growing Your Knowledge*, Review of the Australian Stem Cell Centre: Review Summary (1 February 2006), p 5.

⁹⁹ Ibid, p 13.

7.1.2 Commercialisation of the science: stakeholders and intellectual property

The ASCC is not yet at the stage of development where a large amount of money is being made.¹⁰⁰ However, as contemplated by the Deed of Agreement, intellectual property (IP) ownership is vested in the ASCC for the research it funds.¹⁰¹ The Stakeholders' Agreement governs in detail, the treatment of intellectual property and sharing of commercial benefits between the ASCC and its respective stakeholders (see appendix five).¹⁰² Whilst Government must be apprised in detail about commercialisation activities, its role is to assess the national good in commercialisation activities undertaken.¹⁰³ The provisions made thus far, seem to comply broadly with the *National Principles of IP Management for Publicly Funded Research*.¹⁰⁴

However, a detailed model has not yet been adopted for the spending of future capital. According to Michelle Goldsmith (ASCC Director of Legal Services), there are a range of models that could be employed, and many of these have already been considered. However, ultimately, the model chosen will depend on the product that goes to market (see appendix six). There is no clear answer at this stage.¹⁰⁵

7.2 Conclusions

Problem:

- **ASCC need to achieve financial viability in its own right**

Evaluation:

- **ASCC only has guaranteed funding until 2011**

¹⁰⁰ Michelle Goldsmith, Personal Interview conducted on 25 September, 2006. Michelle Goldsmith is the Director of Legal Services, Australian Stem Cell Centre.

¹⁰¹ Ibid.

¹⁰² Ibid.

¹⁰³ Corrina Richards, Personal Interview conducted on 25 September, 2006. Corrina Richards is the General Manager Biotechnology Policy and Projects, Office of Science and Technology, Department of Innovation, Industry and Regional Development.

¹⁰⁴ Australian Research Council, developed in conjunction with the Australian Vice-Chancellors' Committee, IP Australia, the National Health and Medical Research Council, the Australian Tertiary Institutions Commercial Companies Association, the Department of Education, Science and Training, and the Department of Industry, Science and Resources, *National Principles of Intellectual Property Management for Publicly Funded Research* (2005).

¹⁰⁵ Michelle Goldsmith, Personal Interview conducted on 25 September, 2006. Michelle Goldsmith is the Director of Legal Services, Australian Stem Cell Centre.

Recommendation:

- **It is important that the ASCC develops strategies for financial continuity, by undertaking detailed financial forecasting and modelling based on a variety of possible scenarios**
- **This process may be enhanced by conducting formal benchmarking processes with comparable organisations**

8.0 Conclusion

This report has analysed key State and Federal STI policies, identifying an increased commitment to innovation initiatives. Budgetary frameworks indicate that Victoria has devoted \$1.6 billion to innovation, exceeding the expenditure of any other State.

However, research has shown that innovation, and in particular biotechnology, is not an area without ethical or financial concern. As such, it is imperative that government approaches this sensitive and sometimes controversial research area, within sound regulatory and governance frameworks. An assessment of the ASCC as a key component of this State and Federal biotechnology focus has illustrated both case-specific and general areas of concern.

An analysis of the ASCC tender and selection process has shown that grant evaluation can only retain its integrity with constant scrutiny and review. Current standards are likely to represent the minimum acceptable standard as scientific interconnectedness increases.

An examination of current ASCC frameworks and procedures has indicated an inherent tension between the commercial imperatives of the ASCC as a corporation, and public interest imperatives of transparency and accountability. It has been recommended that both government and the ASCC be more candid with the information that they make publicly available. ASCC ethical procedures are another crucial area to be addressed.

Finally, consideration of the future directions and viability of the ASCC has demonstrated the need for a more comprehensive plan. With a total of \$104.05 million of government funding allocated to the ASCC, we all have a vested interest in generating positive outcomes.

As tax paying citizens, we have the right to be well informed and confident about the operation and direction of the biotechnology industry. The recommendations contained within this report should be adopted accordingly.

POLICY STATEMENTS/ REPORTS/REVIEWS

Australian National Audit Office, *Public Sector Governance Better Practice Guide: Framework, Processes and Practices* (July 2003)

Australian Research Council, developed in conjunction with the Australian Vice-Chancellors' Committee, IP Australia, the National Health and Medical Research Council, the Australian Tertiary Institutions Commercial Companies Association, the Department of Education, Science and Training, and the Department of Industry, Science and Resources, *National Principles of Intellectual Property Management for Publicly Funded Research* (2005)

Australian Stem Cell Centre, *Annual Report* (2005)

Australian Stem Cell Centre, *Annual Report* (2004)

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Blake Industry and Market Analysis Pty Ltd, *Victorian Life Sciences Industry Update* (March 2006)

Commonwealth Department of Industry, Tourism and Resources, *Backing Australia's Ability* (2001)

Commonwealth Department of Industry, *Backing Australia's Ability – Building our Future through Science and Innovation* (2004)

Council of Australian Governments' Meeting Notes, 14th July 2006.

Department of Premier and Cabinet, *Victorian Government response to public accounts and estimates committee report on corporate governance in the Victorian public sector* (November 2005)

Growing Your Knowledge, *Review of the Australian Stem Cell Centre: Review Summary* (1 February 2006)

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Public Accounts and Estimates Committee Report, *Corporate Governance in the Victorian Public Sector* (2006)

Stem Cell Ethics Australia, *Submission to Commonwealth of Australia Review of Human Cloning and Embryo Research Acts* (9 September 2005)

The Allen Consulting Group, Report to the Prime Minister, *Review of the National Biotechnology Centre of Excellence Selection Process* (December 2002)

The Allen Consulting Group, Report to the Department of Innovation, Industry and Regional Development, *Outcome Review of the STI Initiative* (November 2003)

Victorian Biotechnology Ethics Advisory Committee, *Communicating Biotechnology: A position paper on ethical issues concerning community engagement in relation to Biotechnology* (December 2003)

Victorian Biotechnology Ethics Advisory Committee, *Standard Operating Procedures* (2005)

Victorian Department of Human Services, *Map of Ethical Controls and Guidance (including legislative controls) which impact on biotechnology in Victoria* (January 2006)

Victorian Department of Human Services, Public Health Group, Rural and Regional Health & Aged Care Services Division, *Statement of Ethical Principles for Biotechnology in Victoria* (January 2006)

Victorian Department of Innovation, Industry and Regional Development, *Healthy Futures Statement* (2006)

Victorian Department of Innovation, Industry and Regional Development, *Revised Strategic Development Plan* (2004)

Victorian Department of Innovation, Industry and Regional Development, *Strategic Development Plan* (2001)

Victorian Department of Innovation, Industry and Regional Development, *Victoria. Bright Ideas. Brilliant Future* (2002)

MEDIA RELEASES

Minister for Innovation, 'Budget Backs Victoria's Medical Research Leadership',
Wednesday 10 May, 2006

Minister for Innovation, 'Victoria's success in commercialising medical research soars',
Thursday 6 April, 2006

Premier of Victoria, '*Healthy Futures*: \$230 Million Life Science Package to Boost
Victoria's Healthy Future', Tuesday 4 April, 2006

Minister for Innovation, 'Victorian Government's Leadership in Biotechnology Awarded',
Sunday 20 November, 2005

Legislation Review Committee, 'Lockhart Review Supports Strong Regulation of Research
Involving Human Embryos', 19 December, 2005

Prime Minister, 'National Biotechnology Centre of Excellence', 24 December, 2002

Minister for Innovation, 'New Innovation Economy Advisory Board for Victoria',
Wednesday 11 December, 2002

The Age, Gay Alcorn, 'Leaders snap as biotech battle heats up', 27 June, 2001

The Age, Garry Barker, 'Scientists Hail A Brave New Victorian Project', 22 June, 2001

The Australian, 'States must go it alone in the race for stem cell gains', Thursday 3 August,
2006

INTERVIEWS

Corrina Richards, Personal Interview conducted on 25 September, 2006. Corrina Richards is the General Manager Biotechnology Policy and Projects, Office of Science and Technology, Department of Innovation, Industry and Regional Development.

Michelle Goldsmith, Personal Interview conducted on 25 September, 2006. Michelle Goldsmith is the Director of Legal Services, Australian Stem Cell Centre.

Professor Bob Williamson FRS, AO, Telephone Interview conducted on 9 October, 2006. Professor Williamson is a Former Director, Murdoch Children's Research Institute, and a Co-founder and Former Member, Stem Cell Ethics Australia.

Rev Dr Norman Ford SBD, Telephone Interview conducted on 19 September, 2006. Reverend Norman Ford is Director, Caroline Chisolm Centre for Health Ethics, and a Member, Stem Cell Ethics Australia.

WRITTEN CORRESPONDENCE

Alistair Taylor, Response received on 19 September 2006. Alistair Taylor is Assistant Manager, Biotechnology Development, Innovation Division, Department of Industry, Tourism and Resources.

Fran Thorn, Response received on 10 October 2006. Fran Thorn is Secretary, Department of Innovation, Industry and Regional Development.

Jane Sharples, Response received on 10 October 2006. Jane Sharples is Adviser to the Hon. Julie Bishop MP, Minister for Education, Science and Training, Minister Assisting the Prime Minister for Women's Issues.

Rev Colin Honey, Response received on 19 September 2006. Rev Colin Honey is a Bioethicist and Senior Research Associate, Von Hugel Institute, St Edmund's College, Cambridge, and Chair, Stem Cell Ethics Australia.

INTERNET RESOURCES

Australian Policy Online
www.aph.gov.au

Australian Research Council
www.arc.gov.au

Australian Stem Cell Centre
www.stemcellcentre.com.au

Biotechnology Australia
www.biotechnology.gov.au

Biotechnology Victoria
www.biotechnolog.vic.gov.au

Business Victoria
www.business.voc.gov.au

Department of Education, Science and Training
www.dest.gov.au

Department of Innovation, Industry and Regional Development
www.iird.vic.gov.au

Legislation Review Committee
www.lockhartreview.com.au

National Health and Medical Research Council
www.nhmrc.gov.au

National Library of Australia
www.nla.gov.au

Science Portal
www.science.gov.au

Science, Technology and Innovation
www.innovation.vic.gov.au

Synchrotron
www.synchrotron

Victorian Government
www.vic.gov.au

Victorian Government Health Information
www.health.vic.gov.au

Appendices

APPENDIX ONE

Current Victorian Biotechnology Ethics Advisory Committee (VBEAC) Membership

| Name | Category of expertise | Term |
|-----------------------------|---|---------|
| Mr Michael Gorton | Chair | To 2006 |
| Dr Dimitrios Bairaktaris | Layperson | To 2007 |
| Rev Colin Honey | Ethicist | To 2006 |
| Dr Robin Condron | Biotechnology: Agricultural Application | To 2007 |
| A/Prof Marjorie Dunlop | Biotechnology: Biomedical Application | To 2005 |
| Dr Robert Hall (ex-officio) | Chair, Senior Officer Group Biotechnology | To 2006 |
| Rabbi Aviva Kipen | Minister of Religion | To 2006 |
| Vacant | Ethics: Industry | |
| Ms Beth McNeil | Layperson | To 2007 |
| Ms Elaine Nyberg | Community Advocate | To 2006 |
| Ms Meg Parkinson | Animal Health and Welfare Advocacy | To 2005 |
| Mr Richard Reilly | Layperson | To 2006 |
| Mr Mark Richardson | Law | To 2005 |
| Ms Kim Sweetnam | Layperson | To 2005 |
| Dr Peter Temple-Smith | Environmental Advocacy | To 2005 |
| Mr Bob Watters | Biotechnology: Agricultural Application | To 2007 |

Source: Victorian Government Health Information Website
<<http://www.health.vic.gov.au/biotechnology/vbeac/membership.htm>>

APPENDIX TWO

Panel of Experts for Selection of Biotechnology Centre of Excellence

Its members were:

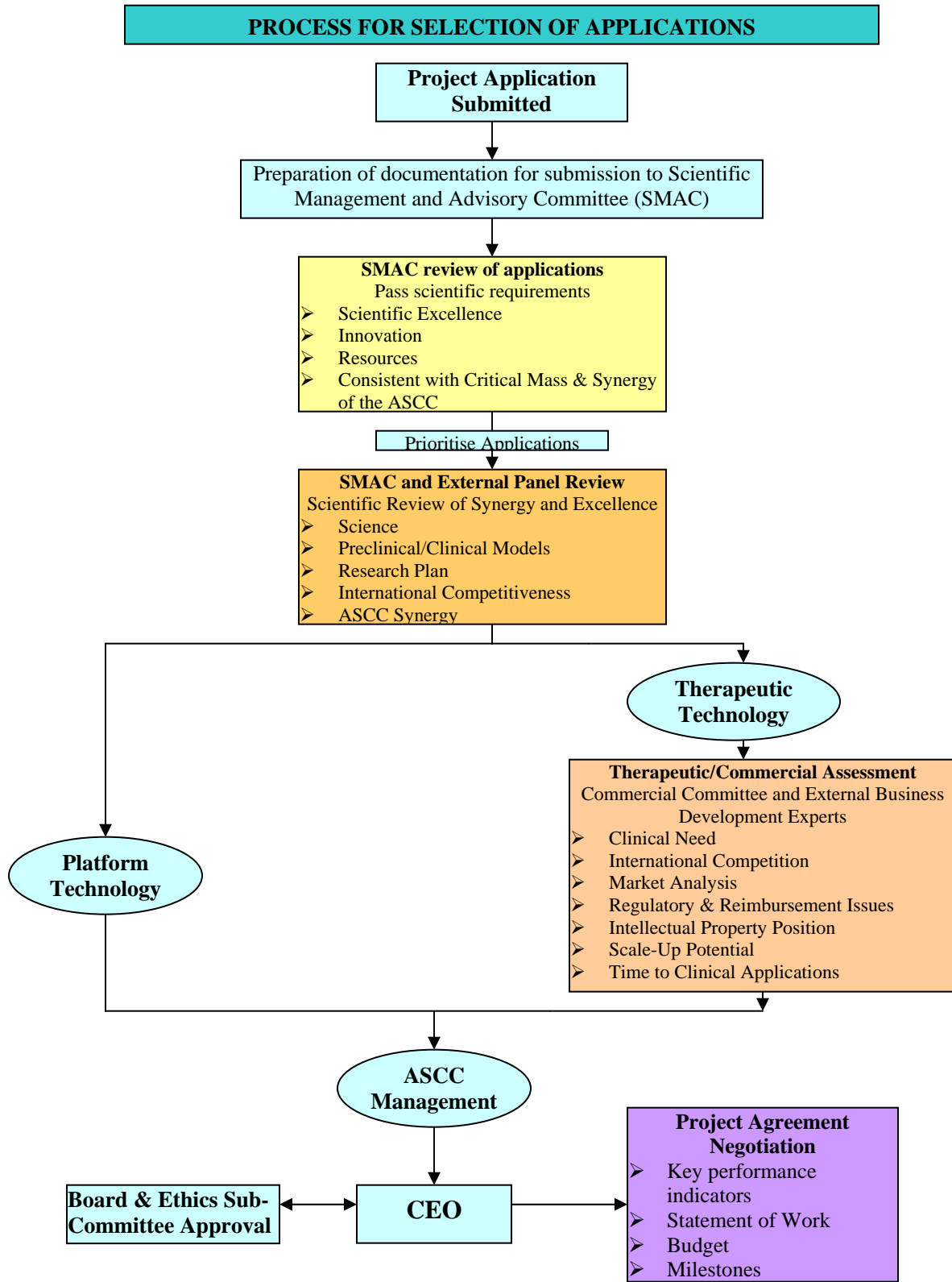
- **Dr Peter Jonson (Chair)**. Former Research Director at the Reserve Bank, former Chairman of ANZ Funds Management and Group Managing Director, Norwich Union Financial Services. His current appointments included Directorship of Village Roadshow and Pro Medicus Ltd; Chairman of the Melbourne Institute Advisory Board; Chair of the Australian Institute of Commercialisation; and Chair of the Major National Research Facilities Committee
- **Professor Marilyn Sleigh (Vice Chair)**. Dean of the Faculty of Life Sciences, University of New South Wales; former Research and Development Director, Peptech Ltd and Chief Research Scientist with the CSIRO (Professor Sleigh resigned from the UNSW in late 2001 to become CEO and MD of start-up company EvoGenix)
- **Dr Geoff Garrett**, CEO, CSIRO and member of the Prime Minister's Science, Engineering and Innovation Council; previously Professor of Physical and Fabrication Metallurgy, University of the Witwatersrand, Johannesburg; Chief Director of the National Institute of Materials Research and subsequently President, South Africa's Centre for Scientific and Industrial Research. (Resigned from the Panel before the assessment of applications due to possible conflicts of interest)
- **Dr David Gearing**, Research Director, CSL; previously Senior Scientist, Millennium Pharmaceuticals, Cambridge, MA; Director of Molecular Biology at SyStematix; Immunex R & D Corp. (Due to pressures of other work Dr Gearing was unable to attend meetings of the Panel and resigned in November 2001)
- **Professor Peter Langridge**, Department of Plant Science, University of Adelaide; Member, Advisory Committee, National Science Foundation Wheat Genomics Project
- **Dr Ian Pitman**, Former Research Director, Fauldings Ltd; Member South Australian Biotechnology Advisory Council; Chair, CSIRO Pharmaceutical and Human Health Sector Advisory Committee
- **Professor Vicki Sara**, CEO, Australian Research Council, Member of the Prime Minister's Science, Engineering and Innovation Council; Member CSIRO Board; previously Dean of Science, Queensland University of Technology. (Professor Sara represented the ARC in the selection process)
- **Mr John Stonier**, LLB, MBA, Company Director and consultant to Davies Collison Cave on intellectual property to technology agreements. Lecturer in Licensing Law

and Technology Transfer, University of Melbourne; previously Director Development and Investments, BHP Ltd and Chair of Working Party on Intellectual Property, Prime Minister's Science and Engineering Council

- **Professor Grant Sutherland AO**, Department of Cytogenetics and Molecular Genetics, Women's and Children's Hospital, Adelaide; Past President, Human Genome Organisation and of the Human Genetics Society of Australasia; co-recipient, 1998 Australia Prize in Molecular Genetics
- **Professor Denis Wade AM**, Chairman and Managing Director, Johnson & Johnson Research Pty Ltd; Chair, Innovation Council of NSW; Member, NSW Ministerial Administrative Council on Biotechnology; Consultant Emeritus Physician, St Vincent's Hospital Sydney

Source: The Allen Consulting Group, Report to the Prime Minister, *Review of the National Biotechnology Centre of Excellence Selection Process* (December 2002)

APPENDIX THREE



APPENDIX FOUR

Stem Cell Ethics Australia (SCEA) Membership

Rev Colin Honey (Chair)

Bioethicist based in Melbourne and senior research associate, Von Hugel Institute, St Edmund's College, Cambridge

Ms Carolyn Cameron, lawyer, Ethics Unit, Murdoch Children's Research Institute

Dr Edgar Dahl, University of Melbourne

Rev Dr Norman Ford, Director, Caroline Chisolm Centre for Health Ethics (Dr Ford dissented from the submission to Lockhart report and recommendations and made a separate submission)

Ms Cassy Harris, The Lion Fund

Mr Graeme Joy, Patient Advocate

Rabbi Dr John Levi, Senior Rabbi, Liberal Jewish Community, Melbourne

Professor Klaus Mattheai, John Curtin School of Medial Research

Professor Margaret Otłowski, Centre for Law and Genetics, University of Tasmania

Professor Julian Savulescu, Philosophy Department Oxford University, and Murdoch Childrens Research Institute

Professor Roger Short, Department of Perinatal Medicine, Royal Women's Hospital

Mrs Monica Walters, Former CEO, Cystic Fibrosis Victoria

Professor Bob Williamson, Former Director, Murdoch Children's Research Institute

Consultant to the committee:

Hon Dr Barry O Jones

Source: Submission to Legislation Review Committee, Report to the Council of Australian Governments (COAG), *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002* (Lockhart Review) (December 2005)

APPENDIX FIVE

Stakeholders of the ASCC

Founding Stakeholders

- University of Adelaide
- Monash University
- University of New South Wales
- University of Queensland
- Howard Florey Institute
- Peter MacCallum Cancer Institute
- Victor Chang Cardiac Research Institute

Additional Stakeholders

- Murdoch Children's Research Institute
- Baker Heart Research Institute

Source: Australian Stem Cell Centre Website
<http://www.stemcellcentre.edu.au/centre_partnerships.aspx>

APPENDIX SIX

ASCC collaborative arrangements with commercial partners

- International company, Stem Cell Sciences Ltd (SCS), to derive, characterise and distribute new human embryonic stem cell lines as a tool for academic researchers (to whom they will be provided unencumbered of intellectual property restrictions);
- Singapore-based ES Cell International Pte Ltd (ESI), for commercialisation of research outcomes at Monash University relevant to diabetes;
- Australian biotechnology company Nephrogenix Pty Ltd, for expertise relevant to the development of kidneys, blood and cardiac tissue, which is closely aligned with the key areas of interest of the ASCC; and
- US-based company LifeCell Corp, to collaborate in the area of tissue repair. This includes a licence to use their proprietary acellular matrix technology in ASCC programs, and the ability to collaborate in future development for products incorporating both LifeCell and ASCC technology.

Source: Australian Stem Cell Centre Website
<http://www.stemcellcentre.edu.au/centre_partnerships.aspx>