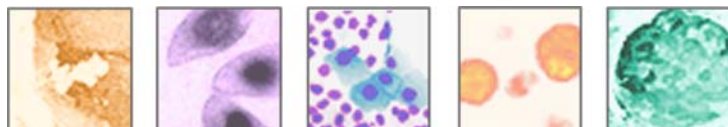


11th Stem Cell Workshop

# Directed Differentiation of Embryonic Stem Cells

Friday 8, August 2008  
8.15am to 3:00pm  
John Dwyer Lecture Theatre  
Edmund Blacket Building  
Prince of Wales Hospital  
Randwick, NSW



## ***Welcome to the 11<sup>th</sup> Stem Cell Workshop***

*The potential of embryonic stem cells (ESC) to become any cell type of the body has stimulated imaginations and hopes that scientists may successfully direct the process towards cures for a wide variety of illnesses. With Geron Corporation on the verge of clinical trials for spinal cord injury, an important step towards realising the potential of ESC is tantalisingly close. Dr Edward Wirth III of Geron Corporation, engaged as he is with the practical challenges of this process in the USA, joins us via the magic of technology to share the progress of his group's research. Another company that is at the forefront of ESC research, Novocell Inc. has made significant advances in the quest for a stem cell therapy for type 1 diabetes, and we are privileged to have Novocell's Chief Technical Officer, Dr Allan Robins dovetail the program with his account of the company's progress and insights into the commercialisation of ESC technologies. We are also fortunate to have pre-eminent Australian scientists in the field; A/Prof Andrew Elefanty, Prof Peter Rathjen, Dr Andrew Laslett and Prof Bernie Tuch give presentations at this workshop on their groups' research progress.*

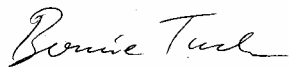
*At least as important as the scientific are the social, philosophical and practical aspects of ESC research. Federal MP, Senator Jan McLucas, Parliamentary Secretary to the Minister for Health and Ageing, will talk about the Federal Government's perspective on scientific innovation in this field. Professor Andrew Webster from the University of York, UK, who is engaged in research with the EC on global developments and implications of embryonic stem cell research, talks about standardisation, stability and new sources of uncertainty. Dr Olivia Harvey from the University of NSW presents research which compares international state strategies and innovation in stem cell science. A window is opened on a very contemporary strategy for effecting legislative change by Gabriel McDowell, Managing Director of Res Publica public relations firm, who talks about the research that underpinned the successful therapeutic cloning campaign.*

*Enjoy this Workshop and we look forward to keeping in touch through the Network.*

*Kind regards,*



**Nola Camden**  
**Manager**



**Prof Bernie Tuch**  
**Director**

**NSW Stem Cell Network**

# WORKSHOP PROGRAM

8:15am Registration open

## **Breakfast seminar hosted by Millipore**

8:30am Embryonic and Adult Stem Cell Differentiation  
**Dr John Ambrosiak, Director of Strategy & Business Development, Millipore Corp. USA**

9:30am Official opening  
**Ms Kerry Doyle, Executive Director of the Office of Science and Medical Research**

## **Session 1: Therapeutic Potential — The Science**

Chair: **Prof Peter Gunning, Head of Oncology Research Unit, Dept. of Pharmacology, UNSW**

9:40am Innovation in science in Australia, the federal government's perspective on hESC research  
**Senator Jan McLucas, Parliamentary Secretary to the Minister for Health and Ageing**

10:05am Derivatives from embryonic stem cells as a therapy for spinal cord injuries  
**Dr Edward D Wirth III, Medical Director, Geron Corporation (via Internet)**

10:30am Growth factor requirements - embryonic stem cells to hematopoietic cells  
**A/Prof Andrew Elefanty, Monash Immunology & Stem Cell Laboratories, Melbourne**

10:55am Embryonic stem cells to pancreatic cells as a cure for type 1 diabetes  
**Prof Bernie Tuch, Diabetes Transplant Unit, Prince of Wales Hospital, Sydney**

11:20am Control of EPL cell differentiation to either ectoderm or the mesoderm/endoderm germ lineages  
**Prof Peter Rathjen, Deputy Vice Chancellor (Research), University of Melbourne**

11:45am Generation of kidney cells from human embryonic stem cells  
**Dr Andrew Laslett, Australian Stem Cell Centre**

12:10pm **Lunch / networking**

## **Session 2: Social Perspectives**

Chair: **Dr Catherine Mills, Centre for Values, Ethics and the Law in Medicine, Sydney University**

1:10pm Standardising stem cells: gaining stability but creating new uncertainty?  
**Prof Andrew Webster, University of York, UK.**

1:35pm Some international comparisons of state strategies and innovation in stem cell science  
**Dr Olivia Harvey, University of NSW**

2:00pm The stem cell debate – winning public opinion  
**Gabriel McDowell, Res Publica Public Relations**

2:25pm Commercial applications of human ES cells  
**Dr Allan Robins, Chief Technical Officer, Novocell**

2:40pm **Refreshments / networking**

**:: SPONSORED BREAKFAST SEMINAR ::**

## **EMBRYONIC AND ADULT STEM CELL DIFFERENTIATION**

This presentation will address the breadth of Millipore's interests in stem cell research and focus on several solutions for research.

**Dr John Ambroziak**  
**Director, Strategy & Business Development**

John has been with Millipore for 5 years serving in various R&D and business development roles. He is based at the Millipore Bioscience Research Reagent Headquarters (formerly Chemicon) in Temecula, California.

John obtained his PhD from Carnegie Mellon University followed by post-doctoral research at UC San Francisco.



# INNOVATION IN SCIENCE IN AUSTRALIA: THE FEDERAL GOVERNMENT'S PERSPECTIVE ON HESC RESEARCH

Australia has a strong and growing capability in biotechnology research and development. Biotechnology is an important innovative sector and is an increasingly important driver of economic growth, wealth creation, high value jobs and supporting industries. Many of our biotech companies are establishing international reputations and strong international alliances to support them into the future.

The Australian Government is looking to capture the potential benefits of biotechnology for the Australian community. Increased and effective collaboration between public and private sectors will help develop multiple pathways for industry to access knowledge and expertise in universities and research agencies. Of particular importance is the convergence of new technologies such as biotechnology, nanotechnology, and Information and Communication Technology which provides a powerful tool to advance Australia's innovation future.



## **Senator Jan McLucas**

### **Senator for Queensland and Secretary to the Minister for Health and Aging**

Senator Jan McLucas was born on the Atherton Tablelands in Far North Queensland and was educated at her local primary school in Ravenshoe, and then at Clayfield College, Brisbane. She trained as a teacher at Townsville College of Advanced Education (now James Cook University), where she was Treasurer, then President of the Student Union.

Jan taught as a primary school teacher, mainly in North Queensland, for 10 years, and continues to have a strong interest in education, especially of children living in rural and remote areas. She maintains close involvement in the North Queensland community, with particular interest in health, the environment, child care and indigenous and women's issues.

Jan began public life with her election as a Cairns City Councillor in 1995, and entered the Senate in July 1999. She has been a member of a number of Senate Committees. Jan chaired the two Senate Select Committees of Inquiry into Medicare and was the Chair of the Senate Community Affairs Reference Committee.

From November 2004 to November 2007, Jan was the Shadow Minister for Ageing, Disabilities and Carers. She is the Parliamentary Secretary to the Minister of Health and Ageing.

## DERIVATIVES FROM EMBRYONIC STEM CELLS AS A THERAPY FOR SPINAL CORD INJURIES

Multiple preclinical studies were performed over a period of several years to assess the efficacy and safety of human embryonic stem cell (hESC)-derived oligodendrocyte progenitors (OPC) in animal models of human spinal cord injury (SCI). Efficacy was assessed with respect to OPC-mediated improvement of locomotor function in rats that had received a contusion injury to the spinal cord at the T9-T10 thoracic level. Safety of intraspinal OPC grafts with respect to toxicology, tumourigenicity, and bio-distribution was evaluated in several long-term pilot experiments, with monitoring up to one year. The preclinical efficacy studies suggest that OPC can improve locomotor ability in rats if the cells are implanted approximately 7 days after injury, but not if the delay before grafting is greater than 2 months. The preclinical safety studies have revealed no evidence of tumours up to one year after implantation. Based on these encouraging preclinical data, a Phase 1 trial has been designed to test the safety of OPC in patients with subacute, neurologically complete, thoracic SCI.



### **Edward D Wirth III, MD, PhD** **Geron Corporation**

Dr Edward Wirth completed the MD/PhD program at the University of Florida (UF) in 1994. He elected to remain at UF to conduct post-doctoral research, and subsequently joined the faculty there in 1996. From 1997 to 2002, Dr Wirth led the UF team that performed the first human embryonic spinal cord transplant in the United States. This pilot study demonstrated the feasibility and safety of implanting embryonic spinal cord cells into patients with post-traumatic syringomyelia. From 2002 to 2004, Dr Wirth held academic appointments at Rush-Presbyterian St. Luke's Medical Center and the University of Chicago. In 2004 he joined Geron Corporation, where he has led the effort to initiate clinical trials of Geron's human embryonic stem cell-derived products.

Dr Edward Wirth is the Medical Director, Regenerative Medicine at Geron Corporation.

## GROWTH FACTOR REQUIREMENTS - EMBRYONIC STEM CELLS TO HEMATOPOIETIC CELLS

Our laboratory focuses on the directed differentiation of embryonic stem cells (ESCs) to mesodermal and endodermal cell types with a potential use in cell transplantation therapies.

The current research directions of our laboratory include the generation of haematopoietic cells, endothelium, cardiomyocytes and pancreatic beta cells from ESCs. The underlying strategy is to guide ESC differentiation along the same developmental pathways traversed by cells during the ontogeny of these cell types or organs during embryogenesis. To accomplish this, we have developed algorithms for the maintenance and expansion of HESCs that provide sufficient cells for experiments whilst maintaining stem cell phenotype and a normal karyotype. We have also developed a technique for the differentiation of HESCs (the spin embryoid body [EB]) which results in the reproducible formation of EBs of uniform size that differentiate predictably in response to exogenously added growth factors.

Integral to the spin EB system is the utilisation of a serum free differentiation medium that permits the growth factor directed differentiation of HESCs in the spin EBs. Over the last two years we have developed and validated a novel, animal product free, wholly recombinant protein based version (denoted APEL medium) that not only minimises batch to batch variability caused by the medium components, but also provides a safe platform relevant for future clinical applications of HESC-derived differentiated cells.

To assist in the analysis of the HESC differentiation process, we have used homologous recombination in HESCs to insert DNA sequences encoding reporters such as green or red fluorescent proteins (GFP or dsRed) into gene loci whose expression marks obligate intermediates in the genesis of the end cell types of interest.

Our laboratory has developed technology for genetic modification of HESCs by homologous recombination that does not rely on expression of the target gene. Therefore, modification of a desired locus is not dependent on promoter trapping or other metabolic selection strategies. We have generated multiple targeted alleles for many different genes in which we have inserted sequences for reporter genes into the coding sequence, thus generating cell lines in which the reporter gene expression can be used as a surrogate for expression of the endogenous gene. Our laboratory is the first to have published this technique in HESCs. Our current work is focused on utilizing these tagged cell lines to refine the growth factor requirements for directed differentiation of HESCs.



### **Prof Andrew Elefanty, MB, BS, PhD, FRACP**

**Embryonic Stem Cell Differentiation Laboratory, Monash Immunology and Stem Cell Laboratories, Monash University**

I trained as a physician in medical oncology and completed a PhD in leukaemogenesis under the supervision of Prof Suzanne Cory at the Walter and Eliza Hall Institute of Medical Research in 1992. In 1993, I took up a position at the National Institute for Medical Research in London in the laboratory of Professor Frank Grosveld, studying the haematopoietic transcription factor, GATA-1. I returned to the Hall Institute in 1995 and, in collaboration with Professor Glenn Begley, I generated ESC and mice in which lacZ was targeted to the locus of the key haematopoietic transcription factor, SCL. In order to study the events antedating blood cell formation, I cloned mouse and human homologues of a *Xenopus laevis*

homeobox gene, *Mixl1*, a key protein patterning mesoderm in the frog. The *Mixl1* deficient mouse embryos that we generated displayed major defects in mesoderm and endoderm. In recognition of the role *Mixl1* plays in endoderm formation, we added pancreatic islet cell development to our research portfolio.

Our laboratory, headed jointly head by myself and Dr Ed Stanley since 2002, has maintained this focus on ESC differentiation along mesodermal (blood) and endodermal (pancreas) lineages. We moved from The Walter and Eliza Hall Institute of Medical Research to Monash University in 2002 in order to expand our scientific endeavours into human (H)ESC. We have generated genetically modified human, ESC lines in which fluorescent reporters have been introduced into key gene loci (such as *MIXL1*) that allow us to objectively monitor in vitro differentiation of ESC in a logical, step-wise fashion. We have developed a robust system for the efficient differentiation of HESC (spin EBs), complemented by the development of a recombinant protein, animal product free medium (denoted APEL) in which HESC differentiation can be reproducibly directed to different lineages by the inclusion of specific growth factors. A major goal of our work is to transfer knowledge and expertise from mouse ES cells to the human system, in order to realise some of the potential health benefits that human ES cells promise.



## EMBRYONIC STEM CELLS TO PANCREATIC CELLS AS A THERAPY FOR TYPE 1 DIABETES

Insulin-dependent diabetes affects at least 130,000 Australians and 1.8 million Americans, many of whom are children, with the incidence of this disorder increasing at the rate of 3% per annum. At present, insulin administration, usually by injections, is required to help control sugar levels in these people. Whilst such treatment does keep recipients alive, it does not control sugar levels in the same minute-by-minute manner of non-diabetic people and thus microvascular complications, especially retinopathy, typically develop over the years. Replacing the insulin-producing cells that have been destroyed in such people is a goal that will overcome the need for insulin injections and prevent such complications from occurring.

One source of replacement insulin-producing cells is from donors after their death, however the number of such people is very limited (fewer than 200 per year in Australia). Stem cells, especially embryonic stem cells, are an alternative source of insulin-producing cells that can be of clinical benefit. A major advantage of using them is their availability in unlimited numbers. The ability to convert stem cells into insulin-producing cells has been progressing rapidly over the past few years, with the formation of pancreatic progenitor cells being achieved by a number of groups using an ontogeny based approach. Scientists at the Diabetes Transplant Unit have efficiently produced such cells by a two stage procedure requiring 9 days of tissue culture, but there is variability between cell lines. The ability to convert these cells into glucose-responsive mature  $\beta$  cell surrogates has yet to be achieved in vitro. The strategy being adopted in the Unit to achieve this target is to seed the cells onto 3D scaffolds made of polylactic co-glycolic acid in an attempt to more closely mimic the in vivo microenvironment. Data collected show that single pluripotent human embryonic stem cells can be efficiently seeded onto scaffolds and differentiated towards definitive endoderm and pancreatic progenitors.

Once surrogate  $\beta$  cells have been produced, they will need to be expanded in a bioreactor to produce the 350 million  $\beta$ -cells needed per person. It will be necessary to show that teratomas will not form when the cells are transplanted. Finally, strategies to prevent immune rejection when the cells are transplanted will need to be implemented. Placing the cells inside microcapsules made of a product from seaweed, alginate, is a way of trying to achieve this target without having to use anti-rejection drugs. This approach is currently being pursued by the Unit in a phase 1 clinical trial with human islets. Delivery of the encapsulated cells is an outpatient procedure that could readily be applied to the large numbers of people with type 1 diabetes at relatively little cost.

Of course, regulatory approval is needed before clinical trials can commence. It is anticipated that with appropriate resources, this target is potentially achievable within 5 years.



**Prof Bernie Tuch, MB, BS, BSc (Med), PhD, FRACP**  
**Diabetes Transplant Unit, Prince of Wales Hospital/University of NSW**

Bernie Tuch, an endocrinologist, is the Director of the Diabetes Transplant Unit at Prince of Wales Hospital and a Professor of Medicine at The University of New South Wales. His Unit is on the cutting edge of research into replacing the missing insulin-producing cells as a treatment of type 1 diabetes. Strategies being utilized by the Unit include insulin-producing cells isolated from donor human pancreas as part of the Seaweed

Diabetes Trial (a phase 1 clinical trial), differentiation of human embryonic stem cells and cord blood stem cells, and insulin-producing pig cells. His Unit has produced human embryonic stem cells and is pursuing platform technology in biomedical engineering, which includes the use of microcapsules and 3D scaffolds.

Professor Tuch is also the Director and co-founder of the New South Wales Stem Cell Network, an entity that helps brings together and educates 550 professionals in NSW interested in stem cells.

# CONTROL OF EPL CELL DIFFERENTIATION TO EITHER ECTODERM OR THE MESODERM/ENDODERM GERM LINEAGES

*James Hughes<sup>1</sup>, Jennifer Washington<sup>1</sup>, Charlotte Yap<sup>2</sup>, Felix Zheng<sup>2</sup>, Joy Rathjen<sup>1,2</sup> and Peter Rathjen<sup>1,2</sup>.*

<sup>1</sup> School of Molecular and Biomedical Science, ARC SRC for the Molecular Genetics of Development and the Australian Stem Cell Centre, University of Adelaide, Adelaide, S.A. 5005

<sup>2</sup> Dept. of Zoology, University of Melbourne, Parkville, Vic. 3010

Embryonic stem (ES) cells can differentiate into all cell types of the mammal, a capability that suggests these cells as a potential source of cell therapeutics. To realize this potential, methodologies for the formation of cell populations highly enriched in functional progenitors and/or differentiated cells from ES cells will need to be developed. In the embryo, cell fate is determined by localized environmental factors and the responsiveness of a cell to these factors. Identification and characterization of the environmental cues and cognate signaling pathways that regulate differentiation in vivo, or of ES cells in vitro, will provide regulators of differentiation that can direct pluripotent cell differentiation to cell populations with clinical utility. One of the key developmental decisions made during development is the generation of the germ lineages, ectoderm, mesoderm/endoderm, from the pluripotent primitive ectoderm. We have previously described the differentiation of mouse ES cells to pluripotent EPL cells. EPL cells are akin to primitive ectoderm in gene expression, differentiation potential and cytokine responsiveness. Like primitive ectoderm in vivo, EPL cells can differentiate into ectoderm and mesoderm/endoderm, a differentiation potential that we have exploited to generate an in vitro model of germ lineage formation. Using this model we have identified roles for mesoderm suppression, the Nodal and FGF signaling pathways, mesoderm inductive activities (BMP4, serum, Wnt3) and modulation of cell:cell contact in determining cell fate in differentiating EPL cells.



**Prof Peter Rathjen, BSc, PhD**  
University of Melbourne

Professor Peter Rathjen has a longstanding involvement in embryonic stem cell research dating from postdoctoral research at the University of Oxford in the late 1980s. On his return to Australia he established a research program directed towards understanding the processes by which stem cells differentiate into functional cell types during embryo development at the University of Adelaide. He was appointed to the Chair of Biochemistry in 1995, became foundation Head of the Department of Molecular Biosciences in 2000, and in 2002 was appointed (Executive) Dean of the Faculty of Sciences. In 2005, he was the recipient of the inaugural Premier's Award for Scientific Excellence (Research Leadership) in South Australia. Professor Rathjen moved his research interests to the University of Melbourne in 2006, where he currently holds the position of Deputy Vice Chancellor (Research).

# GENERATION OF KIDNEY CELLS FROM HUMAN EMBRYONIC STEM CELLS

With the exponential growth in the area of embryonic stem (ES) cell research, it is now possible to derive cells of many lineages from human ES cells. However, the ability of human ES cells to differentiate towards the renal lineage has not been examined in detail. This project represents a critical step in the potential development of cell based therapies for chronic renal disease; a global health issue that effects many Australians and places great financial demands on our health care system. Although renal dialysis and transplantation are life saving treatment options they both have significant limitations and many patients still face short life expectancies.

Using a combination of markers reported to be expressed in the murine metanephric mesenchyme, we have developed a method to isolate populations of cells containing renal precursor cells with a similar phenotype to metanephric mesenchymal cells from human ES cells. The metanephric mesenchyme gives rise to most cell types of the adult kidney. In this method, human ES cells are differentiated for 2 weeks in reduced serum and feeder layer concentration and sorted based on their immunoreactivity to CD24, podocalyxin and the embryonic stem cell marker, GCTM-2. Quantitative PCR performed on the sorted fractions show an increase in the expression levels of the genes critical in kidney development (LHX-1, PAX-2 and WT-1) in the fraction with positive immunoreactivity to CD24 and podocalyxin and intermediate to low GCTM-2- expression. Transcript levels of the stem cell genes, OCT-4 and GDF-3 are concurrently reduced in these fractions. The renal identity of cells in the sorted fractions has been substantiated with WT-1 and PAX-2 co-localisation at the antigenic level. Global gene expression profiling has also been carried out to further characterise these isolated populations and we are currently developing a method to test the functional capacity of these renal-like cells in kidney development. Together, these results show for the first time that it is possible to obtain cells with a renal phenotype from human ES cell cultures and that we have a method to prospectively isolate these renal cells of interest.



## **Andrew Laslett, PhD**

**Department of Anatomy and Developmental Biology at Monash University & Australian Stem Cell Centre**

Dr Laslett is a Senior Scientist and group leader at the Australian Stem Cell Centre (ASCC) and an Honorary Senior Lecturer in the Department of Anatomy and Developmental Biology at Monash University. Prior to joining the ASCC in August 2006 Andrew was a Senior Research Fellow in the Laboratory of Embryonic Stem Cell Biology, Centre for Reproduction and Development, Monash Institute of Medical Research, Monash University. Andrew obtained his BSc (Hons) and PhD from Monash University prior to postdoctoral positions in both Hong Kong and Philadelphia, USA. .

His previous research focused on cellular interactions in the male reproductive system and gave him excellent grounding in cell culture and molecular biological techniques. Since 2001, Andrew has focussed on elucidating the complicated biology of human embryonic stem cells (hESC), examined methods for the differentiation of hESC to cells of the

kidney, and more recently has begun comparing hESC with human induced pluripotent stem (iPS) cells.

Dr. Laslett's research has been both nationally and internationally recognised for increasing the basic understanding of human embryonic stem cells. He leads an independent program as well as having significant national and international collaborations. He has been awarded grant funding from Kidney Health Australia, the NHMRC, the Australian Stem Cell Centre and most recently from the NSW/VIC Government Stem Cell Research Grant Program. Since 2001, his work on human embryonic stem cells has led to multiple peer reviewed publications and patent applications as well as 24 national and international invited presentations in Australia, Asia, North America and Europe. Dr Laslett has been a member of the editorial board of the Journal of Cellular and Molecular Medicine since 2004 and was recently appointed to the editorial board of The Open Tissue Engineering & Regenerative Medicine Journal. In September 2007 Andrew was elected as a Board Member and Director of the Australian Society of Medical Research (ASMR). The ASMR is the peak professional society representing Australian health and medical research. Dr. Laslett also currently supervises 4 PhD students and lectures to third year Anatomy and Developmental Biology students and helped to design a new major of Developmental Biology including a unit entitled "Stem Cells and Regeneration" for the School of Biomedical Sciences at Monash University.

## STANDARDISING STEM CELLS: GAINING STABILITY BUT CREATING NEW UNCERTAINTY?

Setting standards in stem cell research is fraught with difficulties but is an essential part of moving the emerging field of science forwards. The ambition in many quarters to scale up the production of human embryonic stem cell lines and move towards clinical trials requires different laboratories to be able to produce comparable cell lines. But developing common standards in stem cell production is not straightforward as so much is still unknown in this new science.

Accurately describing the lines of human embryonic stem cells is one way to set standards. But each human embryonic stem cell holds the genetic signature of the donor which differs between donors just as people themselves differ. Further the state of a single stem cell is temporary as it has the ability to develop into one of many different cell types.

Some scientists argue that as the stem cell cannot be standardised, the process and materials used should be standardised. Currently differences in laboratory practices often result in differences in stem cell lines. Reporting on recently completed research in UK, the US and Europe, this paper describes some of the ways in which standardisation has been secured but also the problems it has thrown up for the community, and for downstream regulation and safety.



**Prof Andrew Webster, PhD**  
University of York, United Kingdom

Professor Andrew Webster is Director of the Science and Technology Studies Unit (SATSU), and Head of Department of Sociology at the University of York, UK. SATSU undertakes research on the social and cultural implications of science and technology.

Andrew's career has included roles as Specialist Advisor to the Health Committee of the House of Commons for its Inquiry on 'The Introduction of New Medical Technologies within the NHS'; the DoH Advisory Group on Genetics Research; the UK Stem Cell Bank Steering Committee and the Royal Society's Expert Working Group on Health Informatics. He is the national co-ordinator of the UK ESRC's new Stem Cells Initiative and coordinates a new EU-funded project on regenerative medicine, entitled REMEDIE. His most recent book is *Health, Technology and Society: A Sociological Critique* (Palgrave Macmillan) 2007.

## **SOME INTERNATIONAL COMPARISONS OF STATE STRATEGIES AND INNOVATION IN STEM CELL SCIENCE**

Stem cell science and its potential commercial applications form part of the global bioeconomy of the life sciences, in which nation-states compete against one another for competitive advantage. There are a variety of strategies that governments can adopt to enhance the competitiveness of their national stem cell industries within this global dynamic. Such strategies might include: developing public-private partnerships, tax incentives to encourage private investment, centralised organisation of stem cell science, a strong regulatory regime to increase public trust, adherence to international agreements, a strong intellectual property regime and the development of manufacturing, clinical and trade standards. The strategies that states do adopt are shaped by social, cultural, economic and political factors like community attitudes towards the use of embryos, the state's position within the global knowledge economy, the availability of a significant skill-base to conduct cutting-edge research and access to financial resources. A comparison between India, China and the US highlights some of these differences. It should also provoke consideration of what strategies might be adopted in Australia.



**Olivia Harvey, PhD**  
**Faculty of Arts and Social Sciences School of History and**  
**Philosophy, University of New South Wales**

Olivia is a sociologist specialising in science and technology studies, lately focused on the sociology of stem cells. Olivia has a PhD and a BA (Hons 1) in sociology and science and technology studies from UNSW. In 2007 and 2008, Olivia was in the United Kingdom on an ESRC funded postdoctoral fellowship on 'Government strategies and commercial models: the politics of the global stem cell bioeconomy' with the Global Biopolitics Research Group at the University of East Anglia, Norwich and the Centre for Biomedicine and Society at King's College, London. Olivia was also a research fellow on the team's 'The global politics of hESC science' project for three months, contributing data on the EU and the US. Recently returned to Australia, Olivia has just started a new three-year project at the University of New South Wales on translation and innovation in Australian stem cell science. Formal participation in this project will in due course be sought from the Australian stem cell community however initial expressions of interest are welcome and can be directed to Olivia on [o.harvey@unsw.edu.au](mailto:o.harvey@unsw.edu.au), 9385 3768 or in person.

## THE STEM CELL DEBATE – WINNING PUBLIC OPINION

The presentation will identify the key factors that underpin a successful public affairs campaign and draw on the award winning campaign to legalise therapeutic cloning to illustrate how to achieve legislative change. The campaign to legalise therapeutic cloning won the top award for public affairs from the Public Relations Institute of Australia. Res Publica was also named PR agency of the year by the leading trade publication AdNews.



**Gabriel McDowell**  
**Res Publica**

Gabriel McDowell is Managing Director of Res Publica [www.respublica.com.au](http://www.respublica.com.au) one of Australia's leading PR consultancies. He has over twenty years experience in the public relations industry in Europe, Asia and Australia. His work has won eight major industry awards. He advises many of Australia's leading companies and industry groups on a range of communications issues and has directed many highly successful public affairs campaigns in Australia, including the thoroughbred racing industry's campaign to privatize the NSW TAB, a campaign to reverse the Federal Government's beer excise increase in 2000, and, more recently, the campaign to legalise therapeutic cloning for medical research purposes.



## COMMERCIAL APPLICATIONS OF HUMAN ES CELLS

Human embryonic stem cells (hESCs) are a unique cell type isolated from the inner cell mass of pre-implantation blastocysts. Theoretically, hESCs are capable of unlimited self-renewal and can differentiate to every somatic cell type in the body. In addition they may provide a system to study early human development in vitro, and in the future, differentiated populations may be used for cell replacement therapies. There are many scientific, regulatory and funding hurdles to overcome if these applications are to become a reality.

From a commercial perspective cell therapy applications are attractive because they address large markets with currently unmet needs. However the long time frames and uncertain regulatory pathway makes funding a challenge. While other applications such as the development of reagents and drug screening tools are less attractive from a market perspective they offer shorter term lower risk revenue generation.

This talk will focus on Novocell's commercialization strategy and will cover the latest developments in the company's cell therapy program as well as the commercialization of reagents and the development of drug screening assays.



**Allan Robins, PhD**  
**Novocell**

Dr Robins received his BSc with Honors in Biochemistry in 1975 and a Ph.D. in Molecular Biology from the University of Adelaide in 1981. From 1981 until 1991 Dr. Robins undertook postdoctoral work at Cambridge University, where he worked on the development of large-scale DNA sequencing and Adelaide University where he worked on the development of promoters for the control of transgene expression, the development of transgenic animals, as well as the development of E coli based protein expression vectors. Dr. Robins has 17 years experience in the Biotechnology industry. He joined BresaGen Australia as Laboratory Operations Manager in 1991 and became involved in the development of reagents for BresaGen's reagent business. He also conceived and developed a new veterinary biopharmaceutical that is currently registered and sold in five countries. He became Chief Scientific Officer in 1995. In 2000 Dr Robins moved to Athens GA to start BresaGen Inc, a company focused on human Embryonic Stem Cell technology. Dr Robins' team isolated three human embryonic stem cell lines that were derived before August 9th 2001 and are therefore eligible for Federal funding in the USA. Dr Robins is studying the process of self renewal in embryonic stem cells and this work has led to the development of a simple defined medium for the growth of human embryonic stem cells without the use of animal feeder cells. This medium has recently been commercially released by Invitrogen. In addition Dr Robins is studying the relationship between self renewal in human embryonic stem cells and the self-renewal of cancer stem cells.

Dr Robins is currently VP & Chief Technical Officer of Novocell.



## NSW Stem Cell Network

Contact: Nola Camden  
Tel: 02 9382 4856  
Fax: 02 9382 4826  
Email: [stemcellinfo@stemcellnetwork.org.au](mailto:stemcellinfo@stemcellnetwork.org.au)  
URL: [www.stemcellnetwork.org.au](http://www.stemcellnetwork.org.au)

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