



Australian Government

National Health and Medical Research Council

NHMRC Licensing Committee Report to the Parliament of Australia

For the period 1 April 2003 to 30 September 2003



INVESTING IN AUSTRALIA'S HEALTH



Australian Government

National Health and Medical Research Council

NHMRC Licensing Committee

Report to the Parliament of Australia

For the period 1 April 2003 to 30 September 2003

© Commonwealth of Australia 2003

Paper-based publications

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Commonwealth available from the Department of Communications, Information Technology and the Arts.

Requests and inquiries concerning reproduction and rights should be addressed to the Commonwealth Copyright Administration, Intellectual Property Branch, Department of Communications, Information Technology and the Arts, GPO Box 2154, Canberra ACT 2601 or posted at <http://www.dcita.gov.au/cca>.

© Commonwealth of Australia 2003

Electronic documents

This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use or use within your organisation. Apart from any use as permitted under the *Copyright Act 1968*, all other rights are reserved. Requests for further authorisation should be directed to the Commonwealth Copyright Administration, Intellectual Property Branch, Department of Communications, Information Technology and the Arts, GPO Box 2154, Canberra ACT 2601 or posted at <http://www.dcita.gov.au/cca>.

ISBN Print: 1864961856 Online: 1864961791

To obtain details regarding NHMRC publications contact:

Email: nhmrc.publications@nhmrc.gov.au
Phone: Toll Free 1800 020 103 (Extension 9520)
Internet: <http://www.nhmrc.gov.au>



Australian Government

National Health and Medical Research Council

The Hon Julie Bishop MP
Minister for Ageing
Parliament House
CANBERRA ACT 2600

Dear Minister Bishop

I am pleased to present to you the second biannual report from the Embryo Research Licensing Committee of the NHMRC (the NHMRC Licensing Committee) which reports on the operation of the *Research Involving Human Embryos Act 2002* (the Act) in accordance with section 19(3) of the Act.

This report is for the period 1 April 2003 to 30 September 2003, and describes the activities of the NHMRC Licensing Committee undertaken during this reporting period. It also outlines the strategy for monitoring and compliance.

The Licensing Committee has met three times and has made significant progress in the development of the licence framework, procedural guidance and the consideration of licence applications. No licences have been issued during this reporting period.

I have appointed two inspectors who will be undertaking monitoring and compliance activities once licenses have been issued. Monitoring and compliance activities to date have focussed on communication and awareness through information exchange visits to several IVF facilities.

Yours sincerely

A handwritten signature in black ink, appearing to read "Jock Findlay".

Professor Jock Findlay AM
Chair
NHMRC Licensing Committee

2 December 2003

CONTENTS

GLOSSARY	7
INTRODUCTION	9
<i>Research Involving Human Embryos Act 2002 and Prohibition of Human Cloning Act 2002</i>	9
Reporting Period	10
Structure of Report	10
Further Information	10
PART 1 – COMMITTEE OPERATIONS	11
Appointment and Membership of the Committee	11
Operation of the Committee	13
PART 2 – OPERATION OF THE ACT	15
Information on Licences Issued	15
Monitoring and Compliance	15

GLOSSARY

AHEC	Australian Health Ethics Committee (a Principal Committee of the NHMRC)
ART	assisted reproductive technology
COAG	Council of Australian Governments
CIWG	COAG Implementation Working Group
CREGART	Committee to Review the Ethical Guidelines on ART
Ethical Guidelines on ART	<i>Ethical guidelines on assisted reproductive technology</i> (1996)
HREC	Human Research Ethics Committee
IVF	in vitro fertilisation
Licence Application	Application Form for a Licence to Use Excess ART Embryos
National Statement	<i>National Statement on Ethical Conduct in Research Involving Humans</i> (1999)
NHMRC	National Health and Medical Research Council
NHMRC Licensing Committee	the Embryo Research Licensing Committee of the NHMRC
NHMRC Licensing Committee Secretariat	the group of officials within the NHMRC Secretariat that provide support to the NHMRC Licensing Committee and to whom inquiries may be directed

INTRODUCTION

The Embryo Research Licensing Committee of the National Health and Medical Research Council (the NHMRC Licensing Committee) was established on 15 May 2003 by the former Minister for Ageing, the Hon Kevin Andrews. This is the second Parliamentary Report of the Licensing Committee under the *Research Involving Human Embryos Act 2002*.

Research Involving Human Embryos Act 2002 and Prohibition of Human Cloning Act 2002

The Commonwealth legislation was developed in response to community concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos. The legislation prohibits certain practices including human cloning and regulates certain uses of excess human embryos created through ART.

Section 19(3) of the *Research Involving Human Embryos Act 2002* requires the NHMRC Licensing Committee to cause six monthly reports to be tabled in either House of Parliament on or before 30 June and 31 December each year, and at any other time as required by either House of Parliament. The reports must include information about both the operation of this Act, and licences issued under the Act.

Reporting Period

The reporting periods extend from 1 October to 31 March and 1 April to 30 September each year, allowing a three month period to compile the reports and submit them for tabling by 30 June and 31 December respectively.

This report is for the period 1 April 2003 to 30 September 2003.

Structure of Report

This report is divided into two parts:

Part 1 – Committee Operations

Reports on the activities of the Licensing Committee established under the *Research Involving Human Embryos Act 2002* undertaken during this reporting period.

Part 2 – Operation of the Act

Includes information on licences issued and outlines the strategy for monitoring and compliance.

Further Information

Further information about this report and the issue of licences can be obtained by contacting:

NHMRC Centre for Compliance and Evaluation
MDP 109
GPO Box 9848
Canberra ACT 2601

Phone: 02 6289 9889
Fax: 02 6289 9836
Email: embryo.research@nhmrc.gov.au
Website: www.nhmrc.gov.au

PART 1 COMMITTEE OPERATIONS

Appointment and Membership of the Committee

The inaugural NHMRC Licensing Committee was appointed in May 2003 by the Minister for Ageing, the Hon Kevin Andrews. The nine-member Committee is a Principal Committee of the NHMRC, and was established by the *Research Involving Human Embryos Act 2002* which was passed by Federal Parliament in 2002.

The Committee oversees the national regulatory system for the use of excess human embryos for research through the issue of licences, the appointment of inspectors who monitor compliance with the legislation, and the maintenance of a publicly available database with information about licences issued.

Membership Category	Member	State
A person with expertise in a relevant area of research	Professor John (Jock) Findlay AM	VIC
A member of Australian Health Ethics Committee (AHEC)	Dr Kerry Breen	VIC
A person with expertise in research ethics	Dr Megan Best	NSW
A person with expertise in assisted reproductive technology	Dr Peter Illingworth	NSW
A person with expertise in a relevant area of law	Professor Donald Chalmers	TAS
A person with expertise in consumer health issues relating to disability and disease	Dr Christopher Newell AM	TAS
A person with expertise in consumer issues relating to assisted reproductive technology (ART)	Dr Julia Nicholls	SA
A person with expertise in the regulation of assisted reproductive technology	Ms Helen Szoke	VIC
A person with expertise in embryology	Dr Graham Kay	QLD

The Chair of the Committee is Professor John (Jock) Findlay AM, a Victorian-based internationally renowned expert in research in reproductive medicine and Chair of the World Health Organisation's Scientific and Technical Advisory Group on Human Reproduction. Professor Findlay is the Chair of the Victorian Infertility Treatment Authority and is currently the Deputy Director of Prince Henry's Institute of Medical Research in Victoria. He has received a Member of the Order of Australia (AM) as a medical administrator and for services to medical research, in particular, reproductive biology.

Dr Breen has served on the NHMRC Australian Health Ethics Committee since 1997 and was appointed Chairman in 2000 for 2003-06. He is a physician specialising in gastroenterology and served as Director of the Gastroenterology Department at St Vincent's Hospital, Melbourne. Dr Breen is also a past President of the Medical Practitioners' Board of Victoria and the Australian Medical Council.

Dr Best has a Bachelor of Medicine and a Master of Applied Ethics in Healthcare. Dr Best is currently a part-time lecturer in Health Law and Medical Ethics at the University of New South Wales. Dr Best is also a member of the Social Issues Executive of the Anglican Church in Sydney and participated in the NSW Health review of ART legislation. She has published numerous articles on aspects of medical ethics, including assisted reproduction.

Dr Illingworth is currently the Director of Reproductive Medicine at the Westmead Hospital in Sydney. This department runs a number of tertiary referral specialist human reproductive services including an IVF unit and a sub-specialist reproductive endocrine unit dealing with complex reproductive endocrine problems.

Professor Chalmers is the Dean of Law, University of Tasmania. Professor Chalmers is also Director of the Centre of Law and Genetics at the Universities of Tasmania and Melbourne that undertakes research, particularly on the regulatory and commercial aspects of human genetic research. He is past Chair of the NHMRC Australian Health Ethics Committee, which presented the *National Statement on Ethical Conduct in Research Involving Humans* to the Federal Parliament. He is Chair of the Gene Technology Ethics Committee established under the *Gene Technology Act*.

Dr Newell AM is currently a Senior Lecturer on Medical Ethics, University of Tasmania and Consultant to General Practice Training Tasmania. He is a member of the Governing Committee of Consumers' Health Forum of Australia. Dr Newell was appointed as a Member of the Order of Australia (AM) for service to people with disabilities, particularly through advocacy and research, to the development and practice of ethics and to health consumers.

Dr Nicholls was formerly the Editor and Deputy Chair of OASIS, an infertility support group. Dr Nicholls served for nine years as a member of the SA Council on Reproductive Technology representing consumer interests, and was Deputy Chair for the last six years.

Ms Szoke is the current Chief Executive Officer of the Victorian Infertility Treatment Authority having held this position since 1995. Ms Szoke is currently completing a PhD in Public Policy and also brings relevant experience to the Committee from her time as Chairperson of the Ethics Committee of the Royal Women's Hospital in Melbourne.

Dr Kay is the Laboratory Head of the Queensland Cancer Fund Transgenic Laboratory at the Queensland Institute of Medical Research. His laboratory also runs the Transgenic and Knockout Mouse Facility and freezes mouse embryos for further research. His research interests include the role of specific genes in mammalian embryonic development, disease processes, and tumor suppression. Dr Kay has significant relevant expertise in embryology, which will complement the expertise of the rest of the Committee.

These appointments comply with the specific categories of expertise required by the *Research Involving Human Embryos Act 2002*. The term of appointments coincides with the 2003-05 triennium of Council and will cease on 31 December 2005.

Operation of the Committee

Committee Meetings

The NHMRC Licensing Committee has met three times during this reporting period on 4 June, 30-31 July, and 29-30 September 2003. The Committee has made significant progress in the development of procedural guidance and the consideration of applications received.

Committee Members attended a legal awareness seminar which was conducted by the Canberra office of the national legal firm Phillips Fox. The purpose of the seminar was to promote an awareness of all relevant legislation including the *National Health and Medical Research Council Act 1992*, the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002*.

Licence Framework

The Committee has finalised the content of the licence to authorise the use of excess ART embryos. This document, developed in conjunction with the Legal Services Branch of the Australian Government Department of Health and Ageing comprises three parts: a licence document, a set of standard conditions that will apply to all licences, and a schedule of special conditions that will be tailored to individual licence holders.

Applications

As outlined in the previous report to Parliament, an Information Kit has been prepared that contains information on the legislation and guidance to assist with the preparation and submission of applications to the Licensing Committee. Applications may be submitted to the Committee at any time.

The Committee received eight licence applications during this reporting period, and is continuing the consideration of applications. No licences have been issued. Where necessary, Working Groups of the Licensing Committee have conducted meetings with applicants in order to clarify details and expedite consideration of applications.

Procedural Guidance

On the matter of proper consent, a joint Licensing Committee/Australian Health Ethics Committee (AHEC) working committee has prepared detailed advice for applicants and Human Research Ethics Committees (HRECs) in relation to consent procedures in accordance with the *National statement on ethical conduct in research involving humans* (1999) and the *Ethical guidelines on assisted reproductive technology* (1996).

The Committee has also developed guidance to assist potential applicants to determine whether they need to apply for a licence. A critical issue in determining whether an activity requires a licence is deciding whether an embryo is live or when it has succumbed.

This advice is published on the Embryo Research page of the NHMRC website.

Expert Advice

The Committee has acknowledged that it will at times be necessary to seek additional expert advice from relevant external sources. Consideration has been given to the means of determining the likelihood of significant advance in knowledge or improvement in technologies for treatment.

The Committee is working with the Legal Services Branch of the Australian Government Department of Health and Ageing to resolve issues around the protection of commercial-in-confidence material contained in applications, how any additional expert advice received should be made available to the applicant for comment, and whether it is appropriate to withhold the identity of those persons who provide additional advice to the Committee.

PART 2 OPERATION OF THE ACT

Information on Licences Issued

Under Section 29 of the *Research Involving Human Embryos Act 2002*, the NHMRC Licensing Committee is required to make certain information publicly available including the name of the licensee, the number of embryos used, the nature of the research, the date of issue and any conditions imposed on the licence.

When a licence is issued, the above information will be made available to the public via the Embryo Research page of the NHMRC website.

Monitoring and Compliance

The *Research Involving Human Embryos Act 2002* establishes a monitoring and compliance capacity in order to facilitate compliance by all individuals and organisations undertaking activities relevant to the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*.

This includes:

- Activities involving excess ART embryos;
- Activities involving non-excess ART embryos; and
- Prohibited practices such as human cloning and creation of human embryos specifically for research purposes.

In accordance with Section 33 of the *Research Involving Human Embryos Act 2002*, two inspectors were appointed by the Chair of the NHMRC Licensing Committee during the reporting period. The inspectors are Commonwealth public servants employed within the NHMRC Secretariat.

During the reporting period the NHMRC Licensing Committee endorsed the implementation of the following monitoring and compliance strategy:

1. Communication and Awareness – Inspectors will engage in regular information exchange with individuals and organisations undertaking activities that may be covered by the legislation to strengthen understanding and reinforce the legislative requirements under the new regulatory system. This includes researchers, licence holders and members of Human Research Ethics Committees.
2. Advice – In addition to the above, verbal and written advice will be provided to all stakeholders to assist them in meeting and understanding their obligations under the legislation.
3. Monitoring – Inspectors will conduct routine monitoring visits to licence holders on a regular basis to ensure compliance with licence conditions. Inspectors will also gain information on activities being undertaken more generally through the program of regular information exchange visits.
4. Investigations – Allegations of suspected serious non-compliance will be investigated in accordance with the Commonwealth Fraud Control Guidelines and may be referred to the Australian Federal Police.

During the reporting period, inspectors undertook information exchange visits to four IVF Units in the Australian Capital Territory and New South Wales. Other visits are planned for relevant organisations in all States and Territories.