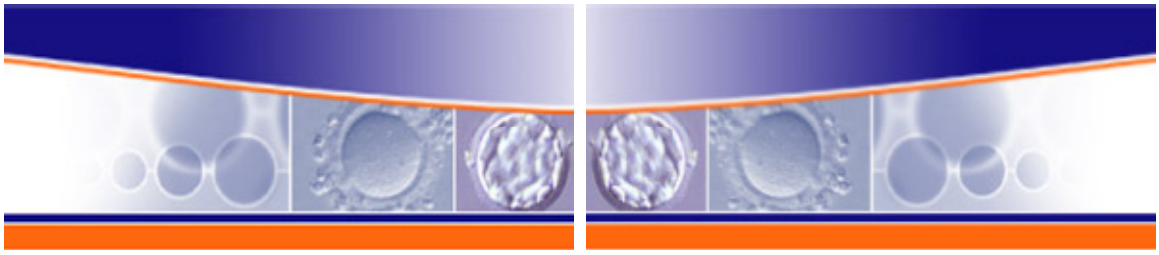
Western Australian Reproductive Technology Council

Annual Report

1 July 2006 – 30 June 2007



Annual Report of the Western Australian Reproductive Technology Council

1 July 2006- 30 June 2007

This Report may be found on the Council's web site or may be obtained free of charge from:

The Western Australian Reproductive Technology Council

189 Royal Street, East Perth WA 6004

For further information please contact-
The Council's web site at

http://www.rtc.org.au

or

Ms Melissa Chantry (08) 9222 4048

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September 2007
Perth, Australia

Reproductive Technology Council

Dr Neale Fong
Chief Executive Officer
Department of Health
1 Alvan Street
SUBIACO WA 6008

Dear Dr Fong

It is with pleasure that I submit to you this Annual Report of the Reproductive Technology Council (Council). This Report is for the financial year 2006-2007. It sets out details of reproductive technology practices in this State and activities of the Council during the year, as required by the *Human Reproductive Technology Act 1991* (HRT Act). It is in a form suitable for submission by you to the Minister for Health and also, as is required, to be laid by the Minister before each House of Parliament.

Over the previous year, the work of the Council has been dominated by applications for diagnostic testing of embryos and applications for extensions to the storage period for embryos. These are both the outcomes of the amendments to the HRT Act, which came into operation on 1 December 2004. The amendments increased the permitted embryo storage period from 3 to 10 years. For extensions beyond 10 years applications must be made to the Council by the participants undertaking ART services. Importantly, the licensee is no longer able to make this application on behalf of a participant. The development of a Council embryo storage policy has been a focus for the 2006-2007 year. This policy is important in providing Council guidance for the assessment of embryo storage applications, and to outline options for ART participants regarding their stored embryos.

Throughout the year Council has been busy refining the policy and processes for the approval of genetic testing of embryos and working with clinics and legal services to clarify the understanding of the requirements of the HRT Act, addressing eligibility for genetic testing of embryos. Other significant amendments implemented on the advice of Council have included the reduction in the cooling off period for psycho-social preparation for known egg and embryo donation, the approval for licensed ART clinics to collect and store eggs for later use for those eligible under the HRT Act.

Council assessed and recommended the approval of provisional practice and storage licenses to a further assisted reproductive technology (ART) clinic, bringing to six the number of licensees offering ART services in Western Australia.

In an advisory role, Council provide feedback concerning the Surrogacy Bill 2007, which is currently before Parliament. Council has collaborated with Legal and Legislative Services in the development of subsidiary legislation for this Bill.

In addition, Council participated in a seminar with visiting members for the National Health and Medical Research Council (NHMRC) Licensing Committee. As set out by the HRT Act, research involving excess ART embryos must be conducted under a NHMRC licence.

The work of the Council is not possible without the ongoing support of a significant number of people. Among these I would like to pay special tribute to the commitment of the Executive Officer and staff. Council would also like to thank Ms Deborah Andrews for her continuing legal support and guidance and to acknowledge the ongoing financial and administrative support provided by the Department of Health. This support is essential to enable the Council to carry out its statutory duties.

Yours sincerely

CA Michael AO
CHAIR
Reproductive Technology Council

13 September 2007

CONTENTS

GLOSSARY

AI	Artificial insemination
ART	Assisted reproductive technology
CEO	Chief Executive Officer
DI	Donor insemination
DOH	Department of Health WA
FET	Frozen embryo transfer
FSA	Fertility Society of Australia
GIFT	Gamete intra fallopian transfer
HRT Act	Human Reproductive Technology Act 1991
HRTA Bill	Human Reproductive Technology Amendment Bill 2007
IVF	In vitro fertilisation
ICS	Intra cytoplasmic sperm injection
IUI	Intra uterine insemination
PGD/PGS	Pre-implantation genetic diagnosis/ Pre-implantation genetic screening
NHMRC	National Health and Medical Research Council
RTAC	Reproductive Technology Accreditation Committee (Committee of the Fertility Society of Australia)
RTC	Western Australian Reproductive Technology Council (Council)
SCNT	Somatic cell nuclear transfer
Surrogacy Bill	Surrogacy Bill 2007

2006-2007 year – refers to the period 1 July 2006 until 30 June 2007

EXECUTIVE SUMMARY

This Annual Report has been prepared by the Reproductive Technology Council for the Chief Executive Officer (CEO), to comply with the requirements of Section 5(6) of the *Human Reproductive Technology Act 1991* (HRT Act). As set out in the HRT Act, the CEO is required to submit an annual report to the Minister, so that copies are laid before each House of Parliament. The Annual Report outlines the use of reproductive technology in the State, and the operations of the Reproductive Technology Council (Council) for the year ending June 30 2007.

As outlined in the HRT Act, the Council has an important role as an advisory body to the Minister and to the CEO on matters in reproductive technology, the administration of the HRT Act and providing advice on licensing matters for artificially assisted human reproduction in Western Australia. The Council is also charged with the responsibility of setting and monitoring the standards of practice for those licensed to carry out assisted reproductive technology (ART) practice, and to promote informed public debate and consultation on issues relating to infertility and reproductive technology.

> As at June 30 2007, there were six establishments in Western Australia providing ART services under both a Practice Licence and a Storage Licence. One newly established clinic was granted provisional licences in 2006-2007.

The HRT Act distinguishes between clinics or establishments which operate for the purpose of assisting human reproduction (regulated by the Council through the issuance of ART practice and storage licences), and the undertaking of research using excess ART embryos, which is regulated by the National Health and Medical Research Council (NHMRC).

> As at June 30 2007 there are no NHMRC licenses authorising the use of excess ART embryos for research in Western Australia.

Scientific interest in undertaking such research in Western Australia could potentially be stimulated with the enactment of the Human Reproductive Technology Amendment Bill 2007. The proposed amendments currently before Parliament may permit, under NHMRC licence, research by establishments using excess ART embryos or therapeutically cloned embryos for the purpose of improving scientific understanding of ART, genetic basis of disease and potential treatment options. The use of therapeutically cloned embryos for reproduction will remain strictly prohibited.

Previous amendments to the HRT Act proclaimed in 2004 have expanded the Council's activities in approval of ART practices. The amendments allowed for licensees to undertake Pre-implantation Genetic Diagnosis (PGD) of embryos. The intent of the PGD provision is to allow the selection and use of ART embryos that avoid potentially inheritable damaging conditions. Sex selection of embryos (PGS) is only considered for approval when there is a risk of embryos carrying or developing a serious sex-linked genetic disease.

Council approval of each individual PGD/PGS application is supported by advice from the PGD (Implantation) Technical Advisory Committee. There are currently 4 licensees offering this service to patients in Western Australia, one of which was granted approval to provide PGD/PGS in the 2006-2007 year.

The Council has an ongoing role to promote public debate on issues pertaining to reproductive technology, and to communicate and collaborate with similar organisations or groups. In this capacity, Council has been active in providing expert advice to assist and inform the development of policy in several areas, covering both State and Commonwealth jurisdictions. In 2006-2007 Council provided advice in relation to the development of subsidiary legislation for the proposed Surrogacy Bill 2007. The Surrogacy Bill 2007,

currently before Parliament, was introduced to the Western Australian Parliament on 1 March 2007, to provide State legislation that deals directly with surrogacy issues. Of particular relevance to the HRT Act is the proposal to allow conditional access of birth parent/s to *in vitro* fertilization procedures if the arranged parent/s are considered eligible for the procedures. Through this means, women who are not able to conceive or carry a child themselves due to medical reasons may be able to arrange for another woman to become pregnant and to carry a child on their behalf. The Surrogacy Bill 2007 also allows for parentage orders to be made for children conceived through ART practices. The strict prohibition of surrogacy for reward is another important component of this proposed legislation. Staff from the Reproductive Technology Unit (Department of Health) have collaborated with officers in the Legal & Legislative Services Directorate responsible for developing draft Directions, and have also sought input from the Council for this purpose.

With regard to the Department of Health (DOH) support received by the Council, the effective loss to the Council of the Executive Officer due to illness during the early part of 2007 has created significant concern to Council members. The position is critical in maintaining and managing ongoing duties of the Council, in providing secretariat support to the Council and its committees, coordinating specific aspects related to the administration of the HRT Act and communication with licensees. Maintenance of the Reproductive Technology Register and Voluntary Register is also an important duty undertaken by the Executive Officer, and Council welcomes the efforts being made by the Department of Health to identify a suitably qualified person to provide the required executive support as a matter of urgency.

The 2006-2007 budget allocation to the Reproductive Technology Council was $38,880. The Financial Statement outlining the distribution of expenses is provided in the Annual Report. The main expenses from the Financial Statement include Council member professional sitting fees, and the cost of a public information campaign highlighting changes to embryo storage periods. Due to advertising and public information program costs arising from the regulatory changes, Council marginally exceeded the budget allocation.

Council has played an active role in the regulation of ART practices in Western Australia in 2006-2007. For the next year, ongoing policy development is regarded as a priority for the Council. This focus will be augmented with the prospect of amendments to the HRT Act, and the anticipated impact these amendments pose to the practice of ART and embryo research in this State.

INTRODUCTION

The Western Australian Reproductive Technology Council (the Council) was established to undertake functions relating to the practice of and research in reproductive technology in Western Australia, as set out by the *Human Reproductive Technology Act 1991* (the HRT Act).

Functions of the Reproductive Technology Council

Section 14 of the HRT Act outlines the functions of the Council. These include;

> providing advice to the Minister on issues relating to reproductive technology, and the administration and enforcement of the HRT Act;
>
> providing advice to the Chief Executive Officer (CEO) of Health on matters relating to licensing, administration and enforcement of the HRT Act;
>
> to formulate and review a Code of Practice and guidelines to govern assisted reproductive technology practices and storage procedures undertaken by licensees, and thereby to regulate the proper conduct, including counselling provision, of any reproductive technology practice;
>
> to encourage and facilitate research, in accordance with the HRT Act, into the causes and prevention of all types of human infertility and the social and public health implications of reproductive technology and
>
> to promote informed public debate on issues arising from reproductive technology, and to communicate and collaborate with other similar bodies in Australia and wider.

The Council is responsible for providing advice to the CEO regarding the issuance of practice and storage licences (or if appropriate, exemptions) in Western Australia. These licences regulate the use of reproductive technology for the purpose of assisting people who are unable to conceive children naturally or without risk to a naturally-conceived child. As a condition of the storage and practice licenses, licensees must have accreditation through the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia, or another prescribed body.

In addition to the above licensing requirements of the HRT Act, amendments to the HRT Act in 2004 also set out that research on excess Assisted Reproductive Technology (ART) embryos must be carried out under a National Health and Medical Research Council (NHRMC) licence. The NHMRC Embryo Research Licensing Committee is charged with the responsibility for undertaking this licensing process in Western Australia.

MEMBERSHIP OF THE COUNCIL 30 June 2007

Member	Nominee of:
Professor Con Michael	The Royal Australian and New Zealand College of Obstetrics
Chair	and Gynaecology
A/Professor Jim Cummins	The Minister for Health
Ms Leonie Forrest	The Law Society of Western Australia
Ms Yvonne Patterson	The Minister for Community Development (until May 2007)
A/Professor Roger Hart	The Department of Obstetrics and Gynaecology, University of Western Australia
Fr Joe Parkinson	The Minister for Health
Dr Beverly Petterson	The Minister for Health
Ms Patrice Wringe	The Health Consumers' Council
Ms Antonia Clissa	Executive Officer *ex officio* Senior Policy Officer, Department of Health
Vacant	The Health Consumers' Council

Deputy Member	Nominee of:
Dr Angela Cooney	The Australian Medical Association
Dr Brenda McGivern	The Law Society of Western Australia
A/Professor Neville Bruce	The Minister for Health
Dr Stephen Junk	The Department of Obstetrics and Gynaecology, University of Western Australia (July- September 2006)
Ms Sonja Lundie-Jenkins	The Health Consumers' Council
Reverend Brian Carey	The Minister for Health
Ms Sue Midford	The Health Consumers' Council
Mr Hans-willem van Hall	The Minister for Community Development
Ms Amalia Burmas	Deputy Executive Officer *ex officio* Research Officer, Department of Health

COMMITTEES OF THE COUNCIL

Counselling Committee

Terms of Reference:

In relation to counselling-

1. a) establishing standards for approval of counsellors as "approved counsellors", as required by the Code of Practice or Directions of *Human Reproductive Technology Act 1991* for counselling within licensed clinics, and for counselling services available in the community;

   b) recommending to the Reproductive Technology Council (Council) those counsellors deemed suitable for Council approval or interim approval, and reconsidering those referred back to the Committee by the Council for further information;

   c) monitoring and reviewing of the work of any approved counsellor;

   d) convening training programs for counsellors if required;

   e) establishing a process whereby counsellors may have approval withdrawn or may appeal a Council decision;

   f) reporting annually as required by Council for its annual report to the CEO of Health, including information on its own activities and information reported to it by Approved Counsellors;

2. Advising and assisting the Council on matters relating to consultation with relevant bodies in the community and the promotion of informed public debate in the community on issues relating to reproductive technology;

3. Advising the Council on matters relating to access to information held on the IVF and Donor Registers; and

4. Advising the Council on psychosocial matters relating to reproductive technology as the Council may request.

Membership:

Ms Sue Midford (Chair), Ms Stephanie Knox (consumer representative) until October 2006, Mr Peter Fox (consumer representative), Ms Colleen Brown (consumer representative), Mr Robert Sterry (consumer representative) until November 2006, Mr Hans-willem van Hall, Ms Iolanda Rodino, Ms Patrice Wringe, Ms Amalia Burmas (*ex officio)* and Ms Antonia Clissa (*ex officio)*.

Embryo Storage Committee

Terms of Reference:

With the agreement of the Minister for Health as required under s(10)(4) of the HRT Act, the Council, by resolution under s11(1) of the HRT Act, may delegate this Committee to-

make decisions on applications for extension of the periods of storage of embryos on a case by case basis, based on the criteria agreed to by the Council, and to provide to the next meeting of Council details of all decisions made since the previous meeting; and

provide other advice or carry out other functions relating to the storage of embryos, as instructed by the Council.

Membership:

Rev Brian Carey (Chair), Dr Brenda McGivern, Ms Sue Midford, Ms Yvonne Patterson, Ms Patrice Wringe, Ms Amalia Burmas (*ex officio)* and Ms Antonia Clissa (*ex officio*).

Licensing and Administration Advisory Committee

Terms of Reference:

1. Advise the Council on matters relating to licensing under the HRT Act, including the suitability of any applicant and the conditions that should be imposed on any licence.

2. Advise the Council generally as to the administration and enforcement of the HRT Act, particularly disciplinary matters.

3. Advise the Council as to suitable standards to be set under the HRT Act, including clinical standards.

4. Advise the Council on any other matters relating to licensing, administration and enforcement of the HRT Act.

Membership:

Professor Con Michael (Chair), Ms Leonie Forrest, Dr Roger Hart, Ms Stephanie Knox and Ms Amalia Burmas *(ex officio*) and Ms Antonia Clissa (*ex officio*).

PGD (Implementation) Technical Advisory Committee

For the purposes of these Terms of Reference the term pre-implantation genetic diagnosis (PGD) is taken to include all diagnostic procedures that may be carried out in vitro upon or with a human embryo or egg undergoing fertilisation prior to implantation.

Terms of Reference:

1. To advise the Council on a suitable framework for the approval of PGD under the HRT Act, both generally and for specific cases.

2. To advise the Council on factors that it should consider when deciding whether to approve PGD.

3. To advise the Council on standards for facilities, staffing and technical procedures.

4. To advise the Council as to how the ongoing process of approval of PGD should be managed effectively by the Council, once the implementation phase is over.

5. To advise the Council on other relevant matters as requested by the Council.

The Committee may consult with relevant experts in the preparation of this advice for the Council including, counselling in relation to PGD, with the Counselling Committee.

Membership:

(Chair to be member of the Council, appointed by the Council from membership of the Committee).

- 2 members of the Council, chosen to maximise relevant experience and expertise on the Committee.
- 1 Clinical geneticist (or in the event none is available a suitably qualified clinician or genetic counsellor)
- 1 Laboratory geneticist
- 1 Human embryologist (to be recommended by RTAC or holding office in RTAC or Scientists in Reproductive Technology (SIRT)
- 1 DOH lawyer with an understanding of requirements of the Act
- Committee Executive Officer (DOH RT Unit staff)

Dr Beverly Petterson (Chair), Ms Daphne Andersen, Dr Steve Junk, Ms Sonja Lundie-Jenkins, Dr Ashleigh Murch, Dr Sharron Townshend, Ms Amalia Burmas (*ex officio)* and Ms Antonia Clissa (*ex officio)*.

Scientific Advisory Committee

Terms of Reference:

With the agreement of the Minister for Health as required under s(10)(4) of the *Human Reproductive Technology Act 1991* (HRT Act) this Committee may-

Provide the Reproductive Technology Council (Council) with scientific advice in relation to:

any project of research;
embryo diagnostic procedure; or
innovative practice,
for which the specific approval of the Council is (or may be) sought;
the review of the Act which is to be carried out as soon as practicable after the expiry of 5 years from its commencement and
any other matter as instructed by the Council.

Membership:

A/Professor Jim Cummins (Chair), Dr Roger Hart, Dr Phillip Matson, Fr Joseph Parkinson, Dr Beverly Petterson and Ms Amalia Burmas *(ex officio)*.

Staff of the Reproductive Technology Unit Department of Health

Ms Antonia R Clissa
Senior Policy Officer and Executive Officer of the Council

Ms Amalia Burmas
Senior Project Officer and Deputy Executive Officer of the Council until June 2007.

Ms Melissa Chantry
Research Officer from December 2006

REPRODUCTIVE TECHNOLOGY COUNCIL
FINANCIAL STATEMENT 1 July 2006 - 30 June

The Department of Health (DOH) funds the administration of the HRT Act, including the operations of the Council, which incorporates infrastructure and workforce development. The 2006/07 budget allocation was $38,880.00 with expenditure of $39,153.30 for the financial year.

This represents over-expenditure of $273.30 (0.7%) of the allocated budget. Council has a long record of remaining within the allocated budget. Council incurred unforecast costs from a requirement to inform the public of changes to embryo storage regulations.

REPRODUCTIVE TECHNOLOGY COUNCIL Expenses by Category	Expenditure ($)	Income ($)
Staff or Council:		
Training/Registration/Course Fees	$1583.91	
Travel interstate Airfares Accommodation	$6916.49	
Motor vehicle/Taxis	$351.52	
TOTAL	**$8851.92**	
Food supplies/catering	$445.66	
Administration and clerical		
TOTAL	**$445.66**	
Purchase of external services:		
Sessional fees: (External Consulting Fees) Reproductive Technology Council Council Committees: Counselling Scientific Advisory Embryo Storage Licensing and Administration Approved counsellors	$20 093.00	
External consulting fees and advertising	$9489.74	
TOTAL	**$29582.74**	
Other expenses:		
Books/magazines/subscriptions	$100.00	
Freight/ cartage/postal		
Printing and stationery incl. Annual Report Website Domain expenses	$314.98	
TOTAL	**$314.98**	
Reimbursement to RTC for Other Expenses	**- 142.00**	
TOTAL	**$ 39153.30**	
Budget Allocation		**$38,880.00**

OPERATIONS OF THE COUNCIL 2006-2007

Meetings

The Council met on 10 occasions during the 1 July 2006 to 30 June 2007 period, with attendances reaching quorum at all meetings. The Counselling Committee met on 4 occasions; the PGD (implementation) Technical Advisory Committee met on 3 occasions, although many applications for PGD were assessed out of session before being approved at the following Council meeting. The Embryo Storage Committee met on 6 occasions during the year, and considered several non-urgent applications for the extension of storage of embryos out of session. These were subsequently discussed for approval at the following Council meeting. The Licensing and Administrative committee met on one occasion, and the Scientific Advisory Committee met on 2 occasions during 2006-2007.

Membership

Outgoing members in 2006-2007

Several valued members of the Council and committees to the Council resigned from Council positions during the year.

Dr Steve Junk, the Deputy nominated by the University of Western Australia (UWA) Department of Obstetrics and Gynaecology resigned from his position on Council in September 2006. However, Dr Junk is continuing on as a valued member of the PGD Committee providing expert advice, in particular in embryology.

Ms Stephanie Knox, a long-term member and consumer representative on the Counselling Committee since 1999, tended her resignation from the committee in October 2006. Ms Knox had also acted as a representative on the embryo storage and the licensing committees, plus as a member of Council.

Mr Robert Sterry, who served on the Counselling Committee since 2002, resigned from this committee in November 2006 due to family relocation. As a consumer representative, Mr Sterry had been a committed spokesperson as a recipient parent in donor conception.

Ms Yvonne Patterson, Council nominee for the Department of Community Development and member of the Embryo Storage Committee, resigned from her positions in May 2007 following the re-organisation of the Department. A representative from the newly established Department for Child Protection is to replace Ms Patterson, who had been on the Council since May 2006.

Ms Amalia Burmas, an *ex officio* member of Council and Ministerial Appointee, resigned from her position as Deputy Executive Officer to the Council in 2007. Ms Burmas had developed a considerable working knowledge of Council matters, and her executive support to the Council will be missed.

Department of Health Staff assisting the work of the Council

For much of the 2006 -2007 year, executive support to the Council was provided by Ms Antonia Clissa and Ms Amalia Burmas.

Ms Clissa, was appointed under the HRT Act as Executive Officer to the committee, following the resignation of Dr Sandra Webb in 2005 and in this role undertook executive functions for Council including liaising with licensees, approved counsellors, and consulting with officers from the Legal & Legislative Services Directorate. Ms Clissa had also been responsible for the management of the Reproductive Technology Unit in the DOH. Ms Clissa, provided significant support to the function of the Council but has been on indefinite leave since June 2007.

Ms Amalia Burmas was appointed as Senior Project Officer for the Department of Health, and held a role on Council as Deputy Executive Officer. As noted above, Ms Burmas tended her resignation from this position in June 2007.

Ms Melissa Chantry was appointed as Research Officer, and has been an invited guest at Council meetings since May 2006. During the 2006-2007 year, Ms Chantry has assisted with the collation of licensee information, and is involved with the ongoing management of the Donor Register and Voluntary Register for information about donation in assisted reproduction.

Acknowledgements

The Council gratefully acknowledges:

Administrative support for the collation and writing of this Annual Report from Dr Peter O'Leary and staff at the Office of Population Health Genomics.

The continuing legal support of Ms Deborah Andrews and Ms Daphne Andersen of Legal and Legislative Services.

Data management and support from Ms Merran Smith and Mr Tony Satti from Information Collection and Management

Accounting and administrative support from Ms Pam Addison and Mr Lex Cassidy.

Complaints

The Council received no formal complaints concerning licensees during the year.

LICENSING ISSUES

Establishments licensed under the *Human Reproductive Technology Act 1991* at 30 June 2007

Practice and Storage Licenses:

In Vitro Laboratory Pty Ltd trading as Concept Fertility Centre
King Edward Memorial Hospital
Bagot Road
Subiaco WA 6008

Fertility North Pty Ltd
Suite 213 Specialist Medical Centre
Joondalup Health Campus
Shenton Avenue
Joondalup WA 6027

Western IVF Pty Ltd trading as Fertility Specialists Western Australia
Bethesda Hospital
25 Queenslea Drive
Claremont WA 6010

Sydney IVF Perth Pty Ltd trading as Hollywood Fertility Centre
Hollywood Private Hospital
Monash Avenue
Nedlands WA 6009

JL Yovich Pty Ltd trading as PIVET Medical Centre
166-168 Cambridge Street
Leederville WA 6007

Practice (AI only) and Storage Licenses:

The Keogh Institute for Medical Research (Inc.)
Sir Charles Gairdner Hospital
2 Verdun Street
Nedlands WA 6009

Establishments licensed in Western Australia by the National Health and Medical Research Council.

Under Part 4B of the HRT Act, the NHMRC (through the Embryo Research Licensing Committee) is authorised to license research projects involving excess ART embryos.

There are no establishments currently undertaking this research in Western Australia under NHMRC licence.

Exemptions under the Human Reproductive Technology Act 1991

Medical practitioners that meet the requirements of the HRT Act may apply for an exemption from a licence to practice artificial fertilisation procedures in Western Australia. No applications for exemptions to practice AI were received by Council in 2006-2007. A list of practitioners currently issued with exemptions under section 28 of the HRT Act is provided in Appendix 1.

Reproductive Technology Accreditation Committee site visits

Accreditation by the Fertility Society of Australia (FSA) is a condition of licence for establishments granted a practice or storage licence under the HRT Act. The FSA has established the Reproductive Technology Accreditation Committee (RTAC) to undertake site visits as part of the accreditation process. A two-member RTAC panel undertook an inspection of the Western IVF Pty Ltd on 29 September 2006 as condition of the provisional accreditation granted until October 2007. The approval of Western IVF Pty Ltd, trading as Fertility Specialists WA, to provide ART services followed an assessment of compliance to the HRT Act. This included the attainment of legal and expert advice.

Information circulated to licensees

In addition to individual licensee correspondence during the 2006-2007 year, all licensees received information from Council concerning the following matters:

Counselling recommendations:

Counselling Committee concerns arose from annual licensee reports that suggested counselling sessions offered to participants were decreasing despite an increasing number of ART participants. Council communication with licensees outlined a request to provide counselling sessions to all new ART patients. Under HRT Act Directions, all participants undergoing IVF must have access to a counsellor. Additionally, Council recommended each licensee's annual report identifies all counselling information sessions, including follow up sessions and telephone counselling, and that clinics develop a strategic plan outlining the range of resources available for patient support.

Direction 7.7:

All licensees were informed that following legal advice, the requirement to seek Council approval to use ART practices to avoid the transmission of infectious diseases such as Hepatitis B and Human Immunodeficiency Virus (HIV) was only applicable when innovative procedures were to be used.

Protocols, Patient Information and Consent Forms.

Part 4 of the Directions for the HRT Act outlines the necessary information licensees and exempt practitioners must provide to enable patients to give effective consent to ART procedures.

The Council recognises the importance of providing clear and accurate information to patients seeking ART services. The quality of consent forms and patient information developed by licensees seeking approval for innovative procedures has been a focus for Council in 2006-2007. Following the review, licensees applying to offer oocyte cryopreservation (collecting and freezing eggs for later use) were requested to ensure that patient information included about the changes relating to posthumous use of oocytes and eligibility for future use of these oocytes. This is an important issue for women seeking this treatment option prior to undergoing chemotherapy for cancer or other life-threatening conditions. This direction is consistent with the implementation of quality assurance systems required under RTAC accreditation.

Council reviewed its policy for assessing all patient information and consent forms in April 2007, and determined that all new and amended documents submitted by ART clinics would be assessed by Council. This assessment was previously undertaken out of session by Dr Mark McKenna (member until May 2006) as Chair of the Licensing and Administrative Advisory Committee.

LICENSEE APPLICATIONS TO COUNCIL 2006-2007

Under the HRT Act, specific approval from Council is required for clinics to carry out certain practices, including embryo diagnostic testing, research projects and innovative practices. Indicated below are practices that obtained approval during the 2006-2007 year. An itemised list of applications made by licensees in 2006-2007 is provided in Appendix 3.

Embryo Storage applications

Amendments to the HRT Act in 2004 extended the initial storage period for stored embryos created for assisted reproductive purposes from 3 years to 10 years. Council has identified the need for the development of a Council Embryo Storage Policy in response to these changes. The criteria in this document will guide Council decision-making with regard to the approval of extension applications, and to provide the basis for information to participants with embryos in storage.

Council recognises that the majority of participants store embryos with the intention to use or to donate these embryos for ART treatments. However, a small proportion of embryos are stored by participants who after completing their ART treatments remain uncertain as to their intended future purpose for their stored embryos. The Council's Embryo Storage Policy and supporting literature, will clarify the options for all participants holding embryos in storage. The policy has yet to be ratified by Council but the draft policy proposes that extension of embryos for storage beyond the 10 year period will only be granted in exceptional circumstances. Currently applications are assessed on a case-by-case basis to determine approval to extend storage of embryos.

An advertising campaign outlining the changes to the HRT Act was conducted over June/July in 2006 in several metropolitan and regional Western Australian newspapers. The campaign generated a number of inquiries from members of the public seeking further information regarding the legislation and policy changes of embryo storage.

For the 2006-2007 year, 23 applications to extend Embryo Storage periods were approved by Council under the advice of the Embryo Storage Committee. Of these applications, 2 were granted a 6 month extension and 21 were granted a 12 month extension. One application required further consideration due to potentially conflicting requests from the participants. Correspondence aiming to establish the intentions of each party continued at the end of the 2006/2007 year.

Research Project applications

Part 4B of the HRT Act states that research conducted using excess ART embryos must be carried out under an NHMRC Licence. Research projects not requiring an NHMRC licence must receive Council approval. Summary information indicating the current status and related matters of any research project must be submitted with the Licensee Annual Reporting.

Research projects approved in 2006-2007

Oocyte cryopreservation: This research project aimed to assess the effectiveness of three different protocols for freezing oocytes. Oocytes unsuitable for implantation would be used, and the proportion of oocytes surviving thawing would be examined. Embryos would not be created from these cells. Approved 17/10/2006.

A list of all projects currently approved by the Council for the period 1 July 2006 to 30 June 2007 is provided in Appendix 3.

Innovative Practice applications

Approval to use an innovative procedure must be sought from Council under Direction 9.4. Innovative procedures are non-routine practices, as set out in Part 2 of Schedule 5 in the Directions. As technology advances and new techniques are utilised, practices may move from an innovative status to routine. For example, Council considered a request to amend the status of blastocyst culture, currently an innovative procedure involving the transfer of embryos at 4-5 days of age for assisted reproduction such as IVF. Routine practice has been to transfer less developed embryos on days 2-3. Peer reported literature and evidence of international practices provided by the licensee would contribute towards the decision to shift the status of a procedure from innovative practice classification to routine. Some examples of innovative practices that were approved during 2006-2007 include assisted hatching (assisting the embryo to escape the zona pellucida to allow implantation), in vitro maturation (of oocytes, which allows oocytes to be collected without ovarian stimulation drugs), and oocyte cryopreservation (preservation of oocytes by freezing techniques). Innovative procedures approved under Direction 9.4 for 2006-2007 are listed in Appendix 3.

Applications to allow diagnostic testing of embryos

Previous amendments to the HRT Act proclaimed in 2004 have expanded the Council's activities in approval of ART practices. The amendments allowed for licensees to undertake PGD of embryos. The intent is to allow the selection and use of ART embryos that avoid potentially inheritable damaging conditions. Sex selection of embryos (PGS) is only considered for approval when there is a risk of embryos carrying or developing a serious sex-linked genetic disease.

Council approval of each individual PGD/PGS application is supported by advice from the PGD (Implantation) Technical Advisory Committee. A feasibility study into the benefits of undertaking testing of particular conditions may be required prior to the approval of a PGD procedure. Advice from a clinical geneticist may be sought. Factors that influence the approval process include the severity of the condition, and the risk of an embryo inheriting the condition. Many of the approvals made under Direction 8.8, which outlines the approval to collect eggs from a participant who has 3 or more embryos or eggs undergoing fertilisation in storage in *exceptional circumstances*, are to allow the performance of PGD on newly created embryos. This is necessary as the ability to biopsy embryos already in storage (at the blastocyst stage of development) is not currently available in Western Australia.

There are currently 4 licensees offering this service to patients in Western Australia, one of which was granted approval to provide PGD/PGS in the 2006-2007 year.

Applications to waive Directions under the Human Reproductive Technology Act 1991.

The Directions to the HRT Act set out the practices for which licensees must seek council approval. For the year 2006-2007, Licensees sought Council approval to waive Directions 6.3 and 7.7, and sought approval under Direction 8.8.

> Direction 6.3: The council may, on compassionate grounds, approve the import of donated gametes, embryos or eggs undergoing fertilisation where the required donor identifying information is not available.
>
> Direction 7.7: the licensee must ensure that an IVF procedure directed at reducing the risk of transmission of an infectious disease, such as AIDS or hepatitis, is not undertaken without the prior approval of the Council (see below).
>
> Direction 8.8: In exceptional circumstances, Council may approve the collection of eggs from a participant who has 3 or more embryos or eggs undergoing fertilisation in storage.

In 2006-2007, Council approved three applications to waive Direction 6.3, five applications to waive Direction 7.7 and four applications under Direction 8.8. In addition, Council considered and approved one application to reduce the cooling off-period to 3 months for known sperm donation. A further application, where the start date of the cooling off period for egg donation was allowed to remain at 3 months despite a delay in access to counselling by the participants, also received approval.

With regard to the requirement to seek Council approval to waive Direction 7.7, legal advice was sought to clarify this matter. Legal opinion was to the effect that applications for approval to waive Direction 7.7 must be sought when an *innovative procedure* was intended to be used for this purpose. Where participants are eligible to receive IVF treatment as they are unable to conceive a child for medical reasons, and, for example, the female partner had an infectious disease such as hepatitis B, the use of routine infection control methods by licensees need not be dependant upon Council approval. This opinion was received by Council in February 2007, and thereafter communicated to licensees.

THE COUNCIL'S ROLE AS AN ADVISORY BODY

The Council has a prescribed role to promote public debate on issues pertaining to reproductive technology, and to communicate and collaborate with similar organisations or groups.

In this capacity, Council has made several submissions to contributing to policy development in the 2006-2007 year. Council's contributions are summarised below.

NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research. The NHMRC conducted a public consultation following amendments to Commonwealth Acts that legislate for reproductive technology and research. The summarised response following Council consideration of Amendments to the guidelines was general agreement with the amendments in the draft documents. Submissions were due by May 2007.

Surrogacy Bill 2007 and Directions:
In reference to the Surrogacy Bill 2007, currently before Parliament, the Council expressed concern regarding that the transfer of parentage as set out in the Bill would be limited to those who were eligible for surrogacy in accordance with Section 23 of the HRT Act.
The Counselling Committee provided feedback in particular with regard to the provision and requirements for counselling, assessment protocols and the structured nature of the assessment regimen. The Reproductive Technology Unit in the Department of Health worked with the Legal & Legislative Services Directorate to draft subsidiary legislation in the form of Directions. Council members with relevant expertise were also consulted throughout this process.

Members from the Council were also invited to provide expert comment at a Surrogacy Forum for members of Parliament.

Australian Commission on Safety and Quality in Health Care- Review of the National Safety and Quality Accreditation Standards:
Council was invited to comment on the Review discussion paper. The discussion paper provided an overview of the current safety and quality accreditation systems and proposed an integrated package of reform. Relevant recommendations in the discussion paper included that an appropriate skilled and resourced body undertake the accreditation of ART providers.
A focus group meeting was arranged with the Review organising officer for February 2007, which provided an opportunity for attending council members to provide comment on the proposed accreditation model.

South Australian Legislative Council inquiry into Gestational Surrogacy:
Council provided a one page submission to this inquiry outlining the important elements of the proposed surrogacy legislation in Western Australia.

In the promotion of public debate and understanding of reproductive technology issues, the Counselling Committee, in particular Colleen Brown, undertook the production of a video/DVD resource for same-sex (female) couples using donor sperm. The video/DVD features interviews with 2 couples and individual parents (biological and non-biological) conducted by interviewer Geraldine Mellet. The production was near completion at the end of the 2006-2007 year.

Council participation at relevant meetings and conferences

Attendances at several meetings and conferences were undertaken by members on behalf of Council during 2006-2007. These included:

Assisted reproductive technology and legislation in WA – talk by Ms Antonia Clissa, October 2006.

The "Regulatory Issues in Pre-implantation Genetic Diagnosis" workshop. This was conducted by the Centre for Health Governance, Law and Ethics at the Faculty of Law, University of Sydney. The workshop was attended, following invitation, by Ms Antonia Clissa, as Executive Officer. Ms Clissa also attended the Centre for Health Governance, Law and Ethics Annual Conference the following day.

Dr Roger Hart and Ms Amalia Burmas (Deputy Executive Officer) were funded by the Council to attend the FSA 25th Anniversary Annual meeting in November 2006. This meeting was to provide an overview of issues in IVF over the past 25 years, and to facilitate discussion about the future of ART.

Council agreed to fund 3 consumer representatives from Western Australia to the national Donor Conception Conference in Sydney, November 2006. Two donor-conceived adults and a donor egg recipient attended the conference, and provided Council with reports following their attendance.

Ms Antonia Clissa attended the Victorian Infertility Treatment Authority (ITA) Symposium titled the "Best interest of the Child". This seminar, held in November 2006, explored the rights of children in the context of infertility treatment.

NHMRC Licensing Committee, Professor Jock Findlay (Chair) and Harry Rothenfluh (Director & Chief Inspector) and other members of the Quality and Regulation Branch visited Perth and held workshops at the Four Seasons Hotel Northbridge on 2 May 2007.

Professor Findlay and members of the NHMRC Licensing Committee attended a half-day seminar held at the Office of Population Health Genomics, in which the work of the Directorate and that of the Reproductive Technology Unit and the Council were presented.

OPERATIONS OF THE COUNSELLING COMMITTEE
1 July 2006 to 30 June

Meetings and Membership

The Counselling Committee met on four occasions during the 2006-2007 year.

Key Focus Areas

During the course of the year, the Counselling Committee has convened to:

- finalise the production of a video resource for same sex (female) couples using donor semen to create a family;
- provide guidance to Council on ethical issues in ART including cooling off-periods, counselling in relation to the use of fetal gametes and gonadal tissue for research and counselling in relation to the donation of oocytes (eggs) by women undertaking IVF treatment. This information contributed to Council's submission for revision of the NHMRC Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research;
- liaise with Council to strengthen the monitoring of counselling provision in ART clinics to allow assessment of compliance to the HRT Act. Actions included:
  - A request sent to clinics to provide counselling sessions to all new ART patients.
  - Recommending each clinic's annual report identifies all counselling information sessions, including follow up sessions and telephone counselling.
  - Recommending the clinics develop a strategic plan outlining the range of resources available for patient support.
- provide guidance to Council regarding the posthumous collection and use of gametes.
- provide guidance to Council on the proposed surrogacy legislation which is currently before Parliament.
- explore issues associated with donor identity security and
- liaise with stakeholders and the Embryo Storage Committee to finalise the draft Embryo Storage Brochure.

Approved Counselling Applications

The Counselling Committee considered one application for Approved Counsellor as required by the HRT Act. It was considered necessary for the applicant to demonstrate wider experience in the issues associated with infertility treatment before the application progressed.

As at July 2007 there were 13 approved counsellors able to provide counselling to participants in infertility treatment.

REPRODUCTIVE TECHNOLOGY REGISTERS

The Reproductive Technology Register

The WA Department of Health keeps a register of all ART treatments carried out in Western Australia known as the Reproductive Technology Register. Access to this information is in keeping with the requirements set out in the HRT Act.

In WA both anonymous and known donation of sperm, eggs and embryos is permitted. The HRT Act currently does not allow for any access, by those born of donation, to identifying information about the donor without the donor's consent. Recent amendments made to the HRT Act, however, require that no donor will be accepted without providing identifying information. If a recipient or mature donor offspring approaches a licensee or the Reproductive Technology Register seeking identifying information about past donors, there is scope for donors who donated previously to give (or refuse) their consent. It is possible that legislation may be further amended to give donor offspring the retrospective right to access identifying information about the donor.

Voluntary Register of information concerning donated material

The Voluntary Register provides a service for donor offspring who wish to find out about their genetic origins. Donors seeking information such as whether a child has been born as a result of their donations(s) and/or are willing to provide information to any donor offspring may also join the Register.

Joining the Register is voluntary. Identifying information about a person is only entered on the register if the person completes a properly signed and witnessed registration form.

The Register records the names, contact details and the wishes about information sharing for people involved in the donation and receipt of human reproductive material such as sperm, eggs and/or embryos, for assisted reproduction.

Voluntary Register applications for 2006-2007:

11 parent-requests for application forms.
7 completed applications returned from parents.

2 donor offspring-requests for application forms
1 completed application received from donor offspring

5 donor-requests for application forms
4 completed applications received from donors

The Voluntary Register has recorded 78 registrations since the inception of the data-base in November 2002. To date the registrants include 42 parents of donor-conceived offspring, 30 donors and 6 donor-conceived adults. The Voluntary Register has received 137 requests for

applications forms since the Register began, of which approximately 60% have been returned for inclusion on the Register.

The development of protocols determining the provision of information in response to requests from interested parties on the Voluntary Register has been recognised as a matter requiring consideration.

Information regarding the Voluntary Register in available on the Department of Health Website: http://www.voluntaryregister.health.wa.gov.au/

SIGNIFICANT DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY DURING 2006-2007

Human Reproductive Technology Amendment Bill 2007

Proposed amendments to Western Australian legislation may engender a significant shift in direction for research using reproductive technologies. The Human Reproductive Technology Amendment Bill 2007 (HRTA Bill) is currently before Parliament. This Bill mirrors recently enacted amendments made to Commonwealth legislation under the *Prohibition of Human Cloning for Reproduction Act 2002* and the *Research Involving Human Embryos Act 2002*. The Commonwealth amendments were based on recommendations arising from the Legislation Review Committee Report (the Lockhart Report), which was commissioned to consider the ethical, social, biological and medical implications of research using new reproductive technologies in a national framework.

The HRT Act currently outlines a position that is *not* supportive of the creation of a human embryo in vitro for purposes other than to assist persons who are unable to achieve pregnancy by natural means, or whose children are otherwise likely to be affected by a genetic abnormality or a disease. By comparison, the HRTA Bill expands the capacity for the creation and use of embryos *under regulated conditions* for the purpose of research. These conditions include the need for NHMRC licensing approval, the provision that no embryo created or used under such a licence will be allowed to mature beyond 14 days development (suspension periods notwithstanding) and that no embryo created by a means other than fertilisation is allowed to be used for reproductive means.

Under the amendments proposed by the HRTA Bill:

A person may apply to the NHMRC Licensing Committee for a licence authorising one or more of the following:

- use of excess ART embryos;
- creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;
- creation of human embryos (other than by fertilisation of a human egg by a human sperm) and containing genetic material provided by more than 2 persons, and use of such embryos;
- creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos;
- research and training involving the fertilisation of a human egg, up to the first mitotic division, outside the body of a woman for the purposes of research or training;
- creation of hybrid embryos by the fertilisation of an animal egg by human sperm, and use of such embryos up to the first mitotic division, if i) the creation or use is for the purposes of testing sperm quality, and ii) the creation or use will occur in an accredited ART centre.

Explanatory Memorandum Human Reproductive Technology Amendment Bill 2007

Penalties for committing an offence under the HRTA Bill have also increased. For example, it is an offence to create a chimeric embryo; Penalty – a fine of 900 penalty units or imprisonment for 15 years or both. This has increased from 600 penalty units and 10 years imprisonment.

The amendments proposed in the HRTA Bill will provide for continued consistency with the Commonwealth Acts and with other relevant State and Territory legislation.

Surrogacy Bill 2007

The Surrogacy Bill was introduced to the Western Australian Parliament on 1 March 2007, to provide State legislation that deals directly with surrogacy issues. Of particular relevance to the HRT Act is the proposal to allow conditional access of birth parent/s to IVF procedures if the arranged parent/s are considered eligible for the procedures. Through this means, women who are not able to conceive or carry a child themselves due to medical reasons may be able to arrange for another woman to become pregnant and to carry a child on their behalf.

The Surrogacy Bill also amends current legislation by providing a legal mechanism for parentage orders to be made establishing the arranged parents as the legal parents of the child on the child's birth certificate, and the regulation of surrogacy arrangements. This only has application for couples accessing surrogacy through IVF. Also of import in the Surrogacy Bill 2007 is the strict prohibition of surrogacy for reward or benefit.

Counselling requirements for patients who believe they wish to take this step will be set out in Directions issued under the HRT Act. The Reproductive Technology Unit, in collaboration with legal advisors and with Council input, has been involved in the drafting of this subsidiary legislation. The Directions are likely to mandate the requirement for recipient couples and potential surrogates to undergo a prescribed and comprehensive counselling and assessment regimen, including a lengthy "cooling off" period and the obtainment of independent legal advice.

Posthumous collection and use of gametes

The contentious issue of posthumous gamete collection, storage and use for ART has been under consideration by Council during 2006-2007. There are several pieces of State legislation that impact on this issue, including the *Coroners Act 1996*, the *Human Tissue and Transplant Act 1982* and the HRT Act. In addition to this legislation, NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research and RTAC accreditation code of practice outline a range of recommendations and requirements. Council discussion on this issue explored the apparent dichotomy between the NHMRC guidelines and the HRT Act. Under the HRT Act, Section 8.9 prohibits a licensee to use or authorise the use of gametes in an artificial fertilisation procedure after the death of the gamete provider. The NHMRC guideline 6.15 *Posthumous Use of Gametes*, while acknowledging that state legislation may prohibit the use of gametes after a person has died, sets out the prescribed conditions that may allow the posthumous use of gametes to be considered.

While reform in this area of WA State legislation has not been proposed, it is interesting to note that the Victorian Law Reform Commission has provided interim recommendations to the effect that the express consent of a person during their lifetime to undergoing a procedure for removal of gametes after death *and* the use of those gametes by the surviving partner to create a child may constitute a circumstance under which posthumous use of gametes might be considered.

PRESENTATIONS AND PUBLICATIONS BY COUNCIL MEMBERS AND STAFF

Associate Professor Roger Hart

Presentations

1. "Fertility Options for a Woman with a Cancer Diagnosis"
   Royal Australian College of Obstetricians and Gynaecologists, Perth 2006

2. "Success in IVF is an ART and not a Science"
   Fertility Society of Australia, Sydney 2006

3. "The reproductive consequences of Obesity" The WA Endocrine and Reproductive Sciences Symposium, Perth 2006

4. "Pregnancy after fertility treatment" Nurse Study Day, Perth 2006

5. Hart R, S. D., Doherty D, Pennell C, Norman R, Franks S, Hickey M. "The effect of growth and intrauterine exposure to maternal androgens on reproductive function in a cohort of Australian adolescents – Preliminary Findings, Fertility Society of Australia, Sydney 2006.

Publications

1. Hart R, Norman R. Polycystic Ovarian Syndrome - prognosis and outcomes. *Best Practice & Research in Clinical Obstetrics and Gynaecology* 2006 ; **20(5)**: 1-28 *****
2. Hart R, Doherty D, Karthigasu K, Garry R. The Value of Virtual-Reality Simulator Training in The Development of Laparoscopic Surgical Skill. *Journal of Minimally Invasive Gynecol* 2006; **13**(2):126-33.
3. Karthigasu K, Garry R, Hart R. Case Report of Failed Tubal Occlusion Using Essure™ pbc (Permanent Birth Control) Hysteroscopic Sterilisation Procedure. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 2006; **46(**4):365-7.
4. Hassan SN, Alfozan H, Qadri H, Hart R. Ovarian cyst aspiration prior to IVF. 2006 Cochrane Protocol In: The Cochrane Library, Issue 3.
5. Khalaf Y, Ross C, El-Touky T, Hart R, Seed P, Braude P. The effect of small intramural uterine fibroids on the cumulative outcome of assisted conception. *Human Reproduction* 2006 **21**: 2640 - 4.
6. Hart R, S. D., Doherty D, Pennell C, Norman R, Franks S, Hickey M. (2006). "The effect of growth and intrauterine exposure to maternal androgens on reproductive function in a cohort of Australian adolescents – Preliminary Findings." Aust N Z J Obstet Gynaecol **46**(Suppl 2): A11.
7. Sloboda DM, Hart R, Doherty DA, Pennell CE, Hickey M. Age at Menarche: Influences of Prenatal and Postnatal Growth. Journal of Clinical Endocrinology and Metabolism 2007; **92**(1):46-50.
8. Angelo A, Hart R, Sallam HN, Abou-Setta. Post embryo transfer interventions for IVF/ICSI patients Protocol In: The Cochrane Library Issue 2; 2007.
9. Glujovsky D, Pesce R, Fiszbajn G, Sueldo C, Hart R, Ciapponi A Endometrial Preparation For Women Undergoing Embryo Transfer With Frozen Embryos Or Embryos Derived From

Donor Oocytes. Protocol In: The Cochrane Library (In Press).2007.

10. Hart R, Karthigasu K, Garry R. Virtual reality simulation training can improve technical skills during laparoscopic salpingectomy for ectopic pregnancy. *British Journal of Obstetrics and Gynaecology* 2007 (*In Press*) 2007; **144**(5): 656.
11. Hart R, Karthigasu K. The benefits of virtual reality simulator training for laparoscopic surgery. In Women's Health. Current Opinion in Obstetrics and Gynaecology (Ed) Davis C:" Lippincott, Williams & Wilkins, London 2007 (In Press)
12. Hart R. Polycystic Ovarian Syndrome – Prognosis and Treatment Outcomes. In Women's Health. Current Opinion in Obstetrics and Gynaecology (Eds) Aquilina J, Ayida G:" Lippincott, Williams & Wilkins, London 2007 (In Press).
13. Hart R. Definitions, Prevalence and Symptoms of Polycystic Ovaries and The Polycystic Ovary Syndrome. *In* Agrawal and Allahbadia (Eds). Polycystic Ovary Syndrome. Chapter 2 2006. Anshan Publishing House, Tunbridge Wells, UK. ISBN 9781904798743
14. Hart R, Magos A. Endometrial Ablation. In: Atlas of Laparoscopic & Hysteroscopic Techniques for Gynecologists 3rd Edition. *Ed* Tulandi T. Informa Healthcare.London 2007 (In Press). ISBN: 9780415414401
15. Menninger I, Hart R. Hysteroscopic sterilisation. In Fallopian Tubes (Eds) Djahanbakhch, Saridogan and Allahbadia Anshan Publishing House, Tunbridge Wells, UK. (In Press 2007).

Presentations by another

1. C Burke, K Karthigasu, R Hart, R Garry. Outpatient pelvic examination in the woman with endometriosis – do abnormal findings correlate with the presence of rectal disease? AGES, Sydney 2006
2. C Burke, R Garry, R Hart, K Karthigasu. Take 500 -the experience of laparoscopic entry amongst gynaecological surgeons of a single unit. AGES, Sydney 2006

Associate Professor Jim Cummins

Okabe M, Cummins JM. Mechanisms of sperm-egg interactions emerging from gene-manipulated animals. Cell Mol Life Sci. 2007 Aug;64(15):1945-58.

Ms Antonia Clissa

Talk on assisted reproductive technology and legislation in WA. October 2006.

APPENDIX 1

EXEMPTIONS ISSUED BY COUNCIL UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

Section 28 of the HRT Act outlines that medical practitioners may apply for an exemption to practice artificial insemination procedures without a licence. Current practitioners issued with such an exemption are identified below.

Exemption No	Practitioner Name	Suburb	Post Code
E023	Dr PK Bairstow	Bunbury	WA 6230
E034	Dr RT Chapman	Katanning	WA 6317
E027	Dr DP Day	Kelmscott	WA 6111
E001	Dr ZN Dorkhom	Bunbury	WA 6230
E050	Dr R Kirk	Carnarvon	WA 6701
E046	Dr TP Knight	Mandurah	WA 6210
E024	Dr DN Lawrance	Kelmscott	WA 6111
E025	Dr HH Leslie	Exmouth	WA 6707
E016	Dr KA McCallum	Kalgoorlie	WA 6430
E003	Dr KT Meadows	Collie	WA 6225
E051	Dr WD Patton	Rockingham	WA 6168
E017	Dr C Russell-Smith	Kwinana	WA 6167
E022	Dr BGA Stuckey	Nedlands	WA 6009
E029	Dr JM Vujcich	West Perth	WA 6050
E028	Dr RJ Watt	Mandurah	WA 6012
E049	Dr M Zafir	Albany	WA 6330

APPENDIX 2

LIST OF APPROVED COUNSELLORS AT 30 JUNE 2007

Name	Professional Address	Telephone Number
Ms Jill Bain*	57A Canning Beach Road, Applecross WA 6153 – Private Practice	Tel / Fax (08) 9364 3665.
Ms Marion Connelly	Concept Fertility Centre c/- KEMH Bagot Rd Subiaco WA 6008	(08) 9383 2388 Fax (08) 9381 3603
Ms Deborah Foster-Gaitskell*	62 Churchill Avenue, Subiaco WA 6008 – Private Practice	(08) 9271 3582 Fax (08) 9388 3740
	Hollywood Fertility Centre, Hollywood Private Hospital Monash Avenue, Nedlands, WA 6009	(08) 9346 7100 Fax (08) 9386 1463
Ms Lisa Hasard	Pivet Medical Centre 166-168 Cambridge St, Leederville WA 6007	(08) 9382 1677 Fax (08) 9382 4576
Ms Jane Irvine	Roe Street Centre for Human Relationships-FPWA, 70 Roe St, Northbridge WA 6003	(08) 9228 3693 Fax (08) 9227 6871
Ms Rosemary Keenan*	6 The Lakes Mews, Karrinyup Lakes Lifestyle Village Gwelup WA 6018	(08) 94478365
Ms Sue Midford*	324 Huntriss Road Woodlands WA 6018 2/36 Ormsby Tce, Mandurah WA 6210	Tel (08) 9581 6545 (Appointments)
	Suite 7/401 Oxford St, Mt Hawthorn WA 6016	Fax (08) 9446 8483
Dr Kaye Miller	Palm Springs Medical Centre, 3 Halliburton Drive, Warnbro WA 6169	(08) 9593 2033 Fax 908) 9593 1913
Ms Helen Mountain	C/ Genetic Services of WA King Edward Memorial Hospital Centre for Women's Health Bagot Road, Subiaco 6008	(08) 9340 1525 Fax (08) 9340 1678
Ms Iolanda Rodino*	64 Farrington Road, Leeming WA 6149 – Private Practice Keogh Institute for Medical Research A Block, 3rd Floor QE Medical Centre Nedlands. WA 6009	(08) 9389 7212 (08) 9346 2008 Fax (08) 9380 6387
Ms Kay Rosen	36 Carnarvon Crescent, Mt Lawley WA 6050 - Private Practice,	(08) 9444 1617 Fax (08) 9242 5882
Ms Margaret van Keppel*	267 Walcott Street North Perth WA 6006 – Private Practice	(08) 9443 3655 Fax (08) 9443 8665
	Pivet Medical Centre 166-168 Cambridge St, Leederville WA 6007 Hollywood Fertility Centre, Hollywood Private Hospital, Monash Ave Nedlands WA 6009	(08) 9382 1677 Fax (08) 9382 4576 (08) 9346 7100 Fax (08) 9386 1463
Ms Elizabeth Webb	Fertility North, Suite 213 Specialist Medical Centre, Joondalup Health Campus Shenton Ave Joondalup WA 6027	(08) 9400 9965
	Mental Health Unit, Joondalup Health Campus Shenton Ave, Joondalup WA 6027	(08) 9400 9788 Fax (08) 9400 9069

*Qualified to assist with child-related "telling issues" associated with donor conception.

From RTC Website August 2007

APPENDIX 3

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2006-2007

The aggregated data, tabulation, graphical representation, analysis and interpretation of the data in this Appendix was kindly provided by Information Collection and Management, Department of Health.

Background

This summary was put together from information submitted, as required by the *Human Reproductive Technology Act 1991* (HRT Act), in relation to six Storage Licences and five Practice Licences authorising artificial fertilisation procedures including in vitro fertilisation (IVF) under the HRT Act. In addition, there is one other Practice licensee, which is licensed to carry out only artificial inseminations. Information required from this Practice licensee on the provision of intra-uterine insemination has been included in this summary. No information has been included from medical practitioners who are exempt from the requirement to be licensed to carry out artificial inseminations (listed in Appendix 1) for the financial year 2006/07 summary. Information about patients referred from the public fertility clinic at King Edward Memorial Hospital to the Concept Fertility Centre has been provided by Concept.

All information was submitted in a collated form and referred to the financial year, which ended at 30 June 2007. While it is not possible to provide any data on outcomes of treatments undertaken during the financial year just ended due to the necessary lag time required for reporting, this summary shows the scale and type of activities carried out under the licences.

Semen storage and donation

During the 2006/07 financial year, 81 men donated semen to WA Storage Licensees. Of these, 13 were new donors. This is a decrease of 6 from the number of new donors in the previous financial year. Although the number of new donors for 2006/07 is higher than for 2002, when the lowest number of new donors was recorded (illustrated in figure 1), there appears to be a consistent decrease in this number from 2004. This may be a consequence of the introduction of amendments to legislation in December 2004, requiring any new donors to consent to release of their identifying information to any offspring conceived from their donation. Therefore, the demonstrated increase in total donor numbers would indicate that clinics are retaining their established donors.

The age distribution of donors (Table 1) indicates that the majority (76.3%) were over 30 years of age, with 33.8% being over 40. There appears to be a general trend showing an increase in the number of older donors and a decrease in the number younger donors over the last fourteen years (figure 2). Where the marital status of the donor was known, in 74.6% the donor was single, 25.4% were married or in a de facto relationship and there were no divorced or separated donors.

Reporting by Storage Licensees indicated that during the year donor semen was supplied to two WA exempt practitioners. As detailed in Appendix 1, there were 16 exempt practitioners at the end of the 2006/07 financial year with no exempt practitioners requesting revocation of their exemptions this year.

Embryo storage

Table 3 shows that the total number of embryos in storage at the end of the financial year 2006/07 was 15,493. The total number of embryos in storage has continued to increase since 1993 (as illustrated in figure 3). Although the figures from the previous three financial years showed a slowed rate of increase, in 2006/07 the number of embryos stored increased by to 10.3% compared to an increase of 6.6% in 2005/06. This increase is due to the growing number of people undertaking IVF as demonstrated by the rise in the number of oocyte pick up cycles commenced, which this year increased by 4.5% from last financial year. It is expected that these embryos will either be used in IVF or for research. The Reproductive Technology Council is also aware that there are a small number of participants who have completed treatment and are continuing to store their embryos as they are finding it difficult to make a decision about the embryos. Council is currently developing an Embryo Storage Policy to address this issue.

A total of 5832 embryos were stored following treatment and 3906 stored embryos were used in treatments during the year. In all 544 embryos were allowed to succumb at the request of the participants.

In Vitro Fertilisation (IVF), Frozen Embryo Transfer (FET) and Gamete Intra Fallopian Transfer (GIFT) treatments

Table 4 shows that during the last financial year 1540 women began oocyte retrieval cycles for IVF, 887 began FET and no women began GIFT procedures.

A total of 4012 cycles were begun for IVF and frozen embryo transfer, a further increase on the previous year (3796). As illustrated in figure 4, of all cycles begun, 2378 (59.3%) were for IVF and 1634 (40.7%) were for frozen embryo transfer.

Of the 2378 cycles begun for fresh IVF with ovarian stimulation, 88.6% proceeded to oocyte retrieval and 72.1% proceeded to transfer fresh embryos or gametes (figure 5). Of the 1634 frozen embryo transfer cycles begun, 1367 (83.7%) proceeded to transfer.

Overall, donated human reproductive material was involved in 4.8% of all IVF cycles with oocyte retrieval during the year. In 3.1% of cycles donor semen was used (65 cycles); donor eggs were used in 1.4% of cycles (29 cycles) and there were 8 IVF cycles with fresh embryos donated. A higher proportion of frozen embryo transfer cycles (12.0%) involved use of donated gametes or embryos. Donor embryos were used in 1.8% of all FET cycles with transfer (24 cycles); donor eggs in 5.7% (78 cycles) and donor semen in 4.5% (62 cycles).

Of all 2108 IVF treatment cycles with successful oocyte retrieval, 1182 (56.1 %) used intra-cytoplasmic sperm injection (ICSI). As illustrated in Figure 6, use of ICSI has increased since the last financial year. Since its introduction in WA in 1994, the early increase in use of ICSI may be explained by ICSI becoming a mainstream practice in cases of male fertility problems and poor fertilisation. The use of ICSI has continued to increase in recent years, but at a slower rate than in earlier years. Fresh or frozen sperm retrieved from the epididymis or testis was used in 186 of the ICSI treatment cycles.

Treatment of patients referred from the Public Fertility Clinic

During the year a number of patients from the King Edward Memorial Hospital (KEMH) Infertility Clinic were referred for treatment at the Concept Fertility Centre, which reported on the treatments and their outcomes. As can be seen from Table 4, 82 women were treated with fresh IVF transfer and 25 with frozen transfer. The results for this year indicate the number of public patients treated is similar to last year. During the year 143 fresh IVF and 91 FET treatment cycles were commenced. This year 63 of the IVF cycles involved micro-manipulation (ICSI). Of all the 234 cycles for public patients only 1 cycle reported using donated gametes or embryos. In this case donor semen was used. In addition, there were 15 cycles reported as using assisted hatching. 82 cycles used extended culture and 2 cycles used embryo diagnostic testing. No cycles used either of these procedures in the previous year.

There were 66 artificial insemination (1 DI, 65 AIH) treatments between 1 July 2006 and 30 June 2007, for public patients. This is a significant decrease from the 120 artificial insemination treatments which were performed in the previous year.

Intra-uterine insemination (IUI)

The Council is continuing to monitor IUI carried out by licensees and exempt practitioners. A total of 1718 IUI cycles were reported by six Practice licensees. The overall ongoing clinical pregnancy rate per treatment cycle carried out was 6.1% (104 ongoing pregnancies), and of the pregnancies where plurality was known, eighty six were singleton (90.5%), seven were twin (7.4%), and two were triplets (2.1%).

The information provided showed that 84.9% of the IUIs used the partner's sperm and 15.1% used donor sperm. Of all cycles carried out, the majority (46.7%) did not involve the use of ovulation induction. Clomid was used in 18% of the cycles, and gonadotrophins were used in 35.3.% of the cycles.

Both sets of triplets reported followed gonadotrophin stimulation, one set using husbands/partner sperm (AIH) and one set using donor sperm (AID). Of the seven sets of twins reported, one followed a natural cycle, one followed a clomid cycle and the other five sets resulted from ovulation induction by gonadotrophins. One set of twins was a result of AID, and all other sets of twins were a result of AIH.

Serious morbidity and mortality in women undergoing treatment

Overall the six clinics reported a total of 28 cases of severe ovarian hyper-stimulation relating to 2378 IVF and GIFT stimulation cycles (1.2% stimulation cycles, with a clinic range of 0–0.9%). The average number of follicles above 12cm for women who were affected by severe ovarian hyperstimulation was 18.5 (with a median of 18).

There were no cases of severe pelvic infection, and 5 cases of other serious morbidity. There were no reports of mortality in association with fertility treatment during the year.

Counselling

There were 1353 counselling sessions provided by the licensed clinics during 2006/07, according to the annual reporting forms, compared to 1090 sessions in the previous year. This represents a 24.1% increase for this financial year. Of all participants who received counselling, 73.6% had only one session of counselling. Of those over ninety two percent (92.3%) had information

counselling, while the remaining participants (7.7%) accessed support or therapeutic counselling. Of those 357 sessions attended by participants who accessed more than one session of counselling, the majority (69.2%) were information counselling sessions, while almost sixteen percent (15.7%) were counselling sessions for support, 11.8% were counselling sessions in relation to a matter associated with infertility and 3.3% of these sessions were regarding counselling for other personal matters not related to infertility. From the clinic reports it appears that the majority of participants who are undertaking ART treatment are only accessing one session of counselling, however the number of participants attending more than one counselling session (26.4%) has increased significantly from last financial year (20.9%). Council correspondended with all licensed clinics in January 2007 reinforcing the importance of counselling for all participants as an integral part of undertaking treatment and acknowledging the psychosocial impact of treatment. Council emphasised that the clinics have a duty of care to patients to ensure that at least one information counselling session is attended.

Counselling concerning issues of donation for donors or recipients (which is mandatory under the Reproductive Technology Accreditation Committee code of practice) made up 28.9% of all counselling which represents a 7.1% decrease from that recorded in the previous year. This is likely to be the result of the decrease in the number of donor from the previous financial year. For one IVF clinic over half (52.5%) of all counselling offered for the year was related to issues of donation. The majority of the counselling took place on site at the clinics. Only one clinic reported not charging participants a fee for counselling.

Approved research and innovative practices

Four clinics with approval to carry out assisted hatching provided data showing that this procedure had been used in a total of 351 fresh and 211 frozen embryo cycles. This shows an increase on last financial year's figures. The procedure ranged from being used in 2.4% to 23.2% of all cycles (fresh and frozen) with transfer. The overall pregnancy rate following assisted hatching was 14.5%, which is a significant drop from last financial year, with quite a varied rate between clinics, ranging from 0% to 25.5%.

Data from the five clinics with approval to carry out blastocyst culture indicated the procedure was used in 913 fresh and 543 frozen embryo cycles. This is a considerable increase from the previous financial year, and is most likely due to this procedure displaying very positive and successful results since its introduction in regard to decreasing the prevalence of multiple pregnancies in patients receiving assisted fertilisation treatment. A greater number of patients are choosing this procedure as part of their treatment as a safer option for both the mother and baby. The use of the procedure varied greatly between clinics from 5.8% to 48% of cycles (fresh and frozen) commenced. The majority of the cycles (50.5%) were carried out in one clinic. A variety of factors, including patient selection, may explain this considerable range in use of blastocyst culture.

Indicated below are practices with current approval (Appendix 3 page xii).

Current approved innovative practices

Under the *Human Reproductive Technology Act 1991*, specific approval from the Reproductive Technology Council is required for clinics to carry out embryo diagnostic testing, research projects and innovative practices. Licensees report information on the progress of each of these approvals each year. Indicated below are practices with current approval (Appendix 3 page xiii).

Significant changes to routine practice reported by licensees during the year

Licensees reported no new changes to routine practice of licenses at the time of annual report submission. However, throughout the year the licensees reported a number of routine changes, predominantly to patient information sheets and consent forms.

Complaints

A total of 12 formal complaints were reported by clinics for issues including accounting, clinical management, confidentiality issues and communication of information. This was a significant decrease from the 28 complaints of the previous financial year.

Figure 1: Semen Donors in WA

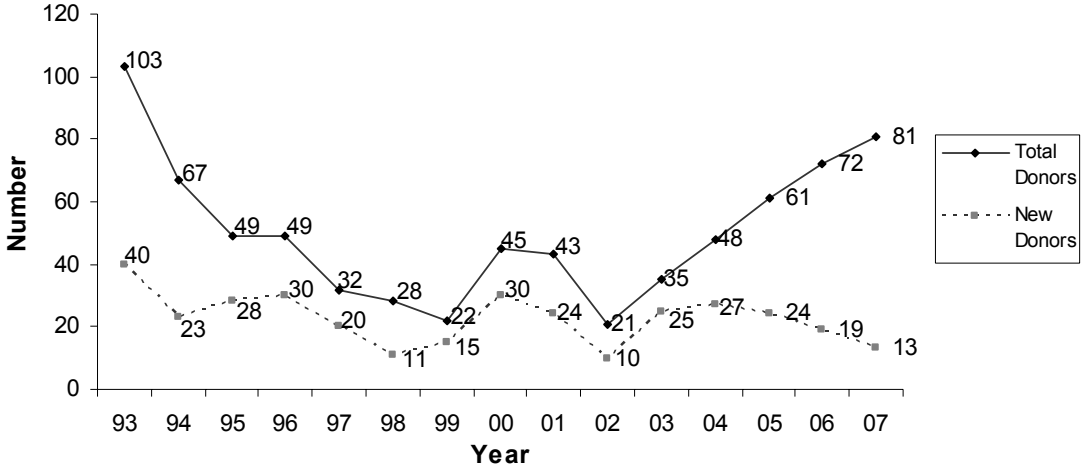


Figure 2: Ages of Semen Donors

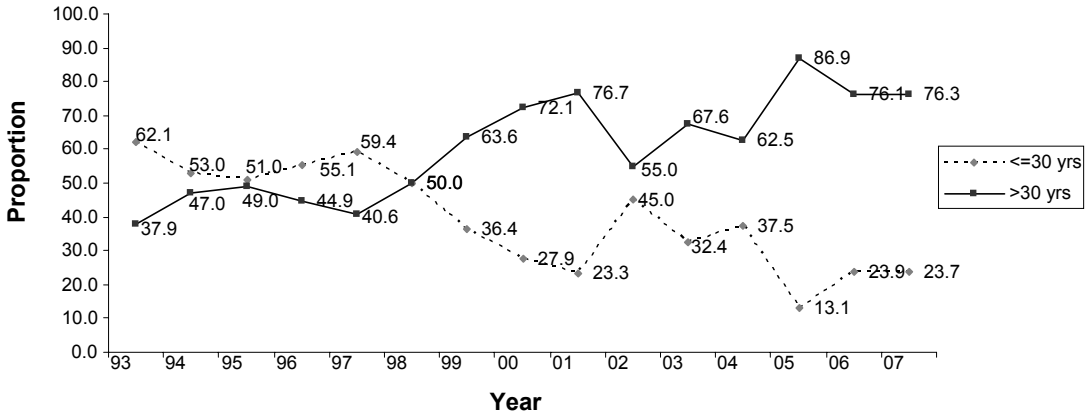


TABLE 1: 2006/07 SEMEN DONOR AGES

Age of Donor (years)	Number (%)
18-25	8 (10.0)
26-30	11 (13.7)
31-35	14 (17.5)
36-40	20 (25)
41-49	22 (27.5)
50 +	5 (6.3)
Total	**81* (100)**

* The age of one donor was unknown

Figure 3: Trends in Embryo Storage

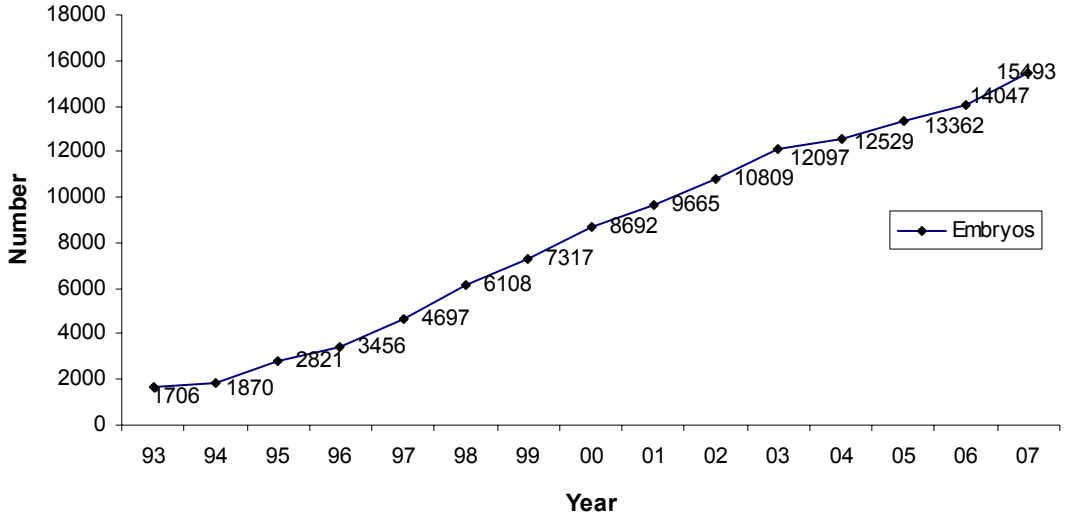


TABLE 2: DISPERSAL OF STORED EMBRYOS 2006/2007

	No of embryos
Embryos in storage 30/06/06	**14047**
Embryos created from IVF	5832
Transferred into WA clinics from interstate	129
Transferred between clinics in WA	204
Transferred to clinics outside WA (Patients moving interstate/overseas)	65
Used in frozen embryo transfer treatments	3906
Allowed to succumb with consent of couples	544
Embryos in storage 30/06/07	**15493**

Figure 4: ART Treatment Trends

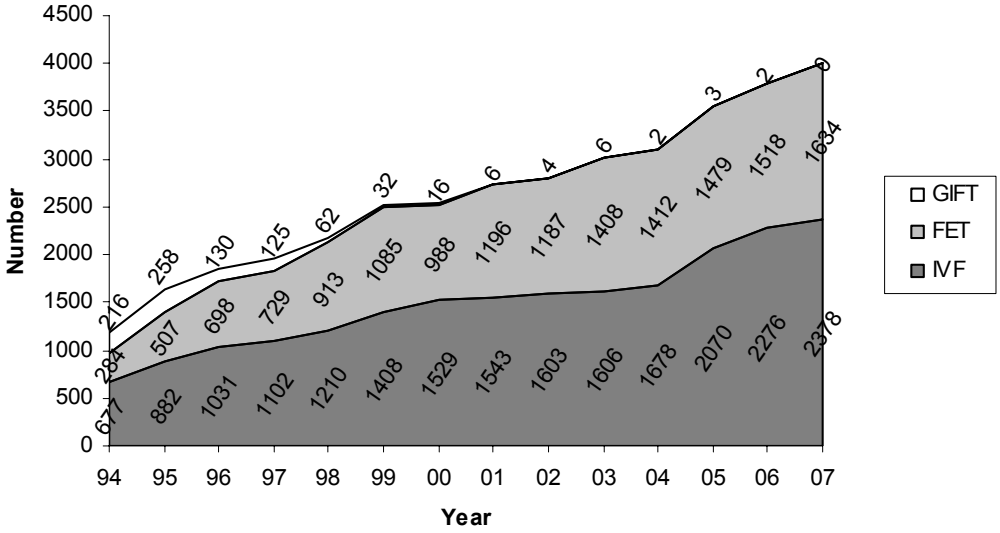


Figure 5: IVF (fresh) and GIFT Treatments

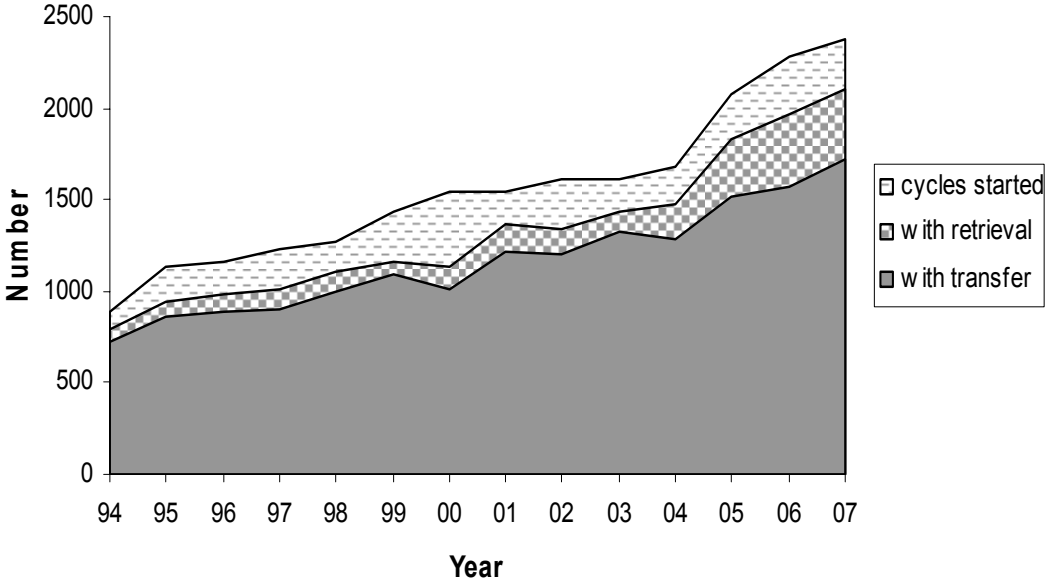


Figure 6: IVF cycles using ICSI

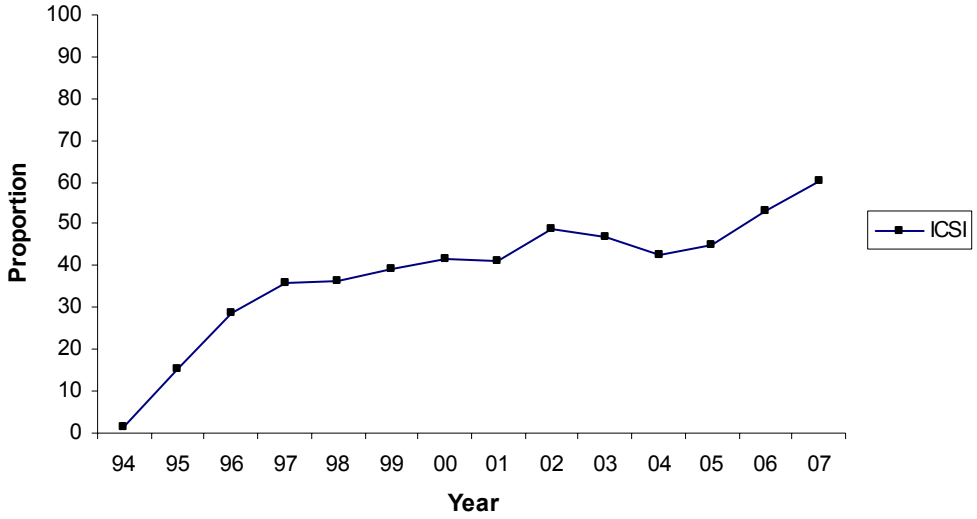


TABLE 3: 2004/05 IVF and GIFT TREATMENTS

	IVF (fresh)	IVF (frozen)	GIFT	TOTAL
Women treated	1540	887	0	N/A
Cycles begun	2378	1634	0	4012
Cycles with egg retrieval	2108	-	0	2108
Cycles with gamete or embryo transfer	1715	1367	0	3082
Cycles with embryos storage	1094	-	0	1094
Number of cycles using donor:				
Semen	65	62	0	127
Eggs	29	78	0	107
Embryos	8	24	0	32
Total	102	164	0	266
Number of cycles from which human reproductive material was donated:				
Eggs donated	49	-	0	49
Embryos donated	0	-	-	0
Breakdown of treatment cycle details				
Cycles with IVF/GIFT same cycle	0	-	0	0
Cycles with surgical sperm aspiration	186	-	0	186
Cycles with ICSI*	1182	-	-	1182
Cycle with Fallopian embryo/egg transfer	0	0	0	0

* ICSI is Intra Cytoplasmic Sperm Injection, a form of microinjection.

TABLE 4: IVF AND RELATED TREATMENT OF PUBLIC PATIENTS

	No. of Patients					No. of Treatment Cycles				
	02/03	03/04	04/05	05/06	06/07	02/03	03/04	04/05	05/06	06/07
IVF	50	65	77	81	82	71	82	111	130	143
GIFT	0	0	0	0	0	0	0	0	0	0
FET	39	27	30	24	25	127	104	115	97	91
TOTAL	**89**	**92**	**107**	**105**	**107**	**198**	**186**	**226**	**227**	**234**

Research Projects

Under the *Human Reproductive Technology Act 1991*, specific approval from the Reproductive Technology Council is required for clinics to carry out embryo diagnostic testing, research projects and innovative practices. Licensees report information on the progress of each of these approvals each year. Indicated below are projects with current Council approval.

R001 Use of granulosa cell co-culture in assisted reproduction procedures
PIVET Medical Centre
Approved 25/05/93
Not active in 2006/07

R005 Comparison of culture media in human in vitro fertilisation
PIVET Medical Centre
Approved 14/12/95
In abeyance

R016 Does ICSI increase the risk of major birth defects?
Telethon Institute for Child Health Research
Approved 24/11/98
In abeyance

R019 Phase III, Multicentre open label randomised trial to assess the efficacy and convenience of orgalutron
PIVET Medical Centre
Approved 08/08/00
Initial data analysis of the study group was completed in 2003, however, ongoing data is still being collected from frozen embryos generated in the study cycles.

R022 Pilot trial using in vitro maturation (IVM) for women with polycystic ovarian disease
Hollywood Fertility Centre
Approved 13/07/2004
Study continuing

R02_ Research into optimal method of oocyte cryopreservation
PIVET Medical Centre
Approved (Out of session) October 2006

Innovative clinical/laboratory practices

Innovative practice number	Procedure approved	Licensee and date approved
I 017	Oocyte cryopreservation	Concept Fertility Centre Approved 17/10/2006
I 018	Blastocyst culture	Fertility Specialists WA Approved 17/10/2006
I 019	Assisted hatching	Fertility Specialists WA Approved 23/01/07
I 020	In vitro maturation	Fertility Specialists WA Approved 23/01/07
I 021	Oocyte cryopreservation	Fertility Specialists WA Approved 23/01/07
I 022	Oocyte cryopreservation	PIVET Medical Centre Approved 20/02/07
I 023	Vitrification of embryos	PIVET Medical Centre Approved 20/02/07

Diagnostic testing of Embryos

Under Direction 9.9, licensees must seek approval from Council to undertake Pre-implantation Genetic Diagnosis (PGD) of embryos. Applications approved for PGD, with conditions tested for, during 2006-2007 financial year are listed below:

PGD Number	Condition tested	Licensee and approval date
PGD 014/2006-03	Cystic fibrosis	Hollywood Fertility Centre Approved 1/08/06
PGD 001/2006-05	Kell Isoimmunisation	Concept fertility Centre Approved 1/08/06
PGD 014/2006-04	Balanced translocation	Hollywood Fertility Centre Approved 1/08/06
PGD 014/2006-05	Balanced translocation	Hollywood Fertility Centre Approved 1/08/06
PGD 003/2006-01	Robertsonian translocation	PIVET Medical Centre Approved 19/09/06
PGD 001/2006-06	Neurofibromatosis Type 1	Concept Fertility Centre Approved (conditional) 19/09/06
PGD 014/2006-06	Cystic fibrosis	Hollywood Fertility Centre Approved 19/09/06
PGD 014/2006-07	Robertsonian translocation	Hollywood Fertility Centre Approved 17/10/06

PGD 001/2006-07	Balanced reciprocal translocation	Concept Fertility Centre Approved 17/10/06
PGD 001/2006-008	Robertsonian translocation	Concept Fertility Centre 12/12/06
PGD	Cri du Chat Syndrome	Concept Fertility Centre Approved 20/03/07
PGS	Sex selection to avoid gonadal dysgenesis	Concept Fertility Centre Approved 17/04/07
PGS	Duchene muscular dystrophy and aneuploidy	Concept Fertility Centre Approved 17/04/07
PGD	Fragile X syndrome	Concept Fertility Centre Approved 15/05/07
PGD	Beta-thalassemia major	Concept Fertility Centre Approved 15/05/07
PGD 003/2007-01	Balanced translocation	PIVET Medical Centre Approved 17/07/07
PGD 001/2007-06	Cystic fibrosis	Concept Fertility Centre Approved 17/07/07
PGD 001/2007-07	Balanced translocation	Concept Fertility Centre Approved 17/07/07

Applications under Directions 6.3, 7.7 and 8.8

Direction 6.3

To import donor sperm from United Kingdom	Hollywood Fertility Centre Approved 23/01/07
To import donor sperm from South Australia	Concept Fertility Centre Approved 17/10/2006
To import frozen embryos	Fertility Specialists WA Approved 20/02/2007

Direction 7.7

ART procedures , Female participant hepatitis B carrier	PIVET Medical Centre Approved 17/10/2006
ART procedures , Female participant hepatitis B carrier	PIVET Medical Centre Approved 21/11/2006
ART procedures , Female participant hepatitis B carrier	PIVET Medical Centre Approved 12/12/06
ART procedures , Female participant hepatitis B carrier	PIVET Medical Centre Approved 23/01/2006
ART procedures , Female participant hepatitis B carrier	PIVET Medical Centre Approved 1/08/2006 (out of session)

Direction 8.8

To allow PGD on embryos (Trisomy 22 combination)	Hollywood Fertility Centre Approved 1/08/2006
To allow PGD on embryos (Balanced translocation)	Hollywood Fertility Centre Approved 19/09/2006
To allow PGD on embryos (Aneuploidy screening)	Hollywood Fertility Centre Approved 17/10/2006
To allow cryopreservation of oocytes prior to rheumatoid arthritis chemotherapy	PIVET Medical Centre Approved 23/01/2006

APPENDIX 4

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER

Registers of assisted reproductive technology treatments were established under the *Human Reproductive Technology Act 1991* (HRT Act). These registers include information on each cycle of *in vitro* fertilisation (IVF), gamete intra-fallopian transfer (GIFT) and donor insemination (DI). This information is collected from all practice licences and exempt practitioners licensed under the HRT Act.

Data from the registers has been collected since 8 April 1993. Recently, data reporting to the Reproductive Technology (RT) Register has been reviewed and as a result a new data structure and system of reporting implemented. Therefore, all reported data since the 2003 calendar year has been provided in a different format, with some alterations to the fields collected. The new data structure for treatment data, which outlines the fields currently being collected, is located in the next section.

Reproductive technology register data structure

Information is collected on all assisted reproductive technology procedures defined as:

- All **Oocyte Pick Ups (OPU)**
- All **Cancelled cycles where follicle stimulating hormones have been administered**
- All Cycles where **frozen embryos are thawed** regardless of the intention or outcome of the thawing process
- All cycles where artificial insemination is performed using donated sperm (ie **donor insemination**)
- Each occasion where embryos are either **donated or moved** into or out of an IVF Unit from a different unit

The following fields of information are to be collected by each licensed assisted reproductive technology clinic in Western Australia and reported to the RT Register as required by the HRT Act.

No	Name	Notes	Type & Length
1	Unit	This is the unit number supplied by the NPSU used to identify the clinic.	Num-3
2	Site	This is the clinic site where the most significant part of the treatment was carried out	Num-2
3	Pat_ID	This is the female participants ID code. This is a unique ID for the patient. This can take whatever form the Unit wishes.	Char-8
76	Partner ID	This is the identification code of the partner of the female participant.. This should also be completed for lesbian couples.	Char-8

4	Mdob	Participant date of birth.	Date-10
5	Pdob	That is the husband/ partners date of birth. Can be left blank if single or oocyte/embryo donor.	Date-10
6	Don_age	Age of the egg or embryo donor. Completed in years at time of donation.	Num-2
7	N_13200	The number of billed Australian Medicare item 13200.	Num-2
8	Ci_tube	Answer "yes" if in the opinion of the treating clinician or clinic there is significant tubal disease present. Otherwise answer "no".	Char-1
9	Ci_endo	Answer "yes" if in the opinion of the treating clinician or clinic there is significant endometriosis contributing to this couple's subfertility. Otherwise answer no.	Char-1
10	Ci_male	Answer "yes" if in the opinion of the treating clinician or clinic there is a significant male problem. Otherwise answer "no".	Char-1
11	Ci_oth	Answer "yes" if in the opinion of the treating clinician or clinic there is subfertility due to any other factors **apart from** female age, tubal disease, male factor, endometriosis or sterilization. Possible examples could include fibroids, ovulation disorders or premature ovarian failure. If there is no clinical subfertility (eg egg donor, preimplantation genetic diagnosis or other non-fertility reason for ART), answer "No".	Char-1
77	Ci_oth specify	This is a description of "Ci_oth", ie the reason for infertility.	Char-50
12	Ci_unex	Answer "yes" if in the opinion of the treating clinician or clinic there is clinical subfertility without any apparent explanation. If there is no clinical subfertility (eg egg donor, preimplantation genetic diagnosis or other non-fertility reason for ART), answer "No".	Char-1
78	Ci_FSter	Answer "yes" if in the opinion of the treating clinician or clinic there is subfertility due to tubal ligation or medical sterilisation of the female participant. Otherwise answer "no".	Char-1
79	Ci_Mster	Answer "yes" if in the opinion of the treating clinician or clinic there is subfertility due to vasectomy or medical sterilisation of the male partner. Otherwise answer "no".	Char-1
13	N_prless	This is the number of all known pregnancies less than 20 weeks in the female partner regardless of whether by ART or by a different partner.	Num-2
14	N_prmore	This is the number of all known pregnancies reaching 20 weeks or more in the female partner regardless of whether by ART or by a different partner.	Num-2
15	Cycle_id	This is a number allocated to the cycle, which is unique to the cycle not just the patient.	Char-10
16	Cycle date	This field must be completed for all cycles. For treatment cycles this is according to the Medicare definition and is the date of LMP for unstimulated cycles or, where FSH is used, the first date of FSH administration. For cycles where the only process is movement or disposal of embryos, this is the date of embryo movement.	Date-10
80	Procedure type	That is the type of procedure. Including: • Donor Insemination (DI) • Gamete Intra-Fallopian Tube Transfer (GIFT) • OPU with or without fresh transfer or egg fertilisation (IVF) • Frozen embryo transfer (FET) • OPU with fresh and frozen embryo transfer (IVF+FET) • GIFT with simultaneous FET (GIFT+FET) • Cancelled OPU (Can OPU) • Cancelled FET (Can FET)	

		• Embryo Move ie embryo disposal or export • Embryo Move for Research	
17	Surr	Is this procedure part of a surrogacy arrangement	Char-1
18	Ov_Stim	Was injectable follicle stimulating hormone (FSH) administered. Does not include clomiphene or hCG alone unless FSH was also administered.	Char-1
19	Di_insem	Where the cycle is for donor insemination this is the date of first donor insemination in this cycle.	Date-10
81	Drug 1	Drug administered one, that is the name of the first drug administered. This should include only drugs which are used to regulate a cycle/ pregnancy.	Char-30
82	Drug 1 Dose	This is the total dose of Drug 1. The dose is that administered over the entire cycle/pregnancy.	Num-10
83	Drug 1 Days	This is the total number of days Drug 1 was administered for over the entire cycle/pregnancy.	Num-3
84	Drug 2	Drug administered two, that is the name of the second drug administered.	Char-30
85	Drug 2 Dose	This is the total dose of Drug 2. The dose is that administered over the entire cycle/pregnancy.	Num-10
86	Drug 2 Days	This is the total number of days Drug 2 was administered for over the entire cycle/pregnancy.	Num-3
87	Drug 3	Drug administered three, that is the name of the third drug administered.	Char-30
88	Drug 3 Dose	This is the total dose of Drug 3. The dose is that administered over the entire cycle/pregnancy.	Num-10
89	Drug 3 Days	This is the total number of days Drug 3 was administered for over the entire cycle/pregnancy.	Num-3
90	Drug 4	Drug administered four, that is the name of the forth drug administered.	Char-30
91	Drug 4 Dose	This is the total dose of Drug 4. The dose is that administered over the entire cycle/pregnancy.	Num-10
92	Drug 4 Days	This is the total number of days Drug 4 was administered for over the entire cycle/pregnancy.	Num-3
93	Drug 5	Drug administered five, that is the name of the fifth drug administered.	Char-30
94	Drug 5 Dose	This is the total dose of Drug 5. The dose is that administered over the entire cycle/pregnancy.	Num-10
95	Drug 5 Days	This is the total number of days Drug 5 was administered for over the entire cycle/pregnancy.	Num-3
96	Drug 6	Drug administered six, that is the name of the sixth drug administered.	Char-30
97	Drug 6 Dose	This is the total dose of Drug 6. The dose is that administered over the entire cycle/pregnancy.	Num-10
98	Drug 6 Days	This is the total number of days Drug 6 was administered for over the entire cycle/pregnancy.	Num-3
99	Retrieval General Anaesthetic	Whether General Anaesthetic was administered for OPU.	Char-1
100	Retrieval Antibiotics	Whether Antibiotics were administered OPU.	Char-1
101	Retrieval Other Medication	Whether any other medication was used OPU. This should include sedatives.	Char-10

102	Transfer General Anaesthetic	Whether General Anaesthetic was administered for embryo transfer.	Char-1
103	Transfer Antibiotics	Whether Antibiotics were administered for embryo transfer.	Char-1
104	Transfer Other Medication	Whether any other medication was used for embryo transfer. This should include sedatives.	Char-10
105	OHSS	Whether there was any ovarian hyper stimulation, and if so the severity.	
106	Retrieval Method	Method of OPU. Cancelled cycles are those where the cycle is stopped prior to any attempt to retrieve oocytes, if oocyte retrieval is attempted and no eggs are retrieved the cycle is not considered cancelled. In this case the method of attempted retrieval should be entered.	Char-20
20	Opu_date	The date that oocyte retrieval was performed. Leave blank if no OPU was performed.	Date-10
21	N_eggs	Number of oocytes which are retrieved at OPU. Include any immature oocytes that are identified.	Num-2
107	N_eggsexp	Number of oocytes which were donated for research or quality assurance.	Num-2
108	N_eggsdisc	Number of oocytes which were discarded as they were abnormal or immature.	Num-2
109	N_eggsfroz	Number of oocytes which were frozen.	Num-2
22	N_donated	Number of oocytes donated to someone else.	Num-2
23	N_recvd	Number of eggs received from someone else.	Num-2
24	N_gift	Number of eggs replaced in a gift procedure	Num-2
110	FertCode	If fertilisation through IVF or ICSI was attempted a code should be attributed to the fertilisation procedure. If there was no fertilisation attempted this field may be left blank. The fertilisation code must be unique to the fertilisation not just the patient. Required when a fertilisation is attempted or for transfer of embryos (eg FET or embryo move), otherwise leave blank.	Char-8
25	N_insem	Number of eggs treated with IVF, do not include ICSI oocytes	Num-2
26	N_ICSI	Number of eggs treated with ICSI	Num-2
111	EggsNotFert	Number of oocytes not fertilised	Num-2
112	EmbryoFresh	Number of embryos fresh transferred	Num-2
39	N_clfroz	Number of zygotes or cleavage stage embryos (i.e. <4 days since fertilisation) frozen.	Num-2
40	N_blfroz	Number of blastocyst embryos (i.e. >4 days since fertilisation) frozen.	Num-2
41	emdonexp	This field serves two purposes: (1) Records the number of embryos that are to be donated to someone else (donor cycle); (2) Records the number of embryos to be exported from the current unit to another unit	Num-2
113	EmbExpLic	If embryos are exported to another unit, please specify receiving units “Unit” code or Licensee number or the Licence number of a NHMRC embryos research approval.	
114	EmbryoAbnorm	Number of embryos that were considered abnormal and allowed to succumb	Num-2
115	EmbryoSurplus	Number of embryos that were normal however excess to patient needs therefore allowed to succumb	Num-2

27	Sp_site	Site of sperm extraction. That is ejaculated, epididymal, testicular or bladder.	Char-1
28	Sp_persn	Person whose sperm was used in insemination. To be filled out for donor insemination or use of sperm in IVF.	Char-1
116	SpDonorLic	If a sperm donor was used the "Unit" code storage licensee from whom that sperm came from is required.	Char-3
117	SpDonorID	If a sperm donor was used the sperm donors id is required.	Char-8
118	SpPrepWashing	If washing was used in sperm preparation.	Char-1
119	SpPrepGradient	If gradient method was used in sperm preparation.	Char-1
120	SpPrepSwimup	If swim up was used for sperm preparation	Char-1
121	SpPrepOther	Any other preparations methods that were used. Include Isolate here. The "Other" method should be specified	Char-20
122	ChemStim	If chemical stimulation was used the name of the chemical stimulant is specified.	Char-20
123	Manipulation	If a micro manipulation technique was used to assist in fertilisation eg. PZD, SUZI please specify the technique used here. Not necessary to include ICSI here.	Char-20
29	N_fert	Number of eggs fertilised normally. The critical issue is the opinion of the treating embryologist. Thus even if two pronuclei are not seen but cleavage occurs, provided the embryologist considers this to be a normal fertilisation then it should be included.	Num-2
30	PGD	Answer yes where PGD in any form has been performed on any of the embryos. Otherwise answer no.	Char-1
132	NumPGD	Number of embryos biopsied for genetic testing.	Num-2
133	N_Aneup_Test	Number of embryos tested for aneuploidy.	Num-2
134	N_SGD_Tested	Number of embryos tested for specific gene disorder.	Num-2
135	SGD_Specify	Please specify the name of the specific gene disorder tested (eg cystic fibrosis).	Char-20
136	N_PGD_Normal	Number of embryos considered normal after testing.	Num-2
137	N_Aneup	Number of embryos with aneuploidy.	Num-2
138	N_SGD	Number of embryos with the specific gene disorder tested for.	Num-2
31	Ass_hatc	Answer yes where assisted hatching in any form has been performed on any of the embryos.	Char-1
32	Emrecimp	This field serves two purposes: (1) Records the number of embryos that are to be received from donation (recipient cycle); (2) Records the number of embryos to be imported into the current unit from another unit.	Num-2
33	N_clthaw	Number of zygotes or cleavage stage embryos thawed with the intention of performing an embryo transfer if they survive.	Num-2
34	N_blthaw	Number of blastocysts (ie greater than 4 days culture from fertilisation) thawed with intention of performing an embryo transfer if they survive.	Num-2
35	Et_date	This is the date of embryos transfer. To be left blank if there was no embryo transfer.	Date-10
124	FertLicensee1	That is the "Unit" code of the clinic where the fertilisation took place. This field is only required where there is embryo transfer, disposal or export, otherwise it may be left blank.	Num-3
125	FertCode1	This is the code attributed to the fertilisation procedure. This field is only required where there is embryo transfer, disposal or	Char-8

		export, otherwise it may be left blank.	
126	FertLicensee2	That is the "Unit" code of the clinic where the fertilisation took place. This field is only required where a second set of embryos was used in the same cycle of embryo transfer, disposal or export.	Num-3
127	FertCode2	This is the code attributed to the fertilisation procedure. This field is only required where a second set of embryos was used in the same cycle of embryo transfer, disposal or export.	Char-8
128	DonorOwnEmbryos	Whether donor embryos or a couples own embryos were used in embryo transfer.	Char-1
129	N_clunsuitable	Number of zygotes or cleavage stage embryos thawed that are unsuitable for transfer.	Num-2
130	N_blunsuitable	Number of blastocysts (ie greater than 4 days culture from fertilisation) thawed that are unsuitable for transfer.	Num-2
36	N_emb_et	Number of zygotes of cleavage stage embryos (i.e. <4 days since fertilisation) transferred.	Num-1
37	N_bl_et	Number of blastocyst embryos (i.e. >4 days since fertilisation) transferred.	Num-1
38	Emb_icsi	Were any of the transferred embryos fertilised by ICSI?	Char-1
131	Transfer Site	This is the site of embryo transfer, ie either uterine or fallopian tube	Char-1
42	Emb_disp	The number of frozen embryos disposed of in accordance with patient or Government request.	Num-2
43	Pr_clin	Whether there was a clinical pregnancy. A clinical pregnancy must fulfil one of the following criteria: 1. Known to be ongoing at 20 weeks; 2. Evidence by ultrasound of an intrauterine sac (with or without fetal heart); 3. Examination of products of conception reveal chorionic villi; or 4. A definite ectopic pregnancy that has been diagnosed laparoscopically or by ultrasound.	Char-1
44	Pr_end_dt	Date the pregnancy ended. This is the date on which delivery, miscarriage or termination takes place. This date must eventually be completed if the answer to pr_clin is "yes". If the exact date is unknown, enter an approximate guess. Where multiple birth occur over more than one date, enter the date of the first baby born.	Date-10
45	N_fh	Number of fetal hearts seen on first ultrasound (intrautreine only)	Num-2
46	Pr_ectop	If this pregnancy is an ectopic pregnancy or a combined ectopic and uterine (heterotopic) pregnancy, enter "yes".	Char-1
47	Pr_top	Elective termination of pregnancy. Do not include pregnancies where a planned fetal reduction of a multiple pregnancy results in subsequent unintended miscarriage, or a pregnancy where there has been an IUFD requiring induced delivery. Give reasons for TOP in Abn_less (field 49).	Char-1
48	Pr_reduc	Where selective reduction was performed due to fetal abnormality. Give details in Abn_less (field 49).	Char-1
49	Abn_less	This field applies to elective terminations of pregnancy and fetal reductions due to fetal abnormality. Specify as much detail as possible.	Text-250
50	Mat_comp	Maternal complications of pregnancy. Insert as much detail as possible.	Text-250
51	N_deliv	Number of babies delivered after 20 weeks. Include all live born and stillborn babies.	Num-1
52	CS	Caesarean delivery. Doesn't matter whether CS was planned or emergency. If any of a multiple birth are a caesarean section	Char-1

		delivery, answer yes.	
53	Bab1_out	Outcome of first baby born. Either stillbirth, live birth or neonatal death.	Char-1
54	Bab1_sex	Gender of first baby born	Char-1
55	Bab1_wt	Birth weight in grams of first baby born	Num-4
56	Bab1_abn	Abnormality in the first baby born, if applicable. Put as much details as known about congenital malformation.	Text-250
57	Bab1_nnd	Date of Neonatal death of first baby born. Leave blank if no neonatal death.	Date-10
58	Bab2_out	Outcome of second baby born.	Char-1
59	Bab2_sex	Gender of second baby born	Char-1
60	Bab2_wt	Birth weight in grams of second baby born	Num-4
61	Bab2_abn	Abnormality in the second baby born, if applicable. Put as much details as known about congenital malformation.	Text-250
62	Bab2_nnd	Date of Neonatal death of second baby born, if applicable.	Date-10
63	Bab3_out	Outcome of third baby born.	Char-1
64	Bab3_sex	Gender of third baby born	Char-1
65	Bab3_wt	Birth weight in grams of third baby born	Num-4
66	Bab3_abn	Abnormality in the third baby born, if applicable. Put as much details as known about congenital malformation.	Text-250
67	Bab3_nnd	Date of Neonatal death of third baby born, if applicable.	Date-10
68	Bab4_out	Outcome of fourth baby born.	Char-1
69	Bab4_sex	Gender of fourth baby born	Char-1
70	Bab4_wt	Birth weight in grams of fourth baby born	Num-4
71	Bab4_abn	Abnormality in the fourth baby born, if applicable. Put as much details as known about congenital malformation.	Text-250
72	Bab4_nnd	Date of Neonatal death of fourth baby born, if applicable.	Date-10
73	Morb_adm	Answer yes if the female partner is admitted to hospital with any condition (excluding any pregnancy-related issues, such as an ectopic pregnancy) that could be in any way related to fertility treatment, eg. OHSS, infection or bleeding after eg. pick up.	Char-1
74	Mrb_ohss	If the cause of the morbidity is OHSS answer yes.	Char-1
75	Morb_inf	Provide details of the morbidity. Put in as much detail as known about the cause of morbidity.	Text-250

APPENDIX 5

INFORMATION CIRCULATED BY COUNCIL TO LICENSEES

Dear Licensee

Re: Compliance with Counselling Requirements under the *Human Reproductive Technology Act 1991*

Access to counselling has been of particular interest to Council since the Select Parliamentary Committee in 1999 recommended a Counselling audit be undertaken which Council carried out in 2001. The audit identified that accessibility to Counselling was an issue and that patients were not aware of their entitlements to Counselling under the *Human Reproductive Technology Act 1991* (the HRT Act).

As part of the re-licensing of ART clinics that took place in March 2006, the Licensing and Administrative Committee recommended to Council that there be follow up on the counselling compliance by the ART Clinics. Furthermore, a matter of concern to Council was the 2005-2006 annual report indicated that overall the reported counselling numbers had decreased even though the number of reported ART cycles had increased. This matter was referred to the Counselling Committee and Council agreed to the following recommendations made by the Counselling Committee.

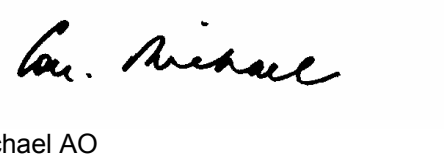
Firstly clinics are to ensure that all new ART patients must meet with the clinic counsellor for an information session as an integral part of undertaking treatment and acknowledging the psychosocial impact of ART treatment. Council agreed with the Committee that ART clinics have a duty of care to patients to ensure that they are aware of the possible psycho-social impact of undertaking ART treatment as well as being recognised as good business practice. It was agreed that these information sessions could be carried out one to one or in small groups. Council requests that this practice be implemented as soon as possible if this is not currently the practice at your clinic.

Secondly that the annual report counselling forms be amended to include the number of the mandatory information sessions and voluntary support sessions as well as the number of telephone counselling, face to face sessions, follow up sessions and group sessions. The annual report is also to include evidence of the clinic counsellors' attendance at clinic meetings. The amended forms will be sent to clinics in time for annual reporting.

Finally, clinics are to develop a strategic plan for patient support, which outlines the range of resources available for patient support during and post treatment. Council requests that clinics submit a strategic plan for patient support by **30 March 2007.**

Should you wish to discuss any of these recommendations please do not hesitate to contact the Executive Officer, Antonia Clissa on (08) 9323 6600.

Yours sincerely



CA Michael AO
Chair, Reproductive Technology Council

29 January 2007

Dear Licensee

Re: Direction 7.7 – IVF Treatment to avoid likely transmission of an infectious disease

It was brought to the Reproductive Technology Council's attention that there was ambiguity with the meaning of Direction 7.7 - IVF Treatment to avoid likely transmission of an infectious disease, which was causing some confusion.

At the last meeting Council considered advice to clarify the meaning of Direction 7.7 which stated that applications for approval under Direction 7.7 are only required where the participants are being treated under section 23(a)(ii) and an innovative practice is being used during the IVF procedure to reduce the risk of infection. Therefore, there appears to be no requirement for Council approval in respect of routine infection control methods where the participant/s are eligible for IVF because they are unable to conceive a child for medical reasons. If a clinic proposes to carry out an innovative procedure in respect of infection control this will require Council approval under Direction 9.4. Also in accordance with Direction 9.3 (f) clinics must raise the matter with Council if there is any doubt as to whether a change is to be regarded as routine or innovative.

In summary, clinics are only required to seek Council approval concerning Direction 7.7 when an innovative practice is being used during the IVF procedure to reduce the risk of infection.

Thank you for your attention to this important information.

Yours sincerely

Antonia R Clissa
Executive Officer
WA Reproductive Technology Council

28 February 2007

APPENDIX 6

FUNCTIONS OF COUNCIL AND ANNUAL REPORTING REQUIREMENTS UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

Functions of Council

The general functions of the Reproductive Technology Council are covered in section 14 of *the Human Reproductive Technology Act 1991*, and in effect set its Terms of Reference. Amendment of the Act in 2004 for excess ART embryos to be donated for research the Council to grant approval for diagnostic procedures upon a human embryo where the embryo is intended for use in the treatment a woman and that the Council is satisfied on the basis of existing scientific and medical knowledge that the diagnostic procedure is unlikely to leave the embryo unfit for implantation and where the diagnostic procedure is for the genetic testing of an embryo, there is a significant risk of serious genetic abnormality or disease being present in the embryo.

Functions of the Council (generally)

14. (1) Subject to section 13(2), the functions of the Council are —

(a) to advise the Minister —
  (i) on reproductive technology and any matter that is connected with, or incidental to, reproductive technology; and
  (ii) generally, as to the administration and enforcement of this Act;

(b) to advise the Commissioner of Health —
  (i) on matters relating to licensing under this Act, including but not limited to the suitability of any applicant for a licence or of any licensee to carry out particular procedures or approved research and as to the conditions that should be imposed on any licence; and
  (ii) generally as to the administration and enforcement of this Act and particularly on disciplinary matters;

(c) after consultation with bodies representing persons having relevant expertise sections of the public having appropriate interests, to compile and to cause to be published, to review, and to amend, a Code of Practice which –

  (i) sets out Rules, guidelines and relevant information;
  (ii) establishes the ethical standards required of licensees, and gives effect to the principles specified in, and the requirements of, this Act; and
  (iii) provides for such other matters as may be instructed by the Minister, or as the Council may determine, regulating the proper conduct of any reproductive technology practice, and of any procedure, required to be licensed and the proper discharge of the functions of the licence supervisor and other persons to whom a licence applies, having due regard to this Act;

(d) subject to paragraph (e), to encourage and facilitate, research —

(i) into the cause, prevention and treatment of all types of human infertility, adequate attention being given both to female and to male infertility; and

(ii) as to the social and public health implications of reproductive technology;

(e) to ensure that no project of research is carried out by or on behalf of a licensee upon or with —

(i) any human egg collected in the course of an in vitro fertilisation procedure;

(ii) human gametes intended for subsequent use in an artificial fertilisation procedure;

(iii) any human egg undergoing fertilisation;

(iv) any human embryo; or

(v) any participant,

otherwise than in accordance with this Act and pursuant to a general or specific prior approval given by the Council;

(f) to consider applications for, and where proper grant, approval to carry out research to which paragraph (e)applies;

(g) to promote informed public debate, and to consult with bodies representing the public or sections of the public, on the ethical, social, economic and public health issues that arise from reproductive technology;

(h) to communicate and collaborate with other bodies having similar functions, in Australia and elsewhere, and, generally, to give effect or to cause effect to be given to the objects of this Act.

(2) Subsection (1)(e)(iv) does not apply in relation to an excess ART embryo except in relation to the use of such an embryo that is an exempt use as defined in section 53W(2).

(2a) The Council must not grant approval to any research being conducted upon or with a human embryo unless —

(a) the embryo is intended for use in the reproductive technology treatment of a woman and the Council is satisfied, on the basis of existing scientific and medical knowledge, that the research is unlikely to leave the embryo unfit to be implanted in the body of a woman; or

(b) the research consists of a use referred to in section 53W(2)(b) or (f).

(2b) The Council must not grant approval to any diagnostic procedure to be carried out upon or with a human embryo unless —

(a) the embryo is intended for use in the reproductive technology treatment of a woman and the Council is satisfied, on the basis of existing scientific and medical knowledge, that —

(i) the diagnostic procedure is unlikely to leave the embryo unfit to be implanted in the body of a woman; and

(ii) where the diagnostic procedure is for the genetic testing of the embryo, there is a significant risk of a serious genetic abnormality or disease being present in the embryo; or

(b) the diagnostic procedure consists of a use referred to in section 53W(2)(d) or (f).

(3) Where a person contravenes —

(a) any provision of, or requirement under, this Act, not being a direction; or

(b) any direction given by the Commissioner, being a direction which is consistent with the Code or is not inconsistent with —

(i) ethical guidelines laid down by the NHMRC, as for the time being prescribed;

(ii) criteria established by a body referred to in section 29(5)(a)(i) or (ii), as for the time being prescribed; or

(iii) a provision of, or any principle set out in, or requirement under, this Act, as from time to time amended, the Council shall endeavour to ensure that effect is given to that provision, requirement or direction.

[Section 14 amended by No. 17 of 2004 s. 11; No. 55 of 2004 s. 523.]

Functions of the Council in relation to permitted embryo storage

24. (1) In relation to the storage of any human gametes, human egg undergoing fertilisation or human embryo —

(a) the primary purpose stated in any consent to the storage of a human embryo must relate to the probable future implantation of that embryo or its probable future use under an NHMRC licence; and

(b) the Code may make provision as to what, in particular circumstances, constitutes an excessive time for the storage of —

(i) human gametes;

(ii) a human egg undergoing fertilisation; or

(iii) a human embryo, but no human egg undergoing fertilisation or human embryo shall be stored for a period in excess of 10 years except with the approval of the Council under subsection (1a).

(1a) The Council may, on an application by an eligible person, approve in writing a longer storage period for a human egg undergoing fertilisation or a human embryo if it considers that there are special reasons for doing so in a particular case.

(1b) An approval under subsection (1a) may be subject to conditions and is to specify the date on which the longer storage period ends.

(1c) An approval under subsection (1a) can only be given before the end of 10 years, or if a longer storage period has previously been approved under subsection (1a), before the end of that period.

(1d) The Council is to inform the Minister of each approval given under subsection (1a), but in such a manner that the identity of the biological parents cannot be ascertained from the approval.

(2) In subsection (1a) —

"eligible person", in relation to a human egg undergoing fertilisation or a human embryo, means —

(a) a person who is or is to be a participant in an artificial fertilisation procedure in which the egg or embryo is to be used;

(b) a person for whom the egg or embryo was developed; or

(c) in the case of an excess ART embryo, except in relation to the use of such an embryo referred to in section 10(2)(e) of the Commonwealth Human Embryo Act, the licensee.

(3) Three months before the end of a period of storage permitted under this section the licensee must take reasonable steps to notify each person for whom the human egg undergoing fertilisation or human embryo is being stored.

(4) If a period of storage permitted under this section comes to an end and no application has been made for the extension of the storage period, the licensee may, if the licensee has complied with subsection (3), allow the human egg undergoing fertilisation or the human embryo to succumb and will not be liable to anyone for so doing.

[Section 24 amended by No. 1 of 1996 s. 5 and 6; No. 3 of 2002 s. 75; No. 17 of 2004 s. 18.]

Annual reporting requirements under the Act

The requirements for reporting on the use of reproductive technology in the State are set out in section 5 (6) and clause 11 of the Schedule to the Human Reproductive Technology Act 1991, as follows:

"**5(6).** A report on the use of human reproductive technology in the State during the preceding financial year shall be furnished annually by the Council to the Commissioner who shall thereafter submit the annual report required by clause 11 of the Schedule to the Minister who shall, within 14 sitting days after submission of that report, cause copies of it to be laid before each House of Parliament";

and from the Schedule-

"**Annual Report on Reproductive Technology**

11. (1) The report to be furnished by the Council to the Commissioner of Health on the use of reproductive technology in the State and the operations of the Council in the preceding year ending 30 June shall be so furnished by such a date as, in the opinion of the Commissioner, will enable the Commissioner to submit an annual report to the Minister not later than 30 September in each year.

(2) The report to be furnished by the Council to the Commissioner, and the annual report to be submitted to the Minister, under subclause (1)-

(a) shall set out-

(i) any significant developments in the use of, or in the procedures or techniques used in, reproductive technology during the year, whether in the State or elsewhere;

(ii) details of research specifically approved by, or being conducted with the prior approval of, the Council during that year;

(iii) in statistical terms, the activities of persons licensed under this Act and carried on during that year; and

(iv) any discernible social trends that became apparent during that year and are, or may be, attributable to the use of reproductive technology;

(b) shall contain particulars of-

(i) any contravention of this Act, or of any terms, condition or direction relating to a licence or exemption; and

(ii) any other matter within the responsibilities of the Council or the Commissioner,

that is, in the opinion of the Council or of the Commissioner, of significance to the public interest;

and

c) shall, if that is practicable, be combined with any annual report that may be required to be submitted in relation to this Act under the *Financial Administration and Audit Act 1985."*

[Schedule amended by No. 78 of 1995 s. 147.]