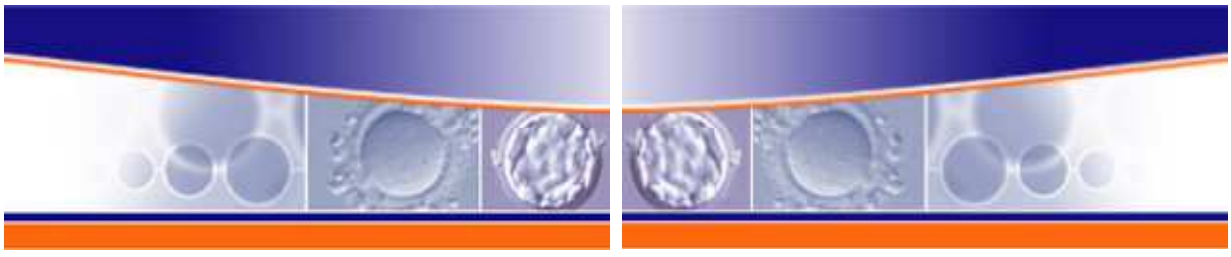
Western Australian Reproductive Technology Council

Annual Report

1 July 2009 - 30 June 2010



Annual Report of the Western Australian Reproductive Technology Council

1 July 2009 – 30 June 2010

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
A/Executive Officers
Dr Nyaree Jacobsen (08) 9222 4387 and Ms Jen Parker (08) 9222 4186

Compiled by:

The Western Australian Reproductive Technology Council

September 2010
Perth, Australia

Council would like to thank Alpha: Scientists in Reproductive Medicine for the permission to use the images included in this report. http://www.alphascientists.org

Reproductive Technology Council

Mr Kim Snowball
Chief Executive Officer
Department of Health
189 Royal Street
East Perth WA 6004

Dear Mr Snowball

It is with pleasure that I submit to you the Annual Report of the Reproductive Technology Council (Council) for the financial year 2009-2010. This report 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.

The Council typically meets on a monthly basis to discuss matters arising from the provision of assisted reproductive technology (ART) services in Western Australia (WA). Correspondence received from the seven fertility clinics licensed to provide ART services in WA includes a range of issues that required Council consideration and feedback, including practices set out in the HRT Act that require Council approval.

A particular issue of Council deliberation during 2009-2010 was that of posthumous collection and use of gametes. Throughout 2009-2010, Council considered several applications for the export of gametes collected or stored posthumously in WA. Whilst current legislation prohibits the use of gametes following the death of the gamete provider, Council has indicated general support for amendment to the HRT Act to allow the conditional posthumous use of gametes. In 2009-2010 Council provided further advice to the Department of Health on this matter, drawing on the collective expertise offered by Council's professional and community representatives. In the provision of such advice, Council also considered changes in community attitudes and recent developments in the legislation of posthumous use of gametes and embryos in other Australian jurisdictions.

Following the passage of the *Surrogacy Act 2008*, Council has continued to liaise with the Reproductive Technology Unit on a range of issues to support the implementation of surrogacy legislation. During 2009-2010 this included the development of application forms to be submitted to Council by participants seeking a surrogacy arrangement. Council anticipates that the forthcoming year will see the first applications to Council from eligible couples seeking surrogacy as a means by which to create a family.

Another matter concerning regulation of ART in WA was that of embryo research. Council has become aware that there is general support from the scientific community to reintroduce legislation in WA that is consistent with Commonwealth legislation on embryo research. Enactment of corresponding legislation would serve to increase the scope for embryo research in WA and provide clarity to the role of the National Health and Medical Research Council (NHMRC) Embryo Research Licensing Committee to approve and monitor embryo research in the State. Council is hopeful that this issue, in

addition to other issues identified by the *Select Committee on the Human Reproductive Technology Act 1991 Report* (1999) may, with the consent of the Parliament be considered in the near future.

Applications for extensions to the storage period for embryos require the approval of Council. The development of an embryo storage policy has been a focus for several years, and Council's 'Policy on Embryo Storage and Applications to Extend Storage Beyond Ten Years' was ratified in 2009. The policy is important in providing guidance for Council members assessing embryo storage applications, in addition to guiding fertility clinics and patients on matters of embryo storage. An embryo storage brochure developed for consumers has also been distributed to fertility clinics to assist patients to seek an embryo storage option appropriate to their personal situation.

It is not possible for Council to operate effectively without the significant support of a number of people who provide their expertise and time to attend to matters requiring Council consideration. I especially wish to acknowledge and thank Council and Committee members for their dedicated and ongoing commitment over the past 12 months. During 2009-2010 Council has been further strengthened by the appointment of several deputy members who have contributed to Council's robust discussions on many important issues.

The Council has continued to liaise with Legal and Legislative Services within the Department of Health to clarify ART regulatory matters and interpretation of the HRT Act. I would like to acknowledge and thank Ms Deborah Andrews for her continuing legal support and guidance regarding the HRT Act, and Ms Linda Taylor for her assistance with the *Surrogacy Act 2008*.

Finally, on behalf of Council I wish to recognise the ongoing financial contribution by the Department of Health, and the administrative support provided by the Executive and Deputy Executive Officers to Council. Executive Officer Ms Jenny O'Callaghan is currently on secondment within the Department of Health, but has continued to support Council activity during this period. Practical assistance through executive support, in addition to the ongoing financial commitment from the Department of Health is essential to enable the Council to carry out its statutory duties set out in the HRT Act.

Yours sincerely

CA Michael AO
Chair
Reproductive Technology Council

9 September 2010

CONTENTS

GLOSSARY

AI	Artificial insemination
ART	Assisted reproductive technology
CEO	Chief Executive Officer, Department of Health
CGH	Comparative Genomic Hybridisation
DI	Donor insemination
DoH	Department of Health WA
FET	Frozen embryo transfer
FISH	Fluorescence In Situ Hybridisation
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
ICSI	Intra cytoplasmic sperm injection
IUI	Intra uterine insemination
IVF	In vitro fertilisation
NHMRC	National Health and Medical Research Council
OHSS	Ovarian Hyperstimulation Syndrome
PAQ	Performance, Analysis and Quality Division (DoH)
PGD	Pre-implantation genetic diagnosis
PGS	Pre-implantation genetic screening (for aneuploidy)
RIHE Act	Research Involving Human Embryos Act 2002
RTAC	Reproductive Technology Accreditation Committee (Committee of the Fertility Society of Australia)
SCNT	Somatic cell nuclear transfer
Surrogacy Act	Surrogacy Act 2008
2009-2010 year	Refers to the period 1 July 2009 until 30 June 2010

EXECUTIVE SUMMARY

This Annual Report has been prepared by the Reproductive Technology Council (Council) for the Chief Executive Officer (CEO), Department of Health, 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 for Health, in order that copies are laid before each House of Parliament. The Annual Report outlines the use of assisted reproductive technology in the State, and the operations of the Council for the year ending 30 June 2010.

As outlined in the HRT Act, the Council has an important role as an advisory body to the Minister for Health 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 (WA). 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.

Figures collected from annual reporting data submitted by Western Australian licensees show that WA fertility clinics undertook more than 5000 cycles of in vitro fertilisation (IVF) or frozen embryo transfer (FET) in the 2009-2010 year, an increase in more than 10% on the previous year's figure. More than 2000 women and couples were treated for infertility. The number of IVF cycles resumed its overall trend of growth over time, after a slight decrease last year. The usage of FET in fertility treatment has consistently increased over the past decade.

Council consideration of ART regulatory matters required response to more than 60 general queries and concerns from WA fertility clinics and ART professionals. In addition, deliberation by Council members was required on more than 50 specific applications where Council approval was sought under the HRT Act. These applications included embryo storage extensions, PGD applications, import applications and export of donated human reproductive material plus research and innovative procedures undertaken by fertility clinics. Requests to export or use gametes collected posthumously also required considerable Council attention during 2009-2010.

Another matter that has required Council discussion during 2009-2010 is the refinement of information regarding surrogacy applications. Council liaised with the Reproductive Technology Unit to provide clinics and consumers with guidance on the legislation and information on the requirements of surrogacy applications. This information has been distributed to clinics and included on the Council website. While no applications for surrogacy arrangements were considered by Council during 2009-2010, it is anticipated that the information provided during this period will lead to a number of applications being submitted to Council for consideration in the 2010-2011 financial year.

In 2009-2010, Council considered a number of cases requesting the posthumous collection, storage and subsequent use of gametes. Council decisions on posthumous collection and use of gametes were directed by what is allowed under current legislation in this State which prohibits the posthumous use of gametes in WA. However, Council has indicated general support for amendment of the HRT Act to allow posthumous use of gametes under certain specific circumstances.

Council finalised and distributed the embryo storage policy and embryo storage brochure in February 2010. The policy provides clarity to the processes dictating embryo storage, applications for extension and donation of embryos in WA. The embryo storage brochure

answers many frequently asked questions regarding the embryo storage process and is available to consumers via fertility clinics or by download from the Council website.

Executive support to the Council experienced a number of changes during 2009-2010. The Executive Officer position was covered by Dr Nyaree Jacobsen (0.6FTE) and Ms Jen Parker (0.4FTE) following secondment of Ms Jenny O'Callaghan to the Office of the Chief Medical Officer in April 2010. Ms Parker returned from maternity leave to her role which had been covered by Ms Stephanie Bolton. Mr Russ Milner assumed the A/Deputy Executive Officer role in April 2010. Transition processes were well managed and ensured the provision of continued support to Council.

Council membership also experienced a number of changes. Ms Leah Bonson stepped down as a Member in August 2009. This position was filled in February 2010 by Ms Anne-Marie Loney who had previously been a Deputy Member. Deputy Members A/Professor Neville Bruce (August 2009) and Ms Leonie Forrest (July 2009) also resigned during the year, replaced in February 2010 by Ms Jane Baker, Ms Justine Garbellini, Dr Kathy Sanders and Ms Julie Panotidis. Council sincerely thanks all outgoing members for their expertise, time and commitment over the duration of their membership.

The 2009-2010 budget allocation to Council was $41,438, with expenditure totalling $24,046 for the year. The Financial Statement outlining the distribution of expenses is provided in this Annual Report. As reflected in the Financial Statement, the under-expenditure was largely due to wider financial issues affecting the global economy and delayed release of the budget allocation. Council has a long record of remaining within the allocated budget, and predicts expenditure for the forthcoming financial year will remain within budget.

The effective operation of Council requires the significant and dedicated support of Council and Committee members, and the ongoing financial and administrative support provided by the Department of Health. This support is essential to enable the Council to meet all of the responsibilities set out in the HRT Act and the recently enacted surrogacy legislation and to ensure the effective regulation of ART services in WA under these Acts.

INTRODUCTION

The Western Australian Reproductive Technology Council (the Council) was established to oversee prescribed reproductive technology practices in WA, as set out by the *Human Reproductive Technology Act 1991* (HRT Act) and since December 2008, the *Surrogacy Act 2008*. Membership of the Council is determined by the Minister for Health, who has responsibility to ensure that the Council is comprised of individuals with special knowledge and experience in matters dealt with under the HRT Act. Expertise in assisted reproductive technology (ART) underpins the Council's membership. However, Council must also be representative of the general community. Membership therefore also includes consumer representation, representatives for children born from ART plus members with experience in public health matters and ethical and legal expertise.

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.

Licences and exemptions regulate the use of reproductive technology in WA for the purpose of assisting people who are unable to conceive or bear children naturally or without risk to a child. The Council is responsible for providing advice to the CEO regarding the issuance of practice and storage licences to clinics providing ART services. As a condition of the storage and practice licenses, licensees must also receive accreditation from the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA), or another prescribed body. Exemptions allowing medical practitioners to carry out artificial fertilisation procedures in WA may also be issued by the CEO.

The Council meets on a monthly basis to discuss ART matters that require consideration and/or approval. ART practices that require Council approval include the import and export of donor human reproductive material, embryo storage beyond ten years, pre-implantation genetic diagnosis applications and innovative procedures performed in fertility clinics. Since the passage of surrogacy legislation, Council approval for a surrogacy arrangement is also necessary in order for a parentage order to be made for a child born from an arrangement in WA.

Continuing developments in the science and practice of ART challenge the ethical and legislative framework in which ART is practiced, both in Australia and worldwide. In WA, the enactment of surrogacy legislation exemplifies such progress and change and was just one area requiring Council focus in 2009-2010. Within Australian jurisdictions, enactment of

specific ART legislation in recent years is notable and reflects recognition of the importance of regulation providing for ongoing scientific development. The HRT Act, enacted in 1991 (amended in 2004) has provided robust regulation of ART in WA since this time. However, ongoing scientific development and attitudinal changes in society requires consideration of practices not previously covered under the legislation. The need for legislation to keep up with such change in ART is a challenge for the government and Council, and consideration of such matters will continue to be a Council focus in future years.

MEMBERSHIP OF THE COUNCIL 2009 – 2010

Member	Nominee of:
Chair: Professor Con Michael	The Australian Medical Association
Ms Leah Bonson	Department of Child Protection (until August 2009)
Ms Anne-Marie Loney	Department of Child Protection (since February 2010)
Dr Simon Clarke	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
A/Professor Jim Cummins	The Minister for Health
Mr Peter Fox	The Health Consumers' Council
Professor Roger Hart	The Department of Obstetrics and Gynaecology, University of Western Australia
Dr Brenda McGivern	The Law Society of Western Australia
Dr Joe Parkinson	The Minister for Health
Dr Beverly Petterson	The Minister for Health
Ms Patrice Wringe	The Health Consumers' Council
Ms Jenny O'Callaghan	Executive Officer *ex officio* (until April 2010) Senior Policy Officer, DoH
Dr Nyaree Jacobsen	A/Executive Officer *ex officio* (since April 2010) Senior Policy Officer, DoH
Ms Jen Parker	A/Executive Officer *ex officio* (since April 2010) Senior Policy Officer, DoH

Deputy Member	Nominee of:
Ms Jane Baker	Department of Child Protection (since February 2010)
A/Professor Neville Bruce	The Minister for Health (until August 2009)
Dr Peter Burton	University of Western Australia
Reverend Brian Carey	The Minister for Health
Dr Angela Cooney	The Australian Medical Association
Ms Leonie Forrest	The Law Society of Western Australia (until July 2009)
Ms Justine Garbellini	The Health Consumers' Council (since February 2010)
Dr Janet Hornbuckle	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Ms Anne- Marie Loney	Department of Child Protection
Ms Sue Midford	The Health Consumers' Council
Dr David Miller	The Minister for Health
Ms Julie Panotidis	The Law Society of Western Australia (since February 2010)
Dr Kathy Sanders	The Minister for Health (since February 2010)
Dr Nyaree Jacobsen	Deputy Executive Officer *ex officio* (until April 2010) Senior Policy Officer, DoH
Ms Stephanie Bolton	Deputy Executive Officer *ex officio* (until April 2010) Senior Policy Officer, DoH
Mr Russ Milner	A/Deputy Executive Officer *ex officio* (since April 2010) A/Senior Policy Officer, DoH

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 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), Mr Peter Fox, Ms Anne-Marie Loney, Ms Iolanda Rodino, Ms Patrice Wringe, Ms Jenny O'Callaghan (*ex officio*), Ms Jen Parker *(ex officio)* and Ms Stephanie Bolton *(ex officio* until April 2010).

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 Patrice Wringe, Ms Jenny O'Callaghan (*ex officio)* and Dr Nyaree Jacobsen (*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), Professor Roger Hart, Dr Brenda McGivern, Ms Sue Midford, Dr Joe Parkinson, Ms Patrice Wringe, Ms Jenny O'Callaghan *(ex officio*) and Dr Nyaree Jacobsen (*ex officio*).

PGD 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 factors that it should consider when deciding whether to approve PGD, both generally and for specific cases.

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

3. To advise the Council as to how the ongoing process of approval of PGD should be managed effectively by the Council.

4. To monitor the outcomes of diagnostic procedures involving embryos.

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, but not limited to, counselling in relation to PGD with the Counselling Committee and legal issues in relation to PGD with a Department of Health lawyer.

Membership:

Dr Beverly Petterson (Chair), Dr Peter Burton, Ms Karen Hajigabriel (until February 2010), Dr Ashleigh Murch, Dr Sharron Townshend, Ms Jenny O'Callaghan (*ex officio)* and Dr Nyaree Jacobsen (*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 Peter Burton, Professor Roger Hart, Dr Joseph Parkinson, Dr Beverly Petterson, Dr Kathy Sanders and Dr Nyaree Jacobsen *(ex officio)*.

Staff of the Reproductive Technology Unit Department of Health

Ms Jenny O'Callaghan
Senior Policy Officer and Executive Officer of the Council (until April 2010)

Dr Nyaree Jacobsen
Senior Policy Officer and A/Executive Officer of the Council (since April 2010) (0.6 FTE)

Ms Jenny Parker
Senior Policy Officer and A/Executive Officer of the Council (since April 2010) (0.4 FTE)

Ms Stephanie Bolton
Senior Policy Officer and Deputy Executive Officer of the Council (until April 2010) (0.4 FTE)

Mr Russ Milner
A/Senior Policy Officer and A/Deputy Executive Officer of the Council (since April 2010)

Ms Melissa Chantry
Research Officer, Performance, Analysis and Quality Division.

REPRODUCTIVE TECHNOLOGY COUNCIL
FINANCIAL STATEMENT 1 July 2009 – 30 June 2010

The Department of Health funds the administration of the HRT Act, including the operations of the Council. The 2009-2010 Council budget allocation was $41,480, with expenditure totalling $24,046 for the financial year. This under-expenditure of the allocated budget can be attributed to the delay in Council's final budget allocation. This delay stemmed from wider global financial uncertainty which impacted upon Department of Health budget allocations in 2009-2010. Council activity such as a proposed public awareness forum had therefore been suspended until the final budget allocation was confirmed.

Council has a long record of remaining within the allocated budget, and anticipates that the 2010-2011 budget will support Council's capacity to meet all Council functions set out in the HRT Act.

REPRODUCTIVE TECHNOLOGY COUNCIL Expenses by Category	Expenditure ($)	Income ($)
Staff or Council:		
Training/Registration/Course fees Travel Interstate	2,035 0	
Food supplies/catering	291	
Administration and clerical	0	
Purchase of external services:		
Sessional fees: (External Consulting Fees) Reproductive Technology Council	19,098	
Other expenses:		
Books/magazines/subscriptions	0	
Freight/ cartage/postal	13	
Printing including Annual Report	1,664	
Audio-visual	402	
Maintenance equipment	346	
Stationery	197	
TOTAL	**24,046**	
Budget Allocation		**41, 480**

OPERATIONS OF THE COUNCIL 2009 – 2010

Meetings

The Council met on ten occasions during the 1 July 2009 to 30 June 2010 period, with attendances reaching quorum at all meetings. The Counselling Committee met on five occasions; the PGD Advisory Committee met on one occasion, with several applications for PGD assessed out of session by this committee before being considered at the subsequent Council meeting. The Embryo Storage Committee met on one occasion during the year. The Licensing and Administrative Committee met once in 2009-2010 to consider documentation from Fertility Specialists South submitted for review prior to renewal of the licences in August 2009. The Scientific Advisory Committee met on one occasion, to discuss data fields collected from assisted reproductive technology practice in WA.

Membership

Outgoing members in 2009-2010

Council membership has seen a number of changes during the 2009-2010 year, with Ms Leah Bonson (August 2009) stepping down from her position as a Council member. In addition, the following deputy members also resigned from Council during the period: A/Professor Neville Bruce (August 2009), Ms Leonie Forrest (July 2009) and Ms Stephanie Bolton (0.4 FTE, April 2010). In particular, A/Professor Bruce and Ms Forrest had been long-standing representatives of Council. Ms Forrest was appointed to Council in November 2004 as a nominee of the Law Society of WA. Ms Forrest's legal expertise informed many complex Council discussions during her appointment. A/Professor Bruce was appointed in May 2006 following nomination by the Minister for Health. A/Professor Bruce's interest in reproductive health and bioethics benefitted Council consideration of reproductive technology issues. Council extends sincere gratitude to these outgoing members for their contributions over the years and wishes them success in their future endeavours.

Incoming members in 2009-2010

Council welcomed two new members and five new deputy members. Ms Anne-Marie Loney of the Department of Child Protection had been a deputy member of Council since June 2009 and was appointed to member status in February 2010. The incoming deputy members in 2009-2010 were Ms Jane Baker of the Department of Child Protection (February 2010), Ms Justine Garbellini of the Health Consumer's Council (February 2010), Dr Kathy Sanders of the University of WA School of Anatomy and Human Biology (February 2010) and Ms Julie Panotidis of the Law Society of WA (February 2010).

Department of Health Staff assisting the work of the Council

A number of changes to the DoH executive support for the Council occurred during 2009-2010, although this was managed to allow minimal disruption to the activities of the Council.

Ms Jenny O'Callaghan was appointed in January 2008 as Senior Policy Officer, DoH and under the HRT Act as Executive Officer to Council. Until April 2010 when seconded as A/Senior Policy Officer of the Office of the Chief Medical Officer, Ms O'Callaghan provided secretariat support for the RTC Counselling Committee and other Council committees as required and as Senior Policy Officer, Ms O'Callaghan also had responsibility for the management of the Reproductive Technology Unit (RTU). Ms O'Callaghan continues to provide guidance and support to Council as required and is an invited guest to Council meetings.

Dr Nyaree Jacobsen (0.6FTE) was appointed in November 2007 as Senior Policy Officer for the DoH, and Deputy Executive Officer to Council under the HRT Act. Responsibilities of this position have included the provision of secretariat support for the PGD Advisory Committee, and the Embryo Storage Committee. In April 2010 Dr Jacobsen began acting in the position of A/Executive Officer to Council and assumed responsibility for the management of the RTU.

Ms Jenny Parker (0.4FTE) Ms Parker was appointed in November 2008 to provide additional administrative and policy development support to the RTU and Council, and shared Deputy Executive Officer duties with Dr Jacobsen. Ms Parker's responsibilities have included management of the Voluntary Register and Council session fees. Ms Parker returned from 12 months maternity leave in April 2010 in the capacity of A/Executive Officer to Council alongside Dr Jacobsen.

Ms Stephanie Bolton (0.4FTE) was appointed from July 2009 to April 2010 as Senior Policy Officer, DoH and Deputy Executive Officer to Council during the period of Ms Parker's maternity leave.

Mr Russ Milner was appointed in April 2010 as A/Senior Policy Officer, DoH and A/Deputy Executive Officer to Council. Mr Milner provides executive support to Council and the PGD Committee and coordinated the submission of the 2009-2010 annual report.

Ms Melissa Chantry holds the position of Research Officer in the Performance, Analysis and Quality Division (PAQ) of DoH and has been an invited guest at Council meetings since May 2006. Ms Chantry has responsibility for the collation of licensee reporting information, and the maintenance of the Reproductive Technology (RT) Register.

Acknowledgements

The Council gratefully acknowledges:

The continuing legal support and expertise in the area of ART and surrogacy legislation provided by Ms Deborah Andrews and Ms Linda Taylor, DoH Legal and Legislative Services.

Data management and support from Mr Tony Satti, Mr Max Le, Ms Melissa Chantry, Alan Joyce and Mr Nam Nguyen from DoH PAQ.

Administrative and accounting support from Ms Sandra Lynch, Ms Annette Davey, Ms Evelyn D'Souza and Mr Louie Miovski.

Supervisory responsibility and management support from Dr Simon Towler and the Office of the Chief Medical Officer (DoH).

LICENSING ISSUES

Establishments licensed under the *Human Reproductive Technology Act 1991* at 30 June 2010

Practice and Storage Licences:

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

Fertility Specialists South Pty Ltd trading as Fertility Specialists South
1st Floor 764 Canning Hwy
Applecross 6153

In Vitro Laboratory Pty Ltd trading as Concept Fertility Centre
Concept Day Hospital
218 Nicholson Road
Subiaco WA 6008

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

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

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

Practice (AI only) and Storage Licences:

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

Issuance of new practice and storage licences

In 2008, interim Practice and Storage licences were issued to a new business entity, Fertility Specialists South Pty Ltd. Fertility Specialists South is affiliated with Fertility Specialists of Western Australia and was established to provide ART services previously unavailable south of the Swan River. The interim licences were issued for a one year period. Following a review of clinic activities over this year to ensure compliance with the HRT Act, and following the clinic's receipt of RTAC accreditation, Council recommended the CEO of the Department of Health issue Fertility Specialists South with Practice and Storage licences. These were issued for the period until April 2012.

In late 2009, In Vitro Laboratory Pty Ltd, trading as Concept Fertility Centre, moved to new premises in Subiaco. Council representatives undertook a site visit of the new custom-designed day hospital facilities, and were satisfied that the requirements of section 29 (5)(b) of the HRT Act were met. This section states that adequate and appropriate premises, equipment, staff supervision, support services and facilities are available, and are likely to remain available, for the purposes to which the licence relates. The day hospital was also issued with a licence to conduct a day hospital – Class A on 1 December 2009 under the *Hospitals and Health Services Act 1927 (HHS Act*). On this basis and conditional on RTAC accreditation, Council recommended the CEO of Health issue Concept Fertility Centre with Practice and Storage licences for the new premises. These were issued for the period until April 2012.

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

The NHMRC (through the Embryo Research Licensing Committee) is authorised to license research projects involving excess ART embryos under Part 4B of the HRT Act. However, the Human Reproductive Technology Amendment Bill (2007) which aimed to provide consistency between WA legislation on embryo research and corresponding Commonwealth legislation was defeated in the Legislative Council in May 2008. This defeat and consequent inconsistency between state and Commonwealth legislation has led to uncertainty regarding the authority for the NHMRC to license and monitor excess ART embryo research in WA and the scope of research permitted in WA. To resolve the legal uncertainty for legislators, researchers and licensees, amendment to the HRT Act is necessary. The possible means of achieving this are currently under legal consideration.

In 2006 the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth)('the amending Act') amended the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth). An independent review of the operation of both Acts must be undertaken as soon as possible three years after the amending Act received Royal Assent. The review was therefore due to commence soon after 12 December 2009. After consulting with the Commonwealth, the States and a broad range of experts, a number of recommendations will be made for any necessary amendments to the Acts. This review and possible subsequent amendments may impact on the progress of any proposed WA legislative amendments that aim to achieve corresponding law status with the Commonwealth Acts.

There are no establishments currently undertaking research in WA 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 insemination (AI) procedures in WA. The Council did not receive any new applications for an exemption to practice an AI procedure during 2009-2010. Since 2007, six exemptions have been revoked and of the remaining nine reporting practitioners only 24 intra uterine insemination (IUI) procedures were performed across WA during 2009-2010. Individually, five exempt practitioners did not perform an AI procedure during this period, one performed four, one performed eight and one performed 12 procedures. A list of practitioners currently issued with exemptions is provided in Appendix 1.

Fertility Society of Australia accreditation

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 oversee accreditation of fertility clinics.

Previously, RTAC had responsibility for undertaking site visits and providing assessment of licensees across all Australian jurisdictions. The RTAC Code of Practice provided guidance and the standards for fertility clinics to gain accreditation. However, in 2008-2009, the FSA and RTAC changed this process, following an earlier review of the FSA Code of Practice. A major change in the revised accreditation process has been the requirement for licensees to appoint their own certifying body through which to seek accreditation. To ensure a consistent standard of accreditation, certifying bodies require approval from the FSA to undertake fertility clinic accreditation and inspectors with expertise in the fertility industry also take part in the accreditation process. Previously, accreditation was granted for three years. With the new system, critical criteria and a selection of good practice criteria are audited on an annual basis, with a complete audit at least once every three years during which all critical and good practice criteria are assessed. As above, accreditation is required for the issuance of practice and storage licences to fertility clinics in WA.

Information circulated to licensees

In the 2009-2010 year, Council considered and provided written responses to more than 50 licensee concerns and enquiries. This was in addition to licensee applications to Council outlined in the following chapter. In addition to this individual licensee correspondence, *all* licensees received information from Council regarding the following matters:

- Transfer of PGD approval between fertility clinics
- Additional egg collection for patients seeking pre-implantation genetic diagnosis or screening of embryos
- Embryo storage policy feedback request
- Final embryo storage policy
- Waiting lists for donor sperm

This correspondence is set out in Appendix 5.

Complaints

The Council did not receive any formal complaints regarding the operations of licensees during the year. The Council received information that applicants to a surrogacy arrangement had lodged a letter of concern regarding their experiences with a fertility clinic. However, Council was not required to act on the matter.

LICENSEE APPLICATIONS TO COUNCIL 2009-2010

Under the HRT Act, specific approval from Council is required for clinics to carry out certain practices, including the storage of embryos beyond ten years, research projects, innovative procedures and diagnostic testing of embryos. Outlined below are practices that were granted approval during the 2009-2010 year. A list of applications received by Council from licensees in 2009-2010 is provided in Appendix 3.

Embryo Storage applications

Amendments to the HRT Act in 2004 increased the initial authorised storage period for embryos created for ART from three years to a ten year authorised period. To permit embryos to remain in storage beyond this ten year period, Council approval must be granted. Approval for an extension may be granted under s24 (1a) of the HRT Act if Council considers there are "special reasons for doing so", and applications are assessed by Council on a case-by-case basis to determine the merits of each application for extension.

Applications for embryo storage extensions must be made on a Form 8 by eligible participants (that is, by those for whom the embryos were created, or by recipients if they have been donated). Under the HRT Act, Council is unable to grant an extension once the embryo storage period expires. Applications to extend the storage period of embryos donated for research purposes are submitted on a Form 9, and can be made by the eligible participants, or by the licensee. In cases where participants are applying to extend the storage of embryos for their 'own use' supporting documentation, for example confirmation that the participants are still eligible to undertake IVF, may be requested.

To guide decision-making in these matters, and inform to participants and clinics with embryos in storage, the Embryo Storage Committee has developed a Council Embryo Storage Policy. Council recognises that the majority of ART participants store embryos with the intention to use or to donate these embryos. However, a small proportion of embryos are stored by participants who, after completing their ART treatments, remain uncertain as to the intended future purpose of their stored embryos. The document sets out Council policy to guide decision-making regarding embryo storage extensions and the responsibilities under the legislation of Council, licensees and participants under the HRT Act. The policy aims to assist clinics to prepare participants to make a decision regarding their embryos in storage prior to the authorised storage period coming to an end. The Embryo Storage Policy was finalised and ratified by Council at the Council meeting held on 9 December 2009.

To complement the Embryo Storage Policy, an Embryo Storage brochure was developed and copies were distributed with the Embryo Storage Policy to fertility clinics. A copy of both documents can be found in Appendix 7 of this Annual Report.

For those participants who find decision-making about their embryos in storage a very difficult process, Council is intending to produce a more specific brochure addressing End of Storage concerns. This additional written support for individuals and couples will set out options including encouraging participants to seek counselling or to consider holding a 'ceremony' for their embryos. This may help participants achieve closure for what is sometimes a very difficult period of their lives. This brochure is in the process of development.

For 2009-2010, twenty Form 8 applications to extend an authorised embryo storage period were approved by Council on the recommendation of the Embryo Storage Committee. Of

these applications, three were granted a one year extension, five were granted a two year extension, one was granted a three year extension and eight were granted five year extensions. One application was granted a three month extension and two were granted a six month extension, for the purpose of providing further information. No Form 9 applications (for use in research) were submitted to Council.

Research Project applications

Research projects undertaken by licensees (other than research on excess ART embryos requiring an NHMRC licence) must receive Council approval. While *general* Council approval has been granted for some types of research, including surveys of participants or research involving additional testing of samples collected at the time of a procedure, *specific* approval is required for all other research projects. Summary information indicating the current status and related matters of any Council approved research project must be submitted with the licensee's annual report. No applications to undertake research were submitted to Council in 2009-2010. A list of approved research projects active in 2009-2010 is provided in Appendix 3.

Innovative Procedure applications

Approval to use an innovative procedure must be sought from Council under Direction 9.4. The HRT Act permits clinics to introduce new and innovative ART procedures, but requires that these procedures are monitored through the approval process and annual reporting requirements. As technology advances and new techniques are more widely adopted, it may be appropriate to consider certain procedures as 'routine' rather than as an innovative. However, while international acceptance of the efficacy and safety of a procedure may deem that the procedure is no longer 'innovative', a licensee will still be required to demonstrate that they have sufficient expertise undertaking the procedure for this to be approved as routine for their clinic.

To provide further clarification of the criteria of procedures that may be considered 'innovative', Council endorsed the definition from the 2007 NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research that an innovative procedure is:

> A therapeutic, diagnostic or laboratory procedure that is aimed at improving reproductive outcomes beyond existing methods but has not been fully assessed for safety and/or efficacy.

As an example, vitrification is a form of cryopreservation in which oocytes or embryos undergo ultra-rapid freezing. The advantage of vitrification over traditional 'slow cooling' methods is the relative simplicity of the method, and that ultra-rapid freezing reduces the likelihood of ice crystal formation and subsequent damage to cell membranes. However, one risk associated with this procedure has been that cells are exposed to higher volumes of potentially toxic cryoprotectants than volumes used in the slow cooling method.

With refinement of the methodology including the use of less toxic cryoprotectants, international and local experience has shown significant improvements in pregnancy rates following the use of embryos preserved through vitrification, with no increased associated adverse outcomes when compared to traditional cryopreservation of embryos. However, pregnancy outcomes following oocyte vitrification are still less successful than embryo cryopreservation, and the long-term safety of the procedure, in particular with regard to outcomes of children born following vitrification of oocytes, still warrants monitoring. For this reason oocyte vitrification remains, in most cases, an innovative procedure in WA.

Innovative Procedures approved during 2009-2010

Council did not receive any new applications from licensees to undertake innovative procedures during the 2009-2010 year.

Innovative to Routine approvals during 2009-2010

In 2009-2010, no additional procedures were reclassified from innovative to routine. Innovative procedures approved under Direction 9.4 to 2009-2010 are listed in Appendix 3.

Applications to allow diagnostic testing of embryos

Amendments to the HRT Act in 2004 noted above in Embryo Storage Applications also allowed approved licensees to undertake pre-implantation genetic diagnosis (PGD) and pre-implantation genetic screening (PGS) of embryos. These procedures allow the testing of embryos at significant risk of a serious genetic abnormality or disease, with an aim to allow an embryo free of the adverse condition to be selected for implantation. Sex selection of embryos 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 application is supported by advice from the PGD Advisory Committee. Each application must be accompanied by a letter from a clinical geneticist. Factors that influence the approval process include the severity of the condition and the risk of a child inheriting the condition.

PGD/PGS services offered in Western Australia

There are currently four licensees offering embryo diagnostic services to patients in WA. Two licensees have approval to perform PGS on embryo biopsies at their respective laboratory facilities in WA. One of these licensees also has approval to undertake PGS analysis on behalf of another WA licensee. All other embryo biopsies, including those taken for PGD, are couriered to laboratories in Victoria or New South Wales for analysis.

One of the licensees offering in-house PGS services is currently seeking to offer Comparative Genomic Hybridisation (CGH) analysis of embryos biopsied for PGS. This is a more comprehensive analysis of chromosomes and chromosomal abnormality than is currently offered by Fluorescence In Situ Hybridisation (FISH) methodology. FISH usually looks at the 7-9 chromosome pairs in the human genome (out of the possible 23 pairs) most commonly associated with aneuploidy conditions. CGH allows testing of all chromosome pairs and therefore offers a more comprehensive detection of aneuploidy. However there is a requirement for caution in how this additional information is used to determine selection of embryos. As at 30 June 2010, Council was considering the clinic's draft patient information and consent forms for patients seeking PGS using CGH.

In WA, since the HRT Act was amended to allow diagnostic testing on embryos in 2004, Council has approved more than 80 applications to undertake PGD.

PGD applications received by Council in 2009-2010 are tabled in Appendix 3.

Practices under the Human Reproductive Technology Act 1991 requiring Council approval

Directions to the HRT Act set out additional practices for which licensees must seek Council approval. For the 2009-2010 year, licensees sought Council approval under Directions 6.6, 6.9, 8.2 and 8.8. Approvals granted in 2009-2010 are set out in Appendix 3.

Approval under Direction 6.6

Direction 6.6 Council may approve export of donated gametes, embryos or eggs undergoing fertilisation for use in an artificial fertilisation procedure: The Council may approve the export for use in an artificial fertilisation procedure of donated gametes, embryos or eggs undergoing fertilisation to an approved person who has given a written undertaking using Form 10 in Schedule 1, to provide the licensee with information that would be required for the registers, had the donated material been used within this State.

Approval under Direction 6.9

Direction 6.8 Maximum storage period of gametes: The licensee must ensure that gametes are not, without the approval of Council stored for longer than 15 years.

Direction 6.9 Council may approve extension of storage period for gametes: The Council may approve an extension of the storage period for gametes, on the application of the licensee or the gamete provider, if the stored gametes are to be used in treatment of the gamete provider or for research.

Approval under Direction 8.2

Direction 8.1 Limits to the recipient families using gametes of a donor: The licensee must ensure that for each donor of gametes there are no more than 5 recipient families known to the licensee, including families that may be outside Western Australia, unless the Council has given approval.

Direction 8.2 Council may approve a use that may result in more than 5 recipient families in exceptional circumstances: The Council may approve the use of a donated embryo or egg undergoing fertilisation created using donated gametes in an artificial fertilisation procedure that may result in more than 5 recipient families in exceptional circumstances.

Approval under Direction 8.8

Direction 8.7 Restrictions on the collection of eggs: Any person to whom the licence applies must not, without the approval of Council, allow collection of eggs where they are to be used in the development of embryos or eggs undergoing fertilisation for the treatment of a participant who has, at that time, the right to make decisions about 3 or more stored embryos of the same biological parentage.

Direction 8.8 Council may approve collection of eggs despite direction 8.7 in exceptional circumstances: In exceptional circumstances, Council may approve the collection of eggs from a participant who has three or more embryos or eggs undergoing fertilisation in storage.

Protocols, Patient Information and Consent Forms

Part 4: "Information" in the Directions under the HRT Act outlines the necessary information that licensees and exempt practitioners must provide patients, in order that their consent to undertake ART procedures is considered "effective" under the HRT Act. The requirement under Direction 2.20 for licensees to notify Council of any changes to these forms acts as an

additional means of monitoring the quality and consistency of patient information and consent forms.

The Council recognises the importance of providing clear and accurate information to patients seeking ART services. Through the licensing process undertaken in 2008-2009, all clinic licensee consent forms and patient information sheets were examined by the Executive and Deputy Executive Officers as well as some members of Council to assess compliance with the HRT Act and to provide feedback on the 'readability' of these documents for patients. Council continued to assess newly developed consent forms and patient information sheets throughout 2009-2010.

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. A primary function of Council, also set out in the HRT Act is to advise the CEO and Minister for Health on matters relating to ART.

In this capacity, Council activity as an advisory body was directed in particular at the legislation permitting surrogacy in WA. While much Council input around this issue was in the period leading up to the passage of the *Surrogacy Act 2008*, Council has continued to liaise with the Reproductive Technology Unit on a range of issues. In 2009-2010 this included the development of additional information regarding applications to Council for a surrogacy arrangement. This information was distributed in November 2009 and made available for download on the Council website.

Another matter generating significant public interest has been the posthumous collection and use of gametes. At the request of the Minister for Health, Council has deliberated on this matter and committed to recommending amendment of the HRT Act to allow the conditional use of gametes posthumously. In 2009-2010 Council provided further advice to the DoH on this matter taking into account the attitudes of the wider community, review of these practices nationally and internationally, in addition to noting the legislative changes in other Australian jurisdictions.

The Scientific Advisory Committee met in May 2010 to review the data fields collected for the RT Register. These changes would be influenced by possible future amendments to the HRT Act and the Directions to the Act. The timing of data collection was also discussed, noting that the administrative burden on clinics was exacerbated by multiple data collection requests within the same year.

Future activity

Other areas identified as warranting future Council attention include:

- Ongoing support and information for professionals and information regarding surrogacy legislation in WA.
- Possible amendments to the HRT Act including posthumous use of gametes and provisions for embryo research.
- Awareness of the Voluntary Register, including a 'Time to tell campaign' encouraging 'openness' in the area of donor conception.
- Sperm donor shortages.
- Infertility associated with delay in starting a family.

Council participation at relevant meetings and conferences

FSA Conference 2009

Council provided funding for a number of members of Council to attend the 2009 Fertility Society of Australia (FSA) Conference held on 26-28 October 2009 in Perth, WA. Council funding was made available to all members of Council and members of Council Committees, to attend the FSA Conference. Convened by Professor Roger Hart, the FSA Conference provided a valuable opportunity for members to gain insight into a wide range of ART-related issues. Topics canvassed scientific, medical and psychosocial perspectives of ART. The Perth location of the Conference also offered DoH staff including the Executive Officer, Deputy Executive Officers and Ms Deb Andrews from Legal and Legislative Services to attend most of the Conference.

Ms O'Callaghan also attended the Australian and New Zealand Infertility Counsellors Association (ANZICA) meeting on Saturday 24 October, organised in large part by Counselling Committee member Ms Iolanda Rodino. Ms Stephanie Bolton and Dr Nyaree Jacobsen attended the Merck Serono Symposium 'Frontiers in Fertility Treatment' held in Perth, prior to the FSA Conference on 25 October 2009.

Other

Dr Nyaree Jacobsen attended the European Society of Human Reproduction and Embryology (ESHRE) Conference held in Italy, in June 2010. Council funding of registration fees allowed Dr Jacobsen to participate in this highly regarded international meeting.

Council policy development

Policy development during the 2009-2010 year included:

- Finalisation of the Embryo Storage Policy, 'Policy on Embryo Storage and Applications to Extend Storage Beyond Ten Years'. This policy was completed and distributed in February 2010, and is available for download on the Council website.

- Development of Voluntary Register Guidelines. While the Voluntary Register is managed by the Department of Health, Counselling Committee members provided input into these guidelines. In particular consideration was given to the psycho-social factors for registrants accessing information about, and potential contact with, other matched parties on the Voluntary Register.

- Policy regarding legislative amendments to allow posthumous collection and use of gametes in prescribed circumstances was developed. Other possible amendments under consideration include the creation of saviour siblings and expansion of embryo research provisions.

OPERATIONS OF THE COUNSELLING COMMITTEE 2009 – 2010

Key Focus Areas

The Counselling Committee met on five occasions during the 2009-2010 year. During the course of the year the Counselling Committee has convened to:

- Provide guidance to Council and Department of Health staff regarding the psychological assessment of surrogacy arrangements. The Counselling Committee made recommendations to Council about the minimum requirements for all parties seeking to participate in a surrogacy arrangement.

- Educate and provide training to Approved Counsellors around issues of the Voluntary Register. This year has seen an ongoing internal audit of the Voluntary Register. The result of this audit has been 11 new matches between registrants. The Counselling Committee has formulated paths of connections between these matches. It is anticipated that the registrants involved in the matches will soon commence counselling with a selected Approved Counsellor (the Chair of the Counselling Committee). Following an assessment of the key issues revealed by the matching process, an education forum for counselling in Voluntary Register matches will be held for all local Approved Counsellors.

- Provide guidance to Council about low sperm donor numbers and to consider the number of donor families that may be created using one donor. Additionally the Counselling Committee provided Council with internal advice as to what constitutes 'exceptional circumstances' for waiving Directions 8.1 and 8.2.

- Provide Council with advice on psychosocial matters in ART, including implications of the five-family limit for donor reproductive material, and the posthumous use of gametes.

Approved Counsellor's Applications

Council received three applications in 2009-2010 for counsellors to be approved to provide fertility counselling as Approved Counsellors under the HRT Act.

One applicant was approved by Council to be recognised as an Approved Counsellor. Council requested further information from one applicant, who ultimately decided to not proceed with her application. The final applicant was approved by Council with a condition of a set period of supervision prior to the applicant being recognised as an Approved Counsellor. As of June 2010 there were 12 Approved Counsellors able to provide specialist counselling services to participants in infertility treatment. Five counsellors have additional training enabling them to undertake work with children regarding "telling issues" about their biological heritage. A list of Approved Counsellors is included in Appendix 2.

REPRODUCTIVE TECHNOLOGY REGISTERS

The Reproductive Technology Register

The Reproductive Technology Register (RT Register) was established in 1993 to record a wide range of data relating to the practice of ART in WA. Licensees and exempt practitioners are required to provide information concerning the treatment of ART patients. The information required is set out in Schedule 2 Part 2 of the Directions under the HRT Act (included in Appendix 4).

The RT Register allows ongoing monitoring of ART practices, provides a significant data resource for epidemiological research in ART in WA and also ensures that information relating to the identity and outcomes of ART treatment cycles are recorded in a central and secure location. This is of particular importance when ART treatments have involved the use of donated reproductive material, as the RT Register provides a record of identifying information relating to donation and birth outcomes that have resulted from those donations (though it should be noted that licensees must also indefinitely retain the original records). In 2004, amendments to the HRT Act set out that all donated reproductive material, including gametes and embryos, must only be accepted when the donor consents to allow identifying information about the donor to be given to any child (reaching 16 years of age) conceived from the donation.

The RT Register is managed through the DoH PAQ. In 2007, concern arose regarding the legality of researchers external to the DoH accessing data on the RT Register. Given the recognised public health benefit that may be gained through epidemiological evaluation of this data, this matter has been flagged by Council. Legislative amendments have been recommended to facilitate researcher access to non-identifying data from the RT Register with linkages to other data sets whilst upholding confidentiality requirements.

The Scientific Advisory Committee met to discuss the possible changes to the data fields collected by the RT Register to capture emerging technologies.

Current Research Projects accessing RT Register data

"Significant adverse health outcomes in children born from assisted conception treatment". Council approval received on 14 November 2001.

"Hospital morbidity outcomes in women following treatment through Assisted Reproductive Technology (ART) in Western Australia". Recommenced in 2008.

"Economic implications of ART infants and spontaneously conceived infants: inpatient costs in the first five years of life" Council approval received on 27 November 2009.

Voluntary Register

Since 2004, amendments to the HRT Act specify that donor material cannot be accepted by a clinic unless a donor consents to identifying information being provided to any child conceived from that donation (when that child reaches 16 years of age). This amendment was made in recognition of the need to know their genetic parentage often experienced by children conceived from donor material.

The Voluntary Register provides a service for parties involved in donor conception in the State who wish to access their donor and/or recipient information. This includes children born from donor material donated *before* 2004: for these children, there is no legislated authority to access information about their donor. Donors who are seeking information about any child born as a result of their donations and parents of donor offspring seeking information about any other children that have been born from the same donated reproductive material (who are biological half-siblings to their children) may also register. Relevant non-identifying information can be passed on to an applicant, and identifying donor information can be passed on to a donor conceived child conceived *before* the 2004 HRT Act amendments who has reached over 18 years of age, when *written consent* from the donor is provided.

For donations given after 1993, Voluntary Register information will be derived from the DoH RT Register. Donations provided before the establishment of the RT Register in 1993 are derived from clinic and practitioner records. In some cases record keeping has been inaccurate or non-existent, so it is not possible to guarantee the availability of information for Voluntary Register registrants with regard to pre-1993 donor procedures. The Voluntary Register does not provide an 'outreach service', so donor parties that have not registered are not contacted on behalf of registrants.

Joining the Register is voluntary, and interested parties contacting the VR Registrar will be forwarded a registration form for completion and return to the DoH for inclusion on the Voluntary Register. A website, http://www.voluntaryregister.health.wa.gov.au has been developed to provide information regarding this process.

Voluntary Register applications for 2009-2010

4 parent-requests for application forms.
5 completed applications returned from parents

6 donor offspring-requests for application forms
4 completed applications received from donor offspring

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

The Voluntary Register has recorded 141 registrations since the inception of the data-base in November 2002. To date the registrants include 74 parents of donor-conceived offspring, 53 donors and 14 donor-conceived adults.

This year an internal audit of the Voluntary Register Database was undertaken by the staff of the RTU. Fertility clinics were contacted and asked to provide missing information (predominately donor codes) from registration forms for the current registrants. The subsequent donor codes have then been matched to other registrants on the Voluntary Register. This internal audit has resulted in 11 new matches amongst registrants. These matches include five donor to parent of donor-conceived offspring matches, five parent to parent matches and one donor offspring to donor offspring match. To date, these matches have not commenced the required counselling with an approved counsellor, but it is anticipated this will be commenced within the next six months. Counselling is considered highly desirable so that all parties have a common understanding of what the exchange of information will entail. Registrants on the Voluntary Register continue to receive updated non-identifying information as requested.

A public awareness campaign has been proposed to increase awareness of the service offered by the Voluntary Register.

SIGNIFICANT DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY DURING 2009-2010

Surrogacy Act 2008

The Report of the Select Committee on the *Human Reproductive Technology Act 1991* made the recommendation that legislation on surrogacy be developed, following a review of the legislation regulating ART in WA in 1999.

The *Surrogacy Act 2008* sets out eligibility requirements for parties seeking a surrogacy arrangement and prescribes the preparation and assessment process for all parties to an arrangement. The parties to the arrangement are defined as each of the arranged parents, the birth mother and her husband or de facto partner (if any) and any donor whose egg or sperm is to be used for the conception of their child or who is their spouse or de facto partner.

For a couple to be eligible to commission a surrogacy arrangement, the couple or the woman must be eligible for IVF under the HRT Act. Hence, women who are infertile or unable to carry a child for medical reasons, but not infertile due to age, may seek to undertake a surrogacy arrangement. Medical and psychological assessments are required for all parties. Independent legal advice about the effect of the surrogacy arrangement must be sought, and implications counselling must also be undertaken by all parties for an arrangement to be approved. Both traditional and gestational surrogacy is permitted under this legislation, although the provision for parentage orders made following the birth of a child through a surrogacy arrangement may vary depending on the genetic input from the birth mother and arranged (surrogate) parents. An arrangement must not be a commercial arrangement between the parties.

The Surrogacy Regulations outline the requirements that must be met before an application can be submitted for Council approval. The strict requirement for all parties to seek counselling and legal advice, plus the medical and psychological assessment process set out by the legislation, aims to protect the parties involved with a surrogacy arrangement and in particular to safeguard the rights and best interests of any child created.

r. 5 Application for approval of surrogacy arrangement

(1) An application to the Council for the approval of a surrogacy arrangement is to be in a form approved by the Council.

(2) The application is to be accompanied by-

(a) evidence of the age and obstetric history of the birth mother; and

(b) evidence of the age of each arranged parent; and

(c) a copy of the signed surrogacy arrangement; and

(d) a copy of the certificate referred to in regulation 4(3); and

(e) a copy of a clinical psychologist's report referred to in section 17(c)(ii) of the Act for each of the parties stating the name of the clinical psychologist who undertook the assessment and the day on which the assessment was completed; and

(f) a written note from each legal practitioner who has provided legal advice about the effect of the surrogacy arrangement to a party stating –

(i) the name of the practitioner providing the advice; and

(ii) the name of the person to whom the advice was provided; and

(iii) the day on which the advice was provided; and
(iv) whether the advice was independent legal advice within the meaning given in section 14 of the Act;
and

(g) a copy of a medical practitioner's report referred to in section 17(d) of the Act for each of the parties stating-
(i) the name of the medical practitioner who undertook the assessment; and
(ii) the day on which the assessment was completed; and
(iii) details of any concerns the medical practitioner has about the effect that involvement of the person in the surrogacy arrangement may have on any known condition of the person; and
(iv) details of any medical condition of the person that may pose a risk to a child born as a result of the surrogacy arrangement; and
(v) in the case of the arranged parents, whether the eligibility criteria set out in section (19)(1)(b) of the Act have been met.

Council approval of a surrogacy arrangement is necessary before a fertility clinic can provide an artificial fertilisation procedure to a couple, and is also a prerequisite for the Family Court to make a parentage order for any child born from an arrangement. An exception to this was available where a child had been born from a surrogacy arrangement *prior* to the proclamation of the Surrogacy Act. In this circumstance, arranged parents could apply for a parentage order within 12 months of the proclamation date, although this period has since elapsed. The Family Court approved three parentage orders in the 12 month period under this provision.

Implementation of surrogacy services in WA

In order to continue to educate practitioners about the legislation and to facilitate the implementation of surrogacy services in WA, the Department of Health presented on the 'Role of the Reproductive Technology Unit and Surrogacy in WA' to the Fertility Nurses Association in May 2010. This presentation aimed to increase awareness and understanding of the legislation and processes underpinning surrogacy applications in WA.

Three fertility clinics in WA currently provide surrogacy services. Development of clinic protocols and documentation and identification of professionals willing to provide advice and assessments for surrogacy has progressed during 2009-2010. For the small number of couples in WA affected by this legislation, the opportunity to undertake a surrogacy arrangement and to achieve legal parentage of a child through surrogacy is very welcome. At 30 June 2010, Council was yet to formally consider an application to undertake a surrogacy arrangement. It is anticipated that the first applications will be considered during the 2010-2011 financial year.

Recent Legislative Developments within Australian Jurisdictions

Introduction

Although there have been no legislative developments in the field of ART in WA in the previous 12 months, a number of other States have made significant enactments. The developments outlined in the table overleaf continue a trend towards more prescriptive legislation rather than relying on NHMRC guidelines. The developments also reflect a shift towards more child-centred legislation. For example, ART legislation in South Australia will include a provision that the welfare of any child born through ART is of paramount importance and is the fundamental principle of the Act. The child focus is also apparent from the increased regulation of ART donor registers and the disclosure of information to gamete donors, donor offspring and the parents of donor offspring. The final trend that is evident from the developments is a greater acceptance of surrogacy arrangements and posthumous reproduction. These matters are discussed in further detail below.

The table below identifies 11 legislative developments that have commenced in the previous 12 months in New South Wales, Queensland, South Australia, Victoria and at the Commonwealth level. The developments cover a wide range of issues, including:

- surrogacy;
- donor registers;
- record keeping;
- registration of ART providers;
- counselling;
- presumptions of parentage;
- posthumous use of gametes; and
- consent.

The table is a summary of the most significant legislative developments in the past 12 months within Australia.

RECENT LEGISLATIVE DEVELOPMENTS			
	ACTS/REGULATIONS/BILLS	**COMMENCED**	**BRIEF SUMMARY**
NSW	Assisted Reproductive Technology Act 2007 No.69	01/01/2010	Regulates the registration of ART providers; requires ART services to be undertaken or supervised by a registered medical practitioner; requires ART providers to make counselling available; requires written consent for storage, use and export of gametes and embryos; limits use of donated gametes to 5 women; establishes a Central ART Donor Register; prohibits commercial surrogacy; permits posthumous use of gametes in certain circumstances.
	Health Legislation Amendment Act 2010 No.52	Assent: 28/6/10	Requires certain information to be provided to the Director-General for the purpose of the Central ART Donor Register.
	Assisted Reproductive Technology Regulation 2009 No.323	01/01/2010	Makes provision with respect to the following: registration of ART providers, infection control standards, qualifications needed for ART counsellors, provision of information between clinics about donated gametes or embryos created from donated gametes, records of gamete donors and donor offspring, matters to be entered in the Central ART Donor Register, disclosure of information to gamete donors and donor offspring, consent to creation of an embryo.
QLD	Surrogacy Act 2010 No.2	01/06/2010	Decriminalises altruistic surrogacy by repealing the Surrogate Parenthood Act 1988; provides a legal process for the transfer of parentage of a child born from a surrogacy arrangement between the birth mother and the arranged parents; provides that the female de facto partner of a birth mother who has undergone ART with her partner's consent is presumed to be a parent of the child.
SA	Family Relationships (Parentage) Amendment Bill 2010	LC 2nd Reading: 23/06/2010	Provides presumptions of parentage arising from ART procedures.
	Assisted Reproductive Treatment Regulations 2010 No.166	01/09/2010	Clarifies that nothing in the *Assisted Reproductive Treatment Act 1988* (SA) requires a registered person to provide ART to another person; provides additional requirements for registration and RTAC licences; provides that ART may be provided in circumstances where a woman or man is suffering from an illness or other medical conditions that may result in him or her becoming infertile in the future, or where the treatment for the illness may have that effect.
	Reproductive Technology (Clinical Practices)(Miscellaneous) Amendment Act 2009 No.43	01/09/2010	Renames the Principal Act the '*Assisted Reproductive Treatment Act 1988* (SA)'; Provides that the welfare of any child born through ART is the paramount principle of the *Assisted Reproductive Treatment Act 1988* (SA); provides for the registration of ART providers; provides for the establishment of a Donor Conception Register; provides for record keeping; introduces provisions concerning the posthumous use of semen.
	Statutes Amendment (Surrogacy) Act 2009 No.64	26/11/2010	Provides for the registration of surrogacy orders for a child born from a surrogacy arrangement; provides that a party to a surrogacy agreement or a surrogate child (where s/he reaches 18 years) is entitled to a certificate certifying all relevant entries; defines 'recognised surrogacy agreement'.
VIC	Assisted Reproductive Treatment Act 2008 No.76	01/01/2010	Repeals the *Infertility Act 1995* (Vic); introduces new guiding principles; establishes the Patient Review Panel and Victorian Assisted Reproductive Treatment Authority (VARTA); alters eligibility requirements; requires patients to undergo criminal and child protection checks; introduces provisions concerning surrogacy and posthumous reproduction; limits treatment with donated gametes to no more than 10 women; creates presumptions of parentage following ART; creates offences; regulates consent requirements, donation, storage, registers, registration of ART providers etc.
	Assisted Reproductive Treatment Regulations 2009 No.177	01/01/2010	Prescribes the information that is to be kept in various registers; provides that ART providers must record sex selected embryos used in ART; prescribes the form to consent to donate and to carrying out a treatment procedure; outlines the considerations to be taken into account in counselling prior to treatment, donation, surrogacy or posthumous reproduction.
COM	Health Insurance (General Medical Services Table) Amendment Regulations 2009	01/01/2010	Restructures Medicare items 13200 to 13251 (Assisted Reproductive Treatment) to reflect the latest developments and to better represent the costs of each stage of the treatment cycle.

Assisted Reproductive Treatment Act 2008 (Vic)

Although the *Assisted Reproductive Treatment Act 2008* (Vic) ('the ART Act') was passed more than two years ago, its substantive provisions only commenced at the beginning of this year. The ART Act repeals the *Infertility Treatment Act 1995* (Vic). New guiding principles include the right of children to access information about their genetic origins, and the right to access assisted reproductive treatment without discrimination on the basis of sexual orientation, marital status or religion. In light of this principle, the eligibility requirements have been altered to accommodate social infertility.

The child welfare focus of the ART Act is also evident from the requirement for participants to undergo a criminal record check and a child protection check. However, these requirements have been criticised by professional and consumer bodies such as the Fertility Society of Australia (FSA) and Access Australia. Access Australia has commented that people who require medical assistance to have children are no less capable of being good, loving and caring parents.[1] Similarly, FSA President Professor Peter Illingworth believes that the requirement to undergo a criminal check could stigmatise infertile couples and add to the emotional burden of infertility.[2] The Victorian Department of Human Services has defended the requirements by arguing that where public funds are used to support assisted reproduction, extra caution is required.

A new statutory body, the Patient Review Panel, is created by the ART Act. The Panel consists of five members and its decisions can be reviewed by the Victorian Civil and Administrative Tribunal (VCAT). The regulatory body has been renamed the Victorian Assisted Reproductive Treatment Authority (VARTA) and has been given new functions relating to public education and community consultation.

The ART Act makes a number of changes in relation to specific clinical issues. For example, the ban on sex selection has been qualified by allowing a person to apply to the Patient Review Panel for approval where sex selection is desired for social rather than medical reasons. Significantly, the Act introduces provisions concerning surrogacy and posthumous reproduction, which are discussed at length below. For the first time, the ART Act clarifies the lawfulness of self-insemination, and of insemination that is assisted by a friend, relative or partner. On the issue of informed consent, the consent of a gamete donor's spouse is no longer required.

The ART Act makes important consequential amendments to the *Status of Children Act 1974* (Vic), which creates presumptions of parentage arising from assisted reproduction. In particular, new parentage presumptions relating to surrogacy, posthumous reproduction and the use of ART by same sex female couples have been introduced.

Assisted Reproductive Technology Act 2007 (NSW)

The *Assisted Reproductive Technology Act 2007* (NSW) is a significant change for New South Wales, which had previously relied only on the NHMRC Ethical Guidelines for regulation of ART services. The Act was passed in 2007 but came into operation at the beginning of this year. The objects of the Act are to prevent the commercialisation of human reproduction and to protect the interests of donors, female participants and children born as a result of ART. The Act regulates the registration of ART providers and requires ART services to be undertaken or supervised by a registered medical practitioner. ART providers must ensure that counselling services are available, though participation is optional. Extensive provisions relating to informed consent have been introduced. Written consent of the gamete provider is required for the storage, use, posthumous use, export, research and supply of gametes or

[1] Mounting concerns about police check requirement in Victorian ART legislation. FSA Update. 2009-10 Summer; 71: 5

[2] McLean T. Crim checks for IVF couples 'abhorrent'. The Age. 2008 20 October. Available from: http://news.ninemsn.com.au/article.aspx?id=650323

embryos. Donated gametes must not be used if the treatment would likely result in offspring of the donor being born to more than five women. The Act establishes a Central ART Donor Register and requires ART providers to collect information relating to gamete donors. The Register enables an adult donor offspring who has reached 18 years of age to access information that identifies the donor. With regards to surrogacy, the Act introduces provisions that prohibit commercial surrogacy arrangements.

Surrogacy

One of the more significant developments was the commencement of the *Surrogacy Act 2010* (Qld) in June this year. The *Surrogacy Act 2010* (Qld) repeals the *Surrogate Parenthood Act 1988* (Qld), which had previously made altruistic surrogacy a criminal offence. The *Surrogacy Act 2010* (Qld) prohibits commercial surrogacy, but provides a legal mechanism for the transfer of parentage following altruistic surrogacy. Significantly, the *Surrogacy Act 2010* (Qld) allows the intended parents to apply for a parentage order where there is a medical *or* social need for the surrogacy arrangement. This is in contrast to the *Surrogacy Act 2008* (WA), where a medical need for surrogacy underpins eligibility for a surrogacy arrangement.

Important amending Acts are due to commence in South Australia in November 2010. The *Statutes Amendment (Surrogacy) Act 2009* (SA) will amend the *Family Relationships Act 1975* (SA) to make recognised surrogacy agreements lawful. Surrogacy agreements are only 'recognised' if they are made in accordance with the provisions of the *Family Relationships Act 1975* (SA). The commissioning parents must be legally married, or have lived continuously as de facto husband and wife for a period of three years preceding the surrogacy agreement. The *Family Relationships Act 1975* (SA) (as amended) will also require at least one of the commissioning parents to provide reproductive material with respect to creating an embryo for the purpose of the surrogate pregnancy, though this requirement can be waived upon presentation of a medical certificate. This is unlike the *Surrogacy Act 2008* (WA), which permits the arranged parents to use a donated embryo, or an embryo created solely from donated gametes. However, the counselling requirements in the *Surrogacy Act 2008* (WA) may prevent the use of anonymous donations.

The *Assisted Reproductive Treatment Regulations 2009* (Vic) were made under the *Assisted Reproductive Treatment Act 2008* (Vic), which incorporates provisions on surrogacy. Part 4 of the ART Act enables the Patient Review Panel to approve a surrogacy arrangement in particular circumstances. The Panel must be satisfied that the commissioning parent is unlikely to become pregnant, or unlikely to maintain a pregnancy or to have a live birth. The ART Act differs from the *Surrogacy Act 2008* (WA) in that the surrogate mother's oocyte must not be used in the conception of the child, though the Patient Review Panel has discretion to waive this restriction. The *Assisted Reproductive Treatment Regulations 2009* (Vic) prescribe various matters that must be discussed during counselling before a surrogacy arrangement is made. The *Assisted Reproductive Treatment Regulations 2009* (Vic) also prescribe costs incurred that may be reimbursed to the surrogate mother.

Donor Registers

The *Reproductive Technology (Clinical Practices) (Miscellaneous) Amendment Act* 2009 (SA) will commence in September 2010 and will amend the *Reproductive Technology (Clinical Practices) Act 1988* (SA) (soon to be renamed the *Assisted Reproductive Technology Act 1988* (SA)) to give the Minister an option of establishing a Donor Conception Register. The Register will contain information identifying donors, recipients and donor offspring. The Minister may require a person to provide this information, and failure to comply without reasonable excuse will attract a maximum penalty of $10,000.

Regulations that commenced in January 2010 in New South Wales prescribe matters that must be entered in a Central ART Donor Register and the information that can be disclosed from the Register to parties to a donation. Upon application by an adult donor offspring who has reached 18 years of age, the Director-General must disclose identifying information

relating to the donor and the sex and year of birth of each other offspring of the donor. Parents of donor offspring may apply for the disclosure of non-identifying information relating to the donor and other offspring of the donor. A donor may be informed of the sex and year of birth of each offspring born from their donation. Parties to a donation may consent to the disclosure of further information by giving written notice to the Director General.

The *Assisted Reproductive Treatment Act 2008* (Vic) permits an adult donor offspring who has attained the age of 18 to apply for the release of information that identifies the donor. The identifying information must be disclosed if the applicant was conceived using gametes that were donated after 1997. If the gametes were donated at an earlier time, identifying information can be disclosed only with the consent of the donor. Identifying information can be disclosed to a child donor offspring who was conceived using gametes donated after 1997 if the parent consents, and if a counsellor certifies that the child is sufficiently mature to understand the consequences of the disclosure.

Regulations made under the *Assisted Reproductive Treatment Act 2008* (Vic) have introduced a detailed schedule of information to be recorded in a register kept by ART providers. The registers must contain information relating to donors, disposal of gametes and embryos, patients and their partners, treatment procedures, collection and storage of gametes and embryos, consents, import and export of gametes and embryos and outcomes of treatment procedures. The regulations also specify the identifying information to be kept by the Registrar of the Central Register, which is managed by the Victorian Registry of Births, Deaths and Marriages (Department of Justice).

Posthumous Use of Gametes

Legislative developments in South Australia, Victoria and New South Wales support a trend towards the regulation of posthumous reproduction, with informed consent being a precondition or a key consideration. Legislative changes in this area address legal inconsistencies between the collection of gametes after death and the posthumous use of gametes or embryos in assisted reproduction. For example, in WA, Direction 8.9 under the *Human Reproductive Technology Act 1991* (WA) currently prohibits ART providers from knowingly using or authorising the use of gametes in an artificial fertilisation procedure after the death of the gamete provider. This is inconsistent with the *Human Tissue and Transplant Act 1982* (WA), which may allow the removal of gametes after death where the senior available next of kin consents and there is no reason to believe that the deceased objected to the removal. This has resulted in a number of applications to the Supreme Court of Western Australia for an order for the removal of gametes from a deceased person. Although gamete removal after death is possible in most Australian jurisdictions, persons who wish to use those gametes in an ART procedure may be required to seek export to a State that allows the posthumous use of gametes.

In September the *Reproductive Technology (Clinical Practices) (Miscellaneous) Amendment Act 2009* (SA) will amend the *Reproductive Technology (Clinical Practices) Act* 1988 (SA) to allow the provision of ART where a semen donor has died. The provision will apply where the donor's semen was collected before his death, or where an ovum was fertilised using the donor's semen or an embryo was created using the donor's semen before his death. The treatment can only be provided if the donor consented to the use of the semen, fertilised ovum or embryo after his death in the proposed treatment. Further, the treatment can only be provided for the benefit of a woman who was genuinely living with the deceased donor immediately before his death. The amendment does not permit the use of an ovum from a deceased woman by her female partner, or by her male partner in a surrogacy arrangement. The *Reproductive Technology (Clinical Practices) (Miscellaneous) Amendment Act 2009* (SA) also introduces provisions relating to the paternity of any child who is born following posthumous reproduction.

In Victoria, the *Assisted Reproductive Treatment Act 2008* (Vic) allows the posthumous use of gametes and embryos in a fertilisation procedure in certain circumstances. The treatment procedure must be carried out on the deceased person's partner, or in the case of a deceased woman, the woman's male partner commissioning a surrogacy arrangement. Further, the deceased person must have consented to the use of the gamete or embryo in the treatment procedure. Approval of the Patient Review Panel is required, as is counselling for the person who is to undergo the treatment. The recent *Assisted Reproductive Treatment Regulations 2009* (Vic) prescribe the matters that must be explored during counselling prior to the posthumous use of gametes or embryos.

The *Assisted Reproductive Technology Act 2007* (NSW) permits the posthumous use of gametes or embryos where the gamete provider has given written consent to posthumous use. The recipient must also consent to the posthumous use of the gametes. Interestingly, the *Assisted Reproductive Technology Act 2007* (NSW) does not require the recipient to have any particular relationship to the deceased. Whereas other State Acts limit posthumous reproduction to the spouse or partner of the deceased, the *Assisted Reproductive Technology Act 2007* (NSW) enables an unknown recipient to take advantage of the deceased person's consent to posthumous reproduction.

Conclusion

The past 12 months has seen the commencement of significant legislative developments in the field of ART. As the *Assisted Reproductive Treatment Act 2008* (Vic) and the *Assisted Reproductive Technology Act 2007* (NSW) have only been in force for eight months, it may be too early to comment on their operation. Other States have made important amendments to their existing legislation, particularly in relation to surrogacy and the posthumous use of gametes and embryos. Whilst these developments provide greater legal certainty to ART participants, the approaches taken by the States are far from consistent. This is demonstrated most clearly by the different eligibility criteria for surrogacy. With an increasingly mobile population, there is some call to streamline ART legislation. This is the sentiment expressed by the Standing Committee of Attorneys-General (SCAG), which is considering a set of draft model provisions for uniform surrogacy legislation. The action of all Australian jurisdictions other than WA and Northern Territory to enact consistent legislation on embryo research based on the Commonwealth's *Research involving Human Embryos Act 2002* and *Prohibition of Human Cloning for Reproduction Act 2002* exemplifies some precedence in this respect. However, the recent enactment of separate and to some extent divergent legislation in Victoria, NSW and QLD indicates that an individual jurisdictional approach to ART regulation will continue to operate for the foreseeable future.

Stem Cell Research and Therapy

Stem cells are undifferentiated cells with the characteristic of being able to develop into other, more specialised cell types such as skin cells, nerve cells, muscle, blood cells and so on. They are also capable of ongoing cell division or renewal: when a stem cell divides, depending on factors and the environment in which it exists, the resultant cells can become specialised cells or the new cells may continue to undergo cell division as stem cells.

However, not all stem cells are equal. Stem cells exist naturally in the body at all stages of development, from embryo to adult. In the laboratory, stem cells can be derived through a number of different procedures. Whether of natural origin or created in the laboratory, stems cells derived from different stages of development behave differently. Embryonic stem cells are distinguished from stems cells collected later in development which are referred to as adult, or somatic, stem cells.

Stem cells are also categorised by the range of cell types they can engender and their capacity for ongoing cell division:

- TOTIPOTENT CELLS: Stem cells that can produce all the cells necessary for the creation of a new organism are called totipotent cells. Totipotent cells are found very early after fertilisation, up to day 2 to 3 after fertilisation in humans, when the developing entity undergoes cell division but has not yet formed the fluid filled cavity known as the blastocoele.
- PLURIPOTENT STEM CELLS: Following blastocoele formation (after 4-7 days in humans) the cells of the developing embryo differentiate into two cell types: *trophoblastic cells* which will go onto develop into extra-embryonic membranes including the placenta, and the *inner cell mass* which will develop into the embryo proper. Cells removed from the inner cell mass are known as pluripotent stem cells. Pluripotent stem cells can produce all cell types other than those that develop into the placenta etc.
- MULTIPOTENT STEM CELLS: Stem cells capable of producing many, but not all cell types are known as multipotent stem cells. Multipotent stem cells can be found in the fetus, umbilical cord blood, juvenile and adult body.

Embryonic versus Adult Stem Cells

Embryonic Stem Cells

Excess Assisted Reproductive Technology Embryos

Embryonic stem cells can be derived from excess assisted reproductive technology (ART) embryos that have been created initially for the purpose of reproduction. To create an embryonic stem cell line, the inner cell mass from a five-to-six day old embryo is extracted, and the pluripotent stem cells of the inner cell mass are cultured in vitro. The extraction process, in general, causes destruction of the embryo.

Somatic cell nuclear transfer

Embryonic stem cells can also be derived from embryos created through other means such as somatic cell nuclear transfer (SCNT). Due to special environmental factors within an unfertilised egg, a new embryo can develop when genetic material (the nucleus) of an adult specialised cell (such as a skin cell), is inserted into an enucleated egg. Because the genetic makeup of the created embryo is the same as the original adult cell (and the 'adult' it was taken from), this is a form of cloning. In animals, such SCNT embryos have been cultured and then implanted into a recipient animal's uterus. Through this method 'cloned' animals have been born, as the offspring has the same genetic makeup as the adult. This is known as 'reproductive cloning'. While this has been considered a scientific breakthrough, significant health issues have been seen with SCNT created cloned animals. 'Reproductive cloning' in humans has been overwhelmingly rejected by the international scientific community.

'Therapeutic cloning' is where SCNT is performed to create an embryo that is then divested of its inner cell mass to culture the stem cells. Therapeutic cloning is predicted to be of significant potential benefit to individuals suffering from conditions such as Parkinson's and heart disease as stem cell transplantation is possible without risk of immune incompatibility. Stem cells from SCNT embryos have been developed in animal experiments. However, SCNT derived *human* stem cells have yet to be successfully cultured and this method still requires the use of a human egg.

Adult Stem Cells

Harvested adult stem cells
As with other mammals, in the human body stem cells exist in tissues and help maintain and repair tissues and organs. As above, these are usually 'multipotent' stem cells and capable of producing a number, but not all differentiated cell types. The number and capacity for specialisation also tends to decrease with aging of the body. Bone marrow and umbilical cord blood have been recognised as a source of adult stem cells and used therapeutically for some time. However, there are limitations with the use of adult stem cells, and the creation of stem cells with more embryonic, or pluripotent, properties is of great scientific interest. The capacity to develop such pluripotent cells from adult cells, first reported in 2006 was therefore considered a breakthrough in the field.[3]

Induced pluripotent stem cells
Induced pluripotent stem cells (iPS) looks at using an adult source of stem cells to achieve a *pluripotent* cell that can behave as an embryonic stem cell. This is achieved by reversing the specialisation or differentiation process of a cell- through manipulation including use of retroviruses inserted into the DNA. This can reprogram a cell, which after a number of divisions may create unspecialised stem cells capable of pluripotency. IPS is of great scientific interest as it may offer stem cell lines (and therapies) to be developed without the need for human donor eggs, or destruction of embryos. However, matters such as genetic stability over time, the potential for viral contamination (when retroviruses are used in the process) and detailed comparison to embryonic derived stem cells have yet to be comprehensively investigated.

Use and Application of Stem Cells

Therapies

As above, the use of bone marrow or peripheral blood transplants to treat conditions such as leukaemia and aplastic anaemia have been well established for many years, and are an example of stem cell therapy. However, these treatments require immune compatibility between the donor and recipient for success, and limitations posed by allogeneic (taken from another individual) transplantations has encouraged consideration of use of tissue or cells taken from the patient themselves.

The transplantation of stem cells from tissue harvested from the same individual requiring the treatment (an *autologous* transplant) has the potential to assist in the treatment of many different conditions including diabetes mellitus, Parkinson's disease, multiple sclerosis, spinal cord injuries, some causes of blindness, genetic mutations and some cancers. Not surprisingly, this has also attracted much attention and activity in the scientific and medical community.

Since the mid 1990's, autologous haemopoetic stem cell transplantation (HSCT) has been gaining acceptance internationally as a treatment for autoimmune diseases. A recently

[3] Australian Stem Cell Centre. Reprogramming and Induction of Pluripotency [Internet] [cited 2010 Sep 3]. Available from:
http://www.stemcellcentre.edu.au/Research/Collaborative_Streams/Stream_2.aspx

published study by the European Group for Blood and Marrow Transplantation (EBMT) Working Party on Autoimmune Diseases looked at survival rates of nine hundred patients with a range of autoimmune conditions treated with HSCT. This study indicated that "autologous HSCT is a valid therapeutic option for patients with an autoimmune disease that is progressing despite standard therapy".[4]

Trials comparing standard therapies with stem cell therapies continue to add to the understanding of the clinical use of stem cells, and improvements to therapeutic regimes such as techniques to remove contaminated immune cells or cancer cells from the stem cell grafts (known as purging) prior to reintroduction into the patient have also improved response to stem cell therapy. Another example of the intense medical interest in stem cell therapy is provided by the recent approval granted to an UK based stem cell company ReNeuron to undertake a clinic trial in the use of neural stem cells to treat moderately to severely affected stroke patients. This treatment will involve injection into the damaged areas of patient's brains. The initial trial will focus on side effects of the treatment, with preliminary assessment of efficacy.[5]

Such clinical trials will progress the body of evidence into the efficacy and safety of stem cell therapy, and extend the range of therapies considered for use. Nevertheless, for many conditions, stem cell therapies are still in the experimental, if no longer controversial, phase and in general regimes seem to be reserved for patients with advanced disease facing significant disability or mortality. The proliferation of international private clinics offering stem cell therapies that are not regulated or required to comply with quality standards also engenders safety concerns for patients desperately seeking to improve their quality of life. Without well conducted and reported clinical trials, claims of success in patient outcomes in such clinics will be treated with scepticism by the medical community, and adverse outcomes associated with poor standards of practice will only act to delay the wider acceptance of stem cell therapy.

Iatrogenic disease (caused by the action of a physician or a prescribed therapy) or adverse outcomes that have been attributed to stem cell therapy include:

- Development of tumours following stem cell therapy. For example one case where a boy with a genetic neurological condition (ataxia telangiectasia) was treated with fetal neural stem cells, and subsequently developed multiple brain tumours and a spinal tumour near the site of injection.[6] Experimentally this has been seen in animal models, with development of teratomas and teratocarcinomas.
- Infectious disease, including viral, bacterial and fungal agents, following immune suppression during for stem cell therapy.
- Reintroduction of cancer cells with stem cells after autologous transplant following chemotherapy

Furthermore in experimental models, identified risks include:

- Transmission of disease from animal sources used in culture of human stem cells.
- Integration of viral genetic material into stem cells following the use of viral vectors to induce pluripotency in adult stem cells.
- Misdirected growth- where specialisation into an undesired cell type is seen.

[4] Farge D, Labopin M, Tyndall A, Fassas A, Mancardi G, Van Laar J, et al. Autologous hematopoietic stem cell transplantation for autoimmune diseases: an observational study on 12 years' experience from the European Group for Blood and Marrow Transplantation Working Party on Autoimmune Diseases. Haematologica. 2010; 95(2): 284 – 292

[5] ReNeuron. ReN001 for Stroke [Internet] [cited 2010 Sep 3]. Available from: http://www.reneuron.com/

[6] Amariglio N, Hirshberg A, Scheithauer B, Cohen Y, Loewenthal R, Trakhtenbrot L, et al. Donor-Derived Brain Tumour Following Neural Stem Cell Transplantation in an Ataxia Telangiectasia Patient. PLos Med. 2009; 6(2): e1000029. doi:10.1371/journal.pmed.1000029

Research

Stem cell research can also offer valuable insight into a vast range of biological matters, including study of specific diseases, genetic mutation, cell behaviour in normal and abnormal cell growth, the factors that determine differentiation and how stem cell division can be controlled. Improvements in culture techniques including the removal of animal products from culture media also add to the body of knowledge and practical understanding of how to support and control stem cells. The use of stem cell lines in the testing of chemicals, including pharmaceutical products, is also considered to offer a potential means of reducing animal testing of such products.

While breakthroughs such as iPS and SCNT in recent years have allowed the creation of stem cell lines without the need for embryo destruction, embryonic stem cells are considered the 'gold standard' for stem cell research due to their truly pluripotent nature. Ongoing research in adult stem cells may eventually offer an alternative to embryonic stem cell research. However, in general, the international scientific community agrees that at this point in time it is important to pursue research using both embryonic and adult stem cells.

Ethical Concerns

Beyond the ethical arguments around the use of animals for scientific purposes which shall not be discussed here, there are ethical and scientific benefits and limitations for human stem cells derived from both adult and embryonic sources.

Ethical concerns about embryonic stem cells primarily follow concerns about the essential nature of a human embryo. The central question is: is the early-stage embryo truly human life? Some individuals and organisations consider that human life begins at conception or fertilisation of the egg and disagree with embryonic stem cell research as, in most cases, derivation of stem cells will lead to the destruction of the embryo. This concern has shaped embryonic stem cell research regulation in many countries. In Australia, the Australian Government (2005) Legislation Review: *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002*[7] (the Lockhart Review) which lead to the Commonwealth legislation that allowed the conditional use and creation of human embryos in research, considered the potential benefits to individuals and to scientific understanding provided by embryonic stem cell research to be great enough to justify the use of human embryos despite these ethical concerns.

<u>Other Ethical Considerations</u>
While the majority of embryos created through ART are used in the attempt to achieve a pregnancy, some embryos will not be used and will be held in storage. Most jurisdictions do not consider that indefinite storage of embryos is ethically or legally appropriate, and regulate embryo storage periods. For example, in WA at the end of an authorised storage period, embryos in storage must be allowed to succumb. Many couples with excess ART embryos that will not be used for their own reproduction wish to allow their embryos to benefit research, rather than allowing them to expire without further purpose.

While the destruction of embryos is central to the ethical debate around stem cell work, the potential to *create* life such as through SCNT is another issue raised from embryonic stem cell research. While the international scientific community has overwhelmingly rejected human cloning for reproductive purposes, reproductive cloning *has* been performed in a range of non-human animal species, and ethical concerns about cloning indicate why careful regulation and monitoring of activity in this area of science is needed.

[7] Australian Government (2005) Legislation Review: *Prohibition of Human Cloning Act 2002* and *the Research Involving Human Embryos Act 2002*, Reports, Canberra, December 2005.

Developments in the area of adult stem cell research may eventually offer an alternative to use of embryos for stem cell research. However, the scientific community in general agrees that at this point in time, it is important to pursue research using both embryonic and adult stem cells.

Regulation

Embryonic Stem Cell Research

Regulation of human embryo research in most Australian jurisdictions falls under the Commonwealth *Prohibition of Human Cloning for Reproduction Act 2002* and the *Research Involving Human Embryos Act 2002* (RIHE Act). These Commonwealth Acts were amended in 2006 following recommendations from the Lockhart Review, the legislative review commissioned to consider the broad implications of research using reproductive technologies. The Commonwealth legislation authorises the NHMRC Embryo Research Licensing Committee (NHMRC Licensing Committee) to approve licences to undertake certain research practices, and to monitor research involving human embryos in Australia.

All Australian jurisdictions other than WA and the Northern Territory have legislation consistent with the Commonwealth legislation. An undertaking by WA to achieve consistency in legislation relating to human embryo research saw the introduction of the Human Reproductive Technology Amendment Bill 2007 (HRTA Bill) to WA Parliament in March 2007. The HRTA Bill passed through the WA Legislative Assembly. However, on 6 May 2008 the Bill was defeated in the Legislative Council. As a result, in addition to limiting the scope for research in WA, this defeat means the system for licensing and monitoring embryo research in this State under the HRT Act is not operational. Support for the reintroduction of amendments to allow consistent legislation for embryo research jurisdictions and to provide the NHMRC Licensing Committee with authority to oversee embryo research has been shown by members of the scientific community in WA.

Practices allowed under the 2006 Commonwealth amendments expand on those allowed on excess ART embryos under NHMRC licence set out in the HRT Act. The following practices that may be approved by the NHMRC Licensing Committee under the Commonwealth Acts, and that are not currently allowed in WA under the HRT Act include:

- The creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;
- The 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;
- The 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.

While the legislation may allow embryos to be *created for research*, the Commonwealth Acts set out that no embryos created or used under such a licence would be allowed to mature beyond 14 days development (suspension periods notwithstanding) and that no embryo created by a means other than by fertilisation would be allowed to be used for reproduction. Under this legislation, a review of the current Commonwealth Acts is required following the third anniversary of the amended legislation, which was therefore set for late 2009.

At the end of the last reporting period by the NHMRC Licensing Committee (28 Feb 2010), nine licences were currently active. Of those, five were to seek to derive stem cells from embryos; two of these licences were to use excess ART embryos, and three of the five performing SCNT to create the embryos.[8]

[8] Embryo Research Licensing Committee. Report to the Parliament of Australia for the period 1 September 2009 to 28 February 2010 [Internet]. Australian Government National Health and Medical

Adult Stem Cell Research Unlike the primarily uniform approach to embryonic stem cell research in Australia provided by the RIHE and *Prohibition of Human Cloning for Reproduction Act 2002*, regulation of adult stem cell research is largely determined by varying state legislation including, where relevant, human tissue and transplant legislation. Where funding has been received from the NHMRC, compliance with the NHMRC National Statement on Ethical Conduct in Human Research (2007)[9] is required. This also applies to funding received from the Australian Research Council and the Australian Vice-Chancellor's Committee. Human research ethics committee approval will also be needed for the majority of research proposals. In the event that the outcome of research is a therapeutic product, the *Therapeutic Goods Act 1989* (Cth) will apply, though current regulation of biological tissue and cellular therapies is arguably inadequate and the Therapeutic Goods Administration is acting to update their regulatory framework to capture such emerging technologies.[10]

Conclusion

The characteristics of stem cells and their capacity to contribute significantly to scientific understanding of growth and development, in addition to future therapies have generated much interest from the international scientific and medical community. Hand in hand with stem cells' potential for ongoing renewal and differentiation are the ethical questions that are posed by such potential. While the development of technologies such as iPS may ultimately obviate the main concerns associated with the use of embryonic stem cells, the technology is arguably not yet at this point. Furthermore, concurrent research into stem cells derived from one source builds on knowledge gained from another, rather than the models being interchangeable. For this reason the scientific community in general agrees that at this point in time, it is important to pursue research using both embryonic and adult stem cells.

Legislation covering the clinical practice of ART in Australia differs between jurisdictions. However, the adoption of uniform legislation on embryo research by most jurisdictions in Australia reflects the complex scientific and ethical arguments that underpin the potential benefits to medical treatment and scientific understanding that stem cell research offers.

From a Western Australian perspective, members of the scientific community in WA have shown support for WA to join other States to enact consistent legislation. Amendments would clarify the NHMRC's authority in overseeing the embryo research licensing process and will allow WA scientists to participate in the potentially profound benefits that advances in this field may promise. It is hoped that the WA Parliament may have the opportunity to consider this issue again in the near future.

Research Council; 2010 June [cited 2010 Sep 3]. Available from: http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/hc136.pdf

[9] Australian Government (2007) National Statement on Ethical Conduct in Human Research, National Health and Medical Research Council and Australian Vice-Chancellors' Committee, Canberra, October 2007.

[10] Then S. Regulation of Human Stem Cell Research in Australia. Stem Cell Rev. 2009; 5(1): 1-5

PRESENTATIONS AND PUBLICATIONS BY COUNCIL MEMBERS AND STAFF 2009-2010

Professor Roger Hart

Presentations

Invited lecturer at international meetings
"Prenatal influences on female reproductive function" International Society of Gynaecological Endocrinology, Florence, Italy 2010

Invited lecturer at national meetings
"Fertility after Breast Cancer" Royal Australian College of Surgeons, Annual Meeting, Perth 2010

Invited lecturer at local meetings
"Polycystic Ovarian Syndrome for GPs" Health Educations seminars for GPs, Perth 2009

"Polycystic Ovarian Syndrome" WA Regional Scientific Meeting, Perth 2009

"PCOS" Diploma of Obstetrics and Gynaecology, Perth July 2010

Oral Presentations to international societies
Clarke JC, Showell MG, Hart RJ. Antioxidants for female subfertility the results of a Cochrane systematic review. European Society of Human Reproduction and Embryology Rome 2010

Poster Presentations to international societies
Hart R, Doherty, Mori T, Hickey M, Sloboda D, Norman R, Huang R-C, Beilin L. The prevalence of features of the metabolic syndrome in girls with menstrual disturbance and PCOS in adolescence. European Society of Human Reproduction and Embryology Rome 2010.

Showell MG, Brown J, Yazdani A, Stankiewicz M, Hart RJ Oral anti-oxidant use for male partners of couples undergoing fertility treatments. European Society of Human Reproduction and Embryology Rome 2010.

Oral Presentations to national societies
Majumder K, Burke C, Doherty D, Menninger I, Karthigasu K, McElhinney, B Garry R, Hart R. A long-term prospective observational study of the impact of radical laparoscopic excision of endometriosis on pain and quality of life parameters. Australian Gynaecological Endoscopy Society, Sydney 2010

Poster Presentations to national societies
Murphy R, Hadlow N, Junk S, Hart R, Waldrop R. Karyotype abnormalities in an infertile population. Fertility Society of Australia and New Zealand Annual Meeting, Perth 2009.

Murphy R, Hadlow N, Hart R, Waldrop R. Thrombophilia abnormalities in an infertile population. Fertility Society of Australia and New Zealand Annual Meeting, Perth 2009.

Murphy R, Hadlow N, Hart R, Waldrop R. Prevalence of thyroid abnormalities in women presenting to an infertility clinic. Fertility Society of Australia and New Zealand Annual Meeting, Perth 2009.

Publications

Hickey M, Sloboda DM, Atkinson, HC, Doherty DA, Franks S, Norman, RJ, Newnham, JP, Hart R. The relationship between maternal and umbilical cord androgens and Polycystic Ovarian Syndrome in adolescence: A prospective cohort study. JCEM 2009;94(10):3714-20.

Abou-Setta AM, D'Angelo A, Sallam HN, Hart RJ, Al-Inany HG. Post-embryo transfer interventions for in vitro fertilization and intracytoplasmic sperm injection patients. Cochrane Database of Systematic Reviews, Issue 2. Art. No.: CD006567. DOI: 10.1002/14651858.CD006567.

Hart R, Sloboda DM, Dorota A. Doherty DA, Norman RJ, Atkinson HC, Newnham JP, Dickinson JE, Hickey M. Prenatal determinants uterine volume and ovarian reserve in adolescence JCEM 2009;Dec; 94(12):4931-7.

Hunter T, Hart R. Endoscopic Surgery for Female Infertility - A Review of Current Management. ANZJOG 2009; 49: 588–593.

Whitehouse AJO, Maybery MT, Hart R, Sloboda DM, Stanley FJ, Newnham JP, Hickey M. Umbilical cord free testosterone levels predict infant head circumference in girls. Developmental Medicine & Child Neurology Mar;52(3):e73-7. 2010

Hart R, Doherty DA, J Norman RJ, Franks S, Dickinson JE , Hickey M, Sloboda DM. Serum Anti-Mullerian Hormone (AMH) levels are elevated in adolescent girls with polycystic ovaries and the Polycystic Ovarian Syndrome (PCOS). Fertility & Sterility (epub ahead of print Jan 6 2010).

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. Review In: *Cochrane Database of Systematic Reviews* 2010, Issue 3. Art. No.: CD006359. DOI: 10.1002/14651858.CD006359.pub2.

Hart R, Sloboda DM, Doherty DA, Norman RJ, Atkinson HC, Newnham JP, Dickinson JE, Hickey M. Circulating maternal testosterone concentrations at 18 weeks gestation predict circulating AMH in adolescence: a prospective cohort study. Fertility & Sterility epub ahead of print Feb 13.

Whitehouse AJO, Maybery MT, Hart R, Mattes E, Newnham JP, Sloboda DM, Stanley FJ, Hickey M. Fetal androgen exposure and pragmatic language ability of girls in middle childhood: Implications for the extreme male-brain theory of autism. Psychoneuroendocrinology (epub ahead of print March 3, 2010).

Hickey M, Hart R, Norman R. Maternal and umbilical cord androgen concentrations do not predict digit ratio (2D:4D) in adolescent females: a prospective cohort study. Psychoneuroendocrinology (in press 2010) epub ahead of print March 3.

Garry R, Hart R, Karthigasu KA, Burke C. Structural Changes in Endometrial Basal Glands During Menstruation. *In press* BJOG 2010, epub ahead of print Jun 18.

Hart R, Hickey M, Maouris P, Buckett W. Excisional surgery versus ablative surgery for ovarian endometriomata. *Cochrane Database of Systematic Reviews* 2010, Issue 7.

Tang H, Hunter T, Hu Y, Zhai S, Sheng X, Hart RJ. Cabergoline for preventing ovarian hyperstimulation syndrome. Cochrane protocol 907009090302205433 *In Press* 2010 Issue 7.

Raval AD, Hunter T, Stuckey B, Hart RJ. Statins for women with polycystic ovary syndrome not actively trying to conceive. Cochrane protocol 402909100100305434 *In Press* 2010 Issue 7.

Sloboda D, Hickey M, Hart R. Reproduction in females: the role of the early life environment. Human Reproduction Update (In Press).

Dr Joe Parkinson

Presentations

'Reproductive Technology in WA'. Mater Dei College secondary students, July 2009.

'Reproductive Technology in Western Australia: Ethical Considerations'. Catholic secondary school teachers professional accreditation, November 2009.

Dr Angela Cooney

Presentations

'Subfertility and Assisted Reproductive Technologies' FPWA General Practice Training Program, October 2009 and March 2010.

Reproductive Technology Unit

Presentations

'Role of the Reproductive Technology Unit and Surrogacy in WA'. Presentation to members of the Fertility Nurses Association, by Ms Jenny O'Callaghan and Dr Nyaree Jacobsen, May 2010.

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. Exempt Practitioners marked with an asterisk * have requested the revocation of their exemption from 2009-2010.

Exemption No	Practitioner Name	Suburb	Post Code
E027	Dr DP Day	Kelmscott	WA 6111
E050	Dr R Kirk	Northam	WA 6401
E024	Dr DN Lawrance	Kelmscott	WA 6991
E025	Dr HH Leslie	Albany	WA 6330
E016	Dr KA McCallum	Kalgoorlie	WA 6430
E003	Dr KT Meadows*	Murdoch	WA 6150
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 6005
E028	Dr RJ Watt	Mandurah	WA 6210

APPENDIX 2

LIST OF APPROVED COUNSELLORS AT 30 June 2010

Name	Professional Address	Telephone / Fax No
Ms Antonia Clissa	Concept Fertility Centre PO Box 966 SUBIACO WA 6008	Ph (08) 9382 2388
Ms Deborah Foster-Gaitskell*	Suite 6 Hollywood Specialist Medical Centre 95 Monash Ave, NEDLANDS WA 6009	Ph (08) 9271 3582 Ph 0430 006 497 Fax (08) 9386 9314
Ms Jane Irvine	661 C Newcastle St, LEEDERVILLE WA 6007	Ph 0418 913 900
Ms Cailin Jordan	Hollywood Fertility Centre Monash Ave, NEDLANDS WA 6009	Ph (08) 9389 4200
Ms Rosemary Keenan*	6 Laxton Way, Karrinyup Lakes Lifestyle Village GWELUP WA 6018	Ph (08) 9447 8365
Ms Mandi MacShane	Bassendean Chiropractic and Wellness Centre 103 Old Perth Road, BASSENDEAN WA 6054	Ph (08) 9379 3838 Ph 0408 479 453
Ms Suzanne Midford*	1) Perth Psychological Services Suite 6/401 Oxford St, MT HAWTHORN WA 6016 2) Perth Psychological Services Unit 2/36 Ormsby Terrace, MANDURAH WA 6210	Ph (08) 9443 3709 Fax (08) 9443 3718 suzanne.midford@perthpsychology.com.au
Ms Helen Mountain	Genetic Services of WA King Edward Memorial Hospital 374 Bagot Rd, SUBIACO WA 6008	Ph (08) 9340 1603 Fax (08) 9340 1725
Ms Marian Rawlins	Genetic Services of WA King Edward Memorial Hospital 374 Bagot Rd, SUBIACO WA 6008	Ph (08) 9340 1525 Fax (08) 9340 1678
Ms Iolanda Rodino*	1) Concept Fertility Centre PO Box 966 SUBIACO WA 6008 2) Private Practice North/South	Ph (08) 9382 2388 Ph (08) 9389 7212
Ms Margaret van Keppel*	1) 267 Walcott St, NORTH PERTH WA 6006 2) PIVET Medical Centre 166-168 Cambridge St, LEEDERVILLE WA 6007	Ph (08) 9443 3655 Fax (08) 9443 8665 Ph (08) 9422 5400
Dr Elizabeth Webb	1) Fertility North Suite 213, Joondalup Health Campus JOONDALUP WA 6027 2) Suite 201, Specialist Medical Centre Joondalup Health Campus JOONDALUP WA 6027	Ph (08) 9301 1075 Ph (08) 9400 9871

*Counsellors able to undertake "telling issues" counselling of children.

APPENDIX 3

OPERATIONS OF LICENSEES FOR THE FINANCIAL YEAR 2009-2010

The aggregated data, tabulation, graphical representation, analysis and interpretation of the data in this Appendix have been kindly provided by the Performance, Analysis and Quality Division of the Department of Health.

Background

Under the *Human Reproductive Technology Act 1991* (HRT Act) fertility clinics licensed under the HRT Act are required to submit annual reporting data at the end of each financial year. This summary was put together from information submitted from these licensees. Six clinics in WA have been issued Storage Licences and Practice Licences authorising artificial fertilisation procedures including in vitro fertilisation (IVF). The remaining (seventh) licensee has a Storage Licence and a Practice Licence limited to providing artificial insemination. Information required from this licensee on the provision of intra-uterine insemination has been included in this summary. Information about patients referred from the public fertility clinic at King Edward Memorial Hospital to the Concept Fertility Centre (Concept) has been provided by Concept.

All information was submitted in a collated form and referred to the financial year, ending at 30 June 2010. 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 licence.

Semen storage and donation

During the 2009-2010 financial year, semen donations from 106 men were stored with WA storage licensees. Of these, 21 were new donors. There has been a general decrease in new sperm donor numbers since 2004 when amendment to the legislation required that all new donors consent to release of their identifying information to any offspring conceived from their donation. The issue of overall low donor numbers compared to demand for donor insemination services has been identified by Council as a matter for further consideration.

The number of donors less than or equal to 30 years of age increased in the past financial year after a decrease in the previous year (Table 1, Figure 2). The majority of donors (81.1%) with donations in storage in 2009-2010 were over 30 years of age, and 39.6% were over 40. The general trend to older donors may be due to the social issues and potential implications associated with the 2004 amendments; younger men who do not yet have families of their own may be more hesitant to donate, knowing that their identifying details will be available to donor offspring at 16 years of age.

The marital status of the donor was unknown in 14% of cases. Figures show 52% of donors were single, 29% were married or in a de facto relationship and 5% of donors were divorced. These percentages have remained relatively consistent when compared with previous years.

TABLE 1: 2009-2010 SEMEN DONOR AGES

Age of Donor (years)	Number (%)
18-25	7 (6.6)
26-30	13 (12.3)
31-35	21 (19.8)
36-40	23 (21.7)
41-49	33 (31.1)
50 +	9 (8.5)
Total	**106 (100)**

FIGURE 1: SEMEN DONORS IN WA

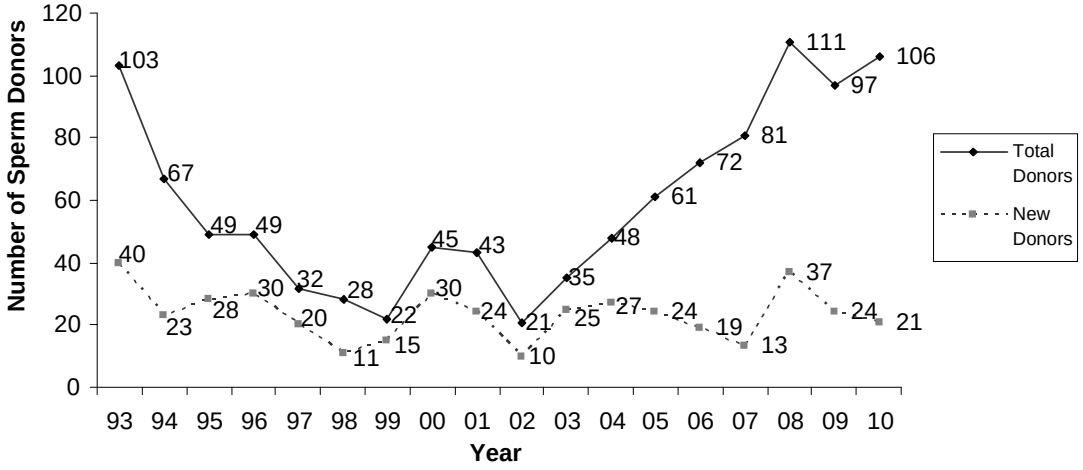
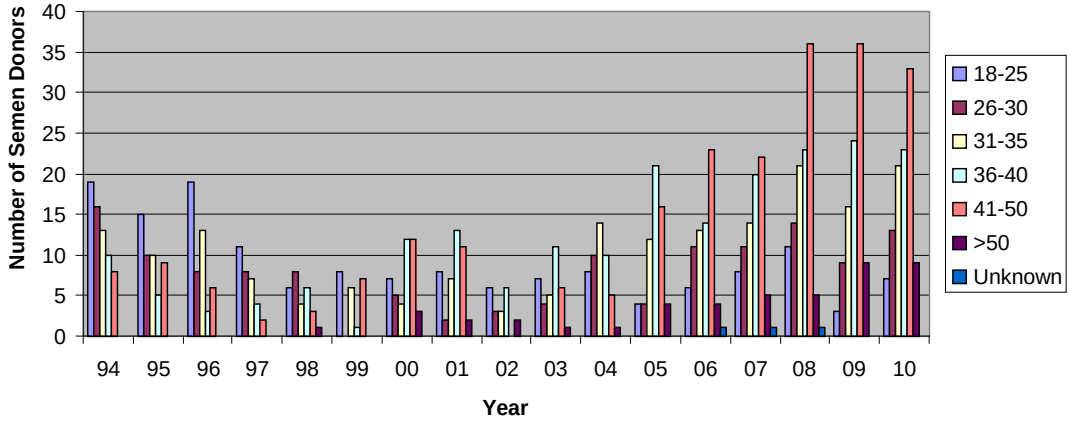


FIGURE 2: NUMBER OF SEMEN DONORS BY AGE



Embryo storage

The number of embryos in storage as at 30 June 2009 is reported as 17,988 in Table 2. This figure differs from that which was reported in Council's 2008-2009 Annual Report (17,334) due to a number of reporting discrepancies that have been adjusted over the past 12 months.

Table 2 shows that 17,901 embryos were in storage at the end of the 2009-2010 financial year. This represents a decrease of 0.5% on the previous year (as illustrated in Figure 3). This is the first time since 1993 that the number of embryos in storage has not risen over the year. The largest factor contributing to this year's decrease was the significantly higher number of embryos that were allowed to succumb in 2009-2010: during this year 1603 embryos were allowed to succumb, compared to 547 in 2008-2009. The number of embryos frozen after oocyte pickup decreased by 803 from the previous financial year. A total of 4763 embryos were stored following treatment and 3212 stored embryos were used in treatments during the year.

TABLE 2: DISPERSAL OF STORED EMBRYOS 2009-2010

	No of embryos
Embryos in storage 30/06/09	**17988**
Embryos created from IVF	4763
Transferred into WA clinics from interstate	41
Transferred in from clinics in WA	149
Transferred out to clinics in WA	149
Transferred to clinics outside WA (Patients moving interstate/overseas)	76
Used in frozen embryo transfer treatments	3212
Allowed to succumb with consent of couples	1603
Embryos in storage 30/06/10	**17901**

FIGURE 3: TRENDS IN EMBRYO STORAGE

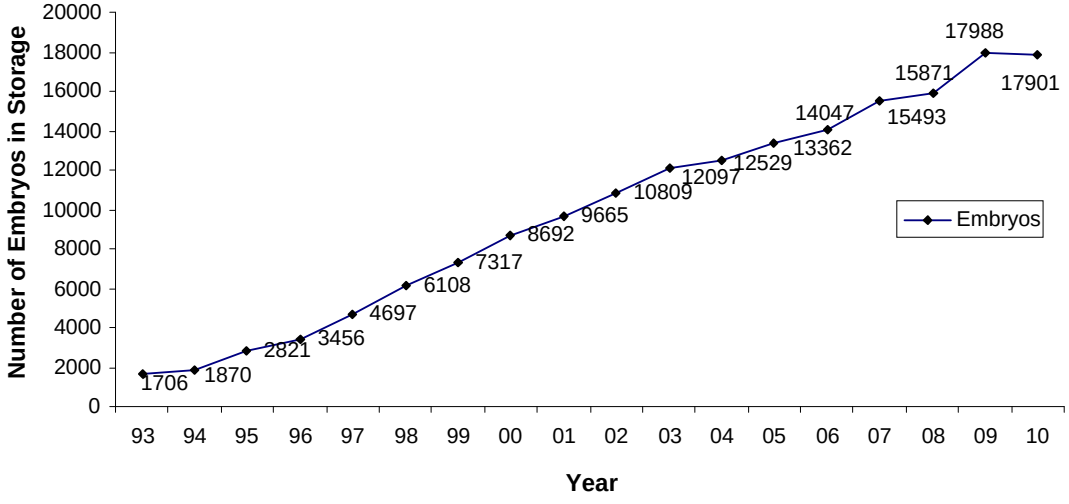
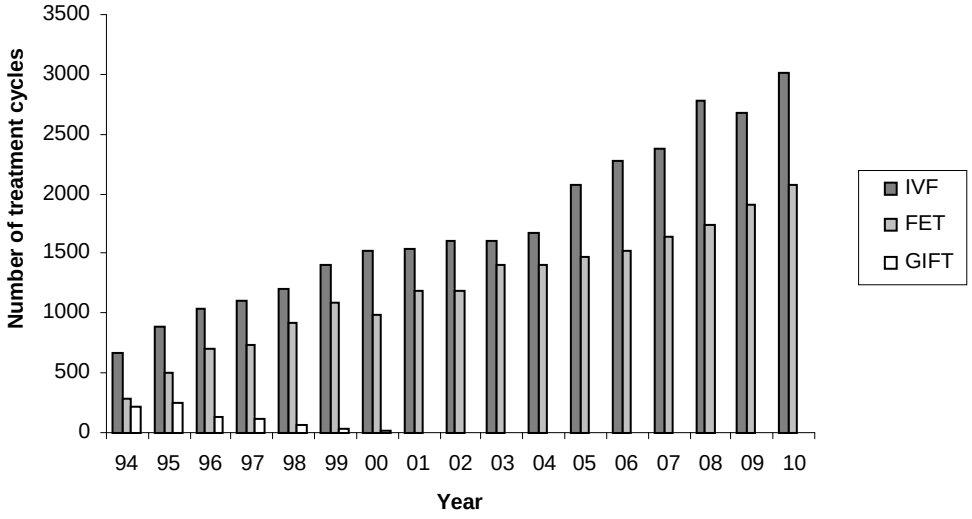


TABLE 3: 2009-2010 IVF TREATMENTS

	IVF (fresh)	FET (frozen)	TOTAL
Women treated	2044	1045	3089
Cycles begun	3012	2078	5090
Cycles with egg retrieval	2639	-	2639
Cycles with gamete or embryo transfer	2043	1867	3910
Cycles with embryos storage	1001	-	1001
Number of cycles using donor:			
Semen	142	93	235
Eggs	49	60	109
Embryos	7	25	32
Total	198	178	376
Number of cycles from which eggs or embryos were donated:			
Eggs donated	22	-	22
Embryos donated	0	-	0
Breakdown of treatment cycle details			
Cycles with IVF/GIFT same cycle	0	-	0
Cycles with surgical sperm aspiration	199	-	199
Cycles with ICSI*	1895	-	1895
Cycle with Fallopian embryo/egg transfer	0	0	0

* ICSI is Intra Cytoplasmic Sperm Injection, a form of microinjection. No GIFT cycles were performed during 2009-2010.

FIGURE 4: ART TREATMENT TRENDS



In Vitro Fertilisation and Frozen Embryo Transfer treatments

Table 3 shows that during the 2009-2010 financial year, 2044 women began oocyte retrieval cycles for IVF and 1045 began frozen embryo transfer (FET). There were 229 more women commencing oocyte retrieval this year than in 2008-2009 (an increase of 12.6%) and the number of cycles for IVF and FET also grew by 10.8% (5090 compared to 4595 in 2008-2009). As with many health services, trends in the usage of ART services behave in some ways as 'luxury' items, and it is possible that the levelling out of cycle numbers which occurred in 2008-2009 had resulted from a more constrained economic environment. As illustrated in Table 3, of all cycles begun, 3012 (59.2%) were for IVF and 2078 (40.8%) were for FET. Figures 4, 5 and 6 illustrate the increase in both IVF and FET cycles performed compared to the last financial year.

Of the 3012 cycles begun for fresh IVF with ovarian stimulation, 87.6% were successful in proceeding to oocyte retrieval and 67.8% proceeded to transfer of fresh embryos (Figure 5). These figures show an increase in the rate of oocyte retrieval by 1.7% from the last financial year, and an increase of 4.6% in the transfer rate from 2008-2009. Of the 2078 frozen embryo transfer cycles begun, 1867 (89.8%) proceeded to transfer.

Overall, donated human reproductive material was involved in 7.5% of all IVF cycles with oocyte retrieval during the year, showing a 0.8% increase from last year. Donor semen was used in 5.4% of cycles (142 cycles); donor eggs were used in 1.9% of cycles (49 cycles) and donor embryos were used in 0.2% of cycles (seven cycles) with fresh embryos donated.

A higher proportion of frozen embryo transfer cycles (9.5%) involved the use of donated gametes or embryos. Donor embryos were used in 1.3% of all FET cycles with transfer (25 cycles); donor eggs in 3.2% (60 cycles) and donor semen in 5% (93 cycles).

FIGURE 5: IVF (FRESH) TREATMENTS

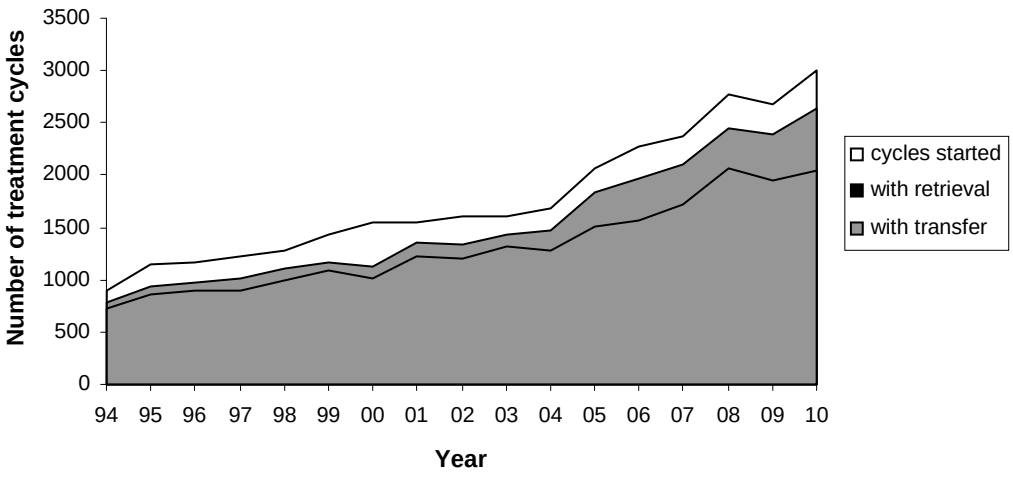
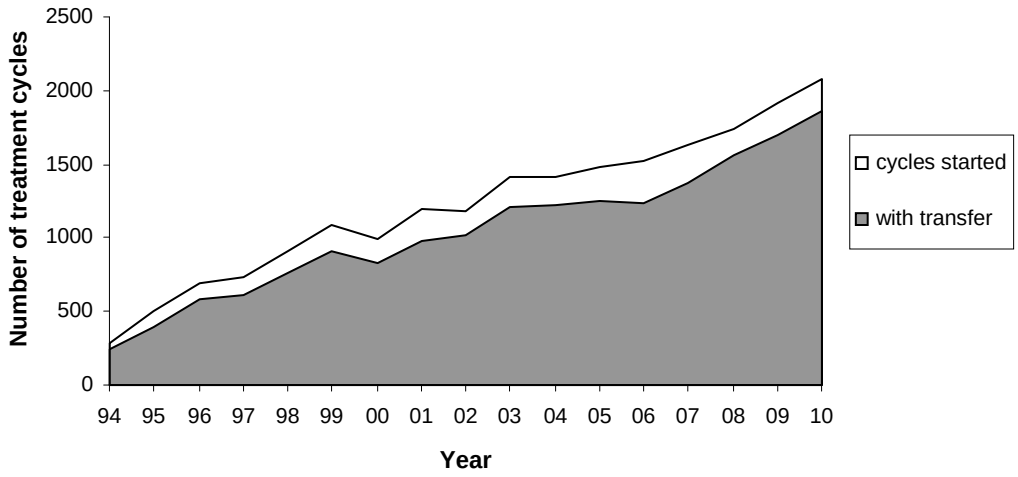
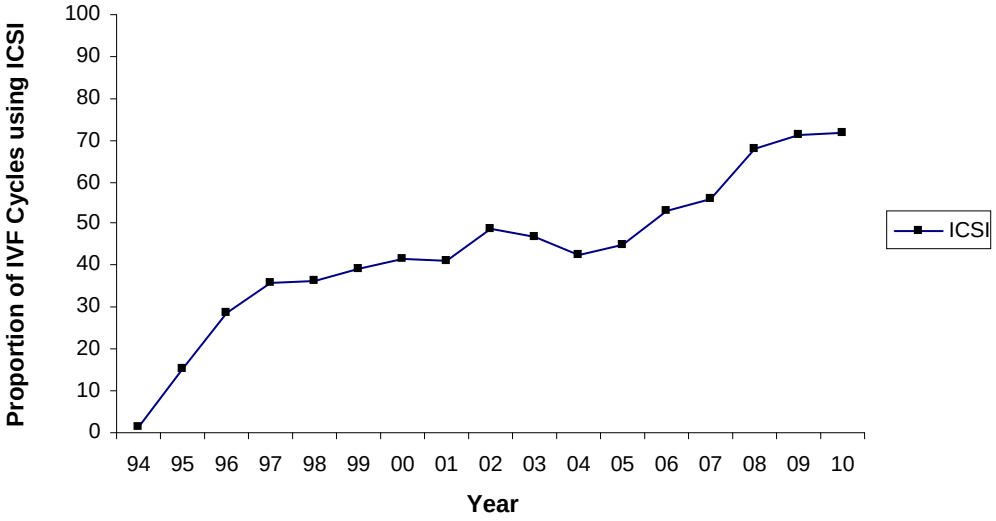


FIGURE 6: FET TREATMENTS



Of the 2639 IVF treatment cycles with successful oocyte retrieval, 1895 (71.8%) involved intra-cytoplasmic sperm injection (ICSI). As illustrated in Figure 7, the use of ICSI has marginally increased since the last financial year, continuing the general upward trend since this technique was taken up by WA clinics in 1994. ICSI, which involves injection of one sperm directly into an egg, has become a routine practice in cases of male fertility problems and poor fertilisation. Sperm retrieved from the epididymis or testis was used in 199 of the ICSI treatment cycles.

FIGURE 7: IVF CYCLES USING ICSI



Treatment of patients referred from the Public Fertility Clinic

During the year 110 patients from the King Edward Memorial Hospital (KEMH) Infertility Clinic were referred to Concept Fertility Centre for fertility treatment. As can be seen from Table 4, 72 women were treated with fresh IVF transfer and 38 with FET. The results for this year indicate an increase in the number of public patients treated from 2008-2009. During the year 142 fresh IVF and 114 FET treatment cycles were commenced for these patients, with more IVF cycles and FET

cycles performed than previous years. This year 83 of the IVF cycles involved micro-manipulation (ICSI). Of the 256 cycles started for public patients, only five cycles reported using donated gametes (All five cycles using donor semen, none using donor oocytes), and no cycles used donor embryos. In addition, there were 32 IVF cycles and four FET cycles reported as using assisted hatching. Blastocyst culture was used in 32 IVF cycles and 38 FET cycles.

There were 69 artificial insemination procedures performed for public patients in the 2009-2010 year. Of these, five treatments used donor sperm and the remaining 64 treatments used the woman's partner's sperm. This is an increase from the 66 artificial insemination procedures performed in the previous year, of which 57 used the partner's sperm.

TABLE 4: IVF AND RELATED TREATMENT OF PUBLIC PATIENTS

	Number of Patients						Number of Treatment Cycles					
	04/05	05/06	06/07	07/08	08/09	09/10	04/05	05/06	06/07	07/08	08/09	09/10
IVF	77	81	82	75	59	72	111	130	143	134	100	142
GIFT	0	0	0	0	0	0	0	0	0	0	0	0
FET	30	24	25	25	28	38	115	97	91	67	74	114
TOTAL	**107**	**105**	**107**	**100**	**87**	**110**	**226**	**227**	**234**	**201**	**174**	**256**

Intra-uterine insemination (IUI)

Both licensees and exempt practitioners are authorised to carry out IUI procedures. A total of 1478 IUI cycles were reported by seven licensees, which was a 14.2% decrease on the 1722 performed in 2008-2009. The overall ongoing clinical pregnancy rate per treatment cycle carried out was 5.7% (84 ongoing pregnancies). Of these pregnancies, 82 were singleton (97.6%), 2 were twin (2.4%), with no triplet or quadruplet births. These figures show that a greater proportion of IUI procedures resulted in singleton pregnancies than in previous years; the proportion of singleton births has increased steadily over the past 15 years. It should be noted that these pregnancy outcome figures may not be complete given the nature of reporting this information within a 12 month period.

The information provided showed that 80.6% of the IUI procedures performed involved use of the partner's sperm and 19.4% used donor sperm. Natural cycles (no ovulation induction) accounted for 43.2%, while 44.5% of cycles involved the use of gonadotrophin, and clomid was used in 12.3% of the cycles. These figures are largely consistent when compared to last year. Gonadotrophin (follicle-stimulating hormone) is used in assisted reproduction as this use is associated with an increased live birth rate when compared to 'no treatment' for women experiencing infertility problems.

The two reported sets of twins followed gonadotrophin stimulation, and both were conceived from the partner's sperm.

Three exempt practitioners carried out IUI in 2009-2010.

Serious morbidity and mortality in women undergoing treatment

Overall the six clinics licensed to provide IVF reported a total of seven cases of severe ovarian hyperstimulation syndrome (OHSS) relating to 3012 IVF stimulation cycles (0.23% of stimulation cycles, with a clinic range of 0.0 – 0.6%). Women presenting with severe OHSS symptoms were diagnosed on ultrasound, showing on average 15.7 follicles measuring over 12mm.

Patients also presented with other conditions, including small bowel obstruction and ovarian haematoma; three patients were hospitalised. There were no reports of mortality in association with fertility treatment during the year.

Counselling (2009-2010)

Licensees reported providing 2090 counselling sessions during 2009-2010, compared to 2316 sessions in the previous year. This figure represents almost a 10% decrease for this financial year. This follows three years of significant increases in counselling numbers (23.2%, 39.2% and 22.8% respectively).

Of those receiving counselling, most (77.5%) participants only received a single session. The majority (83.3%) of these participants sought information counselling, while 15.7% of participants accessed support counselling. Therapeutic counselling only made up 1.0% of sessions provided to patients.

The different types of counselling are defined in Schedule 3 of the HRT Act Directions. Information counselling involves counselling for issues associated with treatment and decision making. Support counselling is the provision of emotional support during times of particular stress, and therapeutic counselling aims to help people to cope with the consequences of infertility and treatment, and resolve any associated problems.

From the remaining 22.5% of participants who accessed more than one session of counselling, 51.7% were support counselling sessions, with 36.6% being information counselling sessions. This shows a significant difference to last year's figures where most counselling sessions were for information (55.5%) and 38.3% were for support. The proportion of participants attending counselling for personal matters not related to infertility was just under 1%, and 2.3% of sessions were cited as being for a personal crisis.

Counselling concerning issues of donation for donors or recipients made up more than 38% of all counselling. This represents a 8% increase on counselling sessions recorded in the previous year, in line with an increase in the number of cycles involving donation seen for 2009-2010. Counselling prior to known donation is mandatory under the HRT Act, and donor and recipient counselling is a requirement for RTAC accreditation. All clinics reported that the majority of the counselling took place on site at the clinic.

Active research projects with Council approval

R019 Phase III, Multicentre open label randomised trial to assess the efficacy and convenience of orgalutron. Completed. Council awaiting study results
PIVET Medical Centre
Approved 08/08/00

R024 Research into optimal method of oocyte cryopreservation
PIVET Medical Centre
Approved (Out of session) October 2006

R025 Research into optimal method of oocyte cryopreservation
PIVET Medical Centre
Approved 17/06/09

Innovative clinical/laboratory practices at 1 July 2010

Innovative practice number	Procedure approved	Licensee and date approved
I 009	Assisted hatching	Concept Fertility Centre Approved 06/02/2001
I 016	In vitro maturation	Concept Fertility Centre Approved 13/12/2005
I 017	Oocyte cryopreservation	Concept Fertility Centre 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 025	Vitrification of oocytes	Hollywood Fertility Centre Approved 09/12/08
I 026	Vitrification of oocytes	Fertility North Approved 20/05/09

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 during the 2009-2010 financial year are listed below. In many cases, approval is subject to a positive feasibility study of the proposed PGD procedure.

PGD Number	Condition tested	Licensee and approval date
PGD 001/2009-03	Type 1 Neurofibromatosis	Concept Fertility Centre Approved 15/07/2009
PGD 001/2009-04	Cystic Fibrosis	Concept Fertility Centre Approved 15/07/2009
PGD 025/2009-06	Translocation between chromosomes 1 and 5	Hollywood Fertility Centre Approved 1/09/2009
PGD 027/2009-02	Aneuploidy	Fertility Specialists of WA Approved 2/10/2009
PGD 027/2009-03	Translocation between chromosomes 13 and 14	Fertility Specialists of WA Approved 3/11/2009
PGD 001/2009-05	Sex-selection for Haemophilia A	Concept Fertility Centre Approved 3/11/2009
PGD 025/2009-07	Robertsonian Translocation between chromosomes 13 and 14	Hollywood Fertility Centre Approved 3/11/2009
PGD 025/2009-08	Balanced translocation between chromosomes 11 and 20	Hollywood Fertility Centre Approved 3/11/2009
PGD 025/2009-09	Dominant Neurofibromatosis Type 2	Hollywood Fertility Centre Approved 3/11/2009
PGD 025/2009-10	Saethre Chotzen Syndrome	Hollywood Fertility Centre Approved 3/11/2009
PGD 025/2009-11	Oligoasthenoteratozoospermia	Hollywood Fertility Centre Approved 3/11/2009
PGD 001/2009-06	Batten Disease	Concept Fertility Centre Approved 3/11/2009
PGD 001/2009-07	Cystic Fibrosis	Concept Fertility Centre Approved 19/01/2010

PGD 025/2010-01	Alagille Syndrome	Hollywood Fertility Centre Approved 16/03/2010
PGD 001/2010-01	Translocation	Concept Fertility Centre Approved 16/03/2010
PGD 003/2010-01	Translocation between chromosomes 7 and 10	PIVET Medical Centre Approved 20/04/2010
PGD 027/2010-01	Laing Distal Myopathy	Fertility Specialists of WA Approved 16/06/2010
PGD 025/2010-02	Jansen's Metaphyseal Chrondrodysplasia	Hollywood Fertility Centre Approved 16/06/2010

Applications under Directions in 2009-2010

Direction 6.6

To export donor gametes, embryos or eggs undergoing fertilisation for use in an artificial fertilisation procedure.	Hollywood Fertility Centre	Approved 16/02/10

Direction 6.9

Waive 6.8 to extend the storage period for gametes.	KEOGH Institute for Medical Research	Approved 09/12/09
	KEOGH Institute for Medical Research	Approved 19/01/09
	KEOGH Institute for Medical Research	Approved 16/03/10
	KEOGH Institute for Medical Research	Approved 20/04/10

Direction 8.2

Waive 8.1 to allow use of donor gametes that may result in more than 5 recipient families in exceptional circumstances.	PIVET Medical Centre	Approved 23/09/09
	Fertility North	Approved 03/09/09

Direction 8.8

Waive 8.7 to allow further oocyte collection where more than 3 or more embryos are in storage under 8.8.	Concept Fertility Centre	Approved 03/09/09
	Concept Fertility Centre	Approved 09/12/09
	Fertility Specialists of WA	Approved 09/12/09
	Fertility Specialists of WA	Approved 16/06/10

APPENDIX 4

REPORT FROM THE REPRODUCTIVE TECHNOLOGY REGISTER

Registers of assisted reproductive technology treatments were established under the 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 have been collected since 8 April 1993. During the 2009-2010 year, the Performance, Analysis and Quality (PAQ) Division collaborated with the Reproductive Technology Unit to provide IT support to update the Register and improve the security and efficiency of the data reporting, importing and management process. Areas for improvement have been identified and include reviewing the relevance of the data fields requested from clinics. Assisted reproduction treatments and technology have progressed and changed significantly over the past ten years, and policy changes must also be taken into account (such as the possibility of treatment cycles associated with surrogacy arrangements) when determining the data fields of relevance today.

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 (i.e. **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 WA 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 (e.g. 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	Char-8

		fertilisation code must be unique to the fertilisation not just the patient. Required when a fertilisation is attempted or for transfer of embryos (e.g. FET or embryo move), otherwise leave blank.	
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 e.g. 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 export, otherwise it may be left blank.	Char-8
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 (i.e. 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, i.e. 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 delivery, answer yes.	Char-1
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

Reproductive Technology Council

RE: WAITING LISTS FOR DONOR SPERM

Dear Licensee

I have been asked to request information from all of the clinics regarding the length of time that clients seeking to use donor sperm are required to wait before sperm becomes available for their use. I understand because donation can be directed in Western Australia, that some men may choose not to allow sperm they are donating to be used by people in certain groups, thus it is important that this information about waiting times be broken down in the following categories:

- Heterosexual couples
- Lesbian couples
- Single women

Of course some recipients may also not avail themselves of the sperm that is offered to them and may choose to wait. For these clients please include the average time taken before they accept sperm offered.

This information will assist the Council understand the pressure on clinics that lead to requests for the importation of donor sperm from other states or countries where there are different requirements in terms of number of donor families that may be created, and information available for inclusion on the Reproductive Technology Register held by the Department of Health.

Kind regards

Jenny O'Callaghan

Executive Officer Reproductive Technology Council
28 July 2009

Reproductive Technology Council

RE: SEEKING FEEDBACK FOR EMBRYO STORAGE POLICY

Dear Licensee

As you may be aware, the Reproductive Technology Council (Council) has for some time been in the process of developing an embryo storage policy. This is for the purpose of guiding Council decision-making regarding embryo storage extensions, and to set out Council, licensee and participant responsibilities under the *Human Reproductive Technology Act 1991*.

Council's Embryo Storage Committee has developed this draft document (enclosed), and seeks feedback from licensees on the policy, including consideration of how implementation of the Draft Policy will fit with current licensee processes.
The Embryo Storage Committee aims to submit the document for tabling at the next Council meeting, on the 3 November 2009.

For this reason, could you please distribute the Draft Policy, for feedback, to any members of staff involved in the process of embryo storage, and send any comments by way of email to Nyaree.Jacobsen@health.wa.gov.au . Alternatively comments can be made directly on the hard copy and sent back to the below postal address by **Monday 26 October 2009**. Your contribution to the development of the final policy will be much appreciated.

In addition, Council would like to thank you for the feedback received regarding **waiting lists for donor sperm at Hollywood Fertility Centre.** In light of the information provided from all WA licensees, the issue of the five family limit per donor has been referred once more to the Reproductive Technology Council Counselling Committee for further debate and consideration. Council will notify you regarding the outcome of this process.

For any further queries, please do not hesitate to contact me, Nyaree Jacobsen on 9489 2819 or Jenny O'Callaghan on 9489 2818.

Yours sincerely

Dr Nyaree Jacobsen
Deputy Executive Officer
Reproductive Technology Council 5 October 2009

Reproductive Technology Council

Dear Licensee

Re: Transfer of PGD approval between fertility clinics.

The Reproductive Technology Council (Council) has recently considered two cases where patients with approval to undertake pre-implantation genetic diagnosis (PGD) at a Western Australian licensed fertility clinic have opted to transfer to another WA licensed fertility clinic and seek to undertake PGD at this second clinic.

Council, on the recommendation of the PGD Advisory Committee, has determined that where Council approval for PGD has already been given for a couple, this PGD approval may be transferred to the second (receiving) clinic without a repeat PGD application, where the same diagnostic test is to be performed and where the receiving clinic has general approval to undertake PGD. It will be the receiving clinic's responsibility to seek a copy of the PGD approval from the transferring clinic.

As PGD applications are deidentified, the RTU will be unable to provide a copy of the original approval for the receiving clinic. However, in order that the Reproductive Technology Unit (RTU) may maintain accurate records, it is requested that the receiving clinic notify Council Executive Officer, Ms Jenny O'Callaghan, that a transfer of PGD approval has occurred. A new PGD approval number will then be assigned for the receiving clinic's records.

While Council agrees that transfer can occur without reapplying to Council for approval to undertake PGD, please note Council's recommendation that where a significant period of time has passed since a couple undertook genetic counselling for their particular condition, the couple may benefit from a further genetic counselling session before undertaking a repeat IVF cycle for PGD.

Re: Additional egg collection for patients seeking pre-implantation genetic diagnosis or screening of embryos.

Council recognises that where a woman undergoes egg collection for the purpose of embryo creation for PGD or pre-implantation genetic screening (PGS), a sub-optimal number of eggs (or, after fertilisation, suitable embryos) may make PGD/PGS less feasible in terms of both the likelihood of being able to select an unaffected embryo for transfer and the anticipated cost to patients of PGD analysis.

In this event, clinics may wish to discuss with their patients the option of seeking Council approval to undertake a second egg collection in order to create additional embryos for analysis.

Direction 8.8 from the *Human Reproductive Technology Act 1991* states:

> **8.7 Restrictions on collection of eggs**
> Any person to whom the licence applies must not, without the approval of the Council, allow collection of eggs where they are to be used in the development of embryos or eggs undergoing fertilisation for the treatment of a participant who has, at that time, the right to make decisions about 3 or more stored embryos of the same biological parentage. However, if there are only one or 2 embryos of the same biological parentage in storage for that participant, a further egg collection may be carried out.

8.8 Council may approve collection of eggs despite direction 8.7 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 exceptional circumstances.

While seeking further egg collection (where 3 or more embryos or eggs undergoing fertilisation will be in storage) requires Council approval, further egg collection for PGD or PGS has been regarded by Council as an *exceptional circumstance* under which approval may be granted.

In the case that Council approval to waive direction 8.7 is sought when an ultrasound prior to egg collection reveals a sub-optimal number of eggs are likely to be collected, please provide information about the anticipated number of embryos that will result from the cycle. Any other relevant information such as the mode of inheritance of the condition to be avoided would also be useful to assist Council to determine that the circumstances for the request can be considered as 'exceptional'.

As this will be a matter requiring a prompt response by Council, such a request may be emailed to Executive Officer Ms Jenny O'Callaghan on Jenny.O'Callaghan@health.wa.gov.au .

If you have any further enquiries regarding these matters, please feel free to contact Ms O'Callaghan on 9489 2818 or Deputy Executive Officer, Dr Nyaree Jacobsen on 9489 2819.

Yours sincerely

CA Michael AO
Chair Reproductive Technology Council 12 November 2009

Reproductive Technology Council

RE: POLICY ON EMBRYO STORAGE AND APPLICATIONS TO EXTEND STORAGE BEYOND TEN YEARS

Dear Licensee

Please find enclosed a copy of the Reproductive Technology Council (Council) Policy on Embryo Storage and Applications to Extend Storage beyond Ten Years (Embryo Storage Policy). This policy was developed by the Council's Embryo Storage Committee to provide guidance to Council on decision-making for embryo storage extensions, and to set out Council, licensee and participant responsibilities under the *Human Reproductive Technology Act 1991* (HRT Act).

As you will be aware, during the time of developing this policy Council held an interim policy position where many embryo storage applications were granted a one year extension. However, following the ratification of the Embryo Storage Policy, closer adherence to requirements for embryo storage extensions approved under section 24 (1a) of the HRT Act will be sought from licensees and patients applying for an extension.

- The HRT sets out that Council may approve an embryo storage extension beyond ten years if it considers that *there are special reasons for doing so in a particular case*. To comply with this requirement, participants (with clinic assistance) are advised to provide adequate information and, where necessary, supporting documentation to substantiate these special reasons.

- Due to the administrative difficulties posed by applications with short or impending expiry dates, compliance with direction 6.12 (a) which sets out that "applications must be received by the Council at least one month before the Council meeting that precedes the expiry of the storage period" will also be more stringently applied. Failure to submit embryo storage applications in the required time period may result in Council being unable to consider applications. It is advised that the date one month before the next Council meeting is clearly set out in any notice sent to participants. To assist this matter, please find attached a list of Council meeting dates for 2010. This will also be available on the Reproductive Technology Council website on www.rtc.org.au

- In recent months Council has been very concerned by the number of applications where the authorised storage period has already expired. Where storage beyond ten years is sought, Council can only consider an application before the expiry of the authorised storage period. Once the authorised storage period expires, Council cannot consider an application. Licensees, participants and Council can then be in a difficult situation where the only option is to allow the embryos to succumb, or if a case exists, for participants to seek a court order to allow for the continued storage of the embryos. This situation potentially has serious implications for all parties.

  To avoid such a scenario, Council strongly recommends that where patients have elected to stored their embryos for ten years, a reminder after nine years of storage is sent to participants. Furthermore, the use of registered mail is recommended to help verify that the participants have received the reminder. Any indication that the participant has not received the reminder should be actively followed up, so to establish the contact details of the participants before the mandatory notification three months prior to expiry of the authorised storage period.

  The HRT Act requires that reasonable steps are taken to notify participants of the impending expiry and for the licensee to assist participants to apply for an extension, where this is their

intention. When no contact has been made despite reasonable steps (as set out in the HRT Act) being taken then the embryos must be allowed to succumb.

To assist licensees, Council has included example reminder letters in the Embryo Storage Policy (Appendix 5). A brochure 'Embryo storage' has also been developed to aid participant understanding of the requirements of the HRT Act on this matter. Copies of the brochure will be available for your use.

Additional recommendations and requirements covering matters on embryo storage are set out in the Embryo Storage Policy. Please ensure that all staff members with responsibility for managing embryo storage matters in your clinic are familiar with the requirements of the HRT Act and with Council's Embryo Storage Policy. Should you have any further queries or if you choose to use the reminder letters and would like a pdf of the letter formatted for your clinic, please do not hesitate to contact Council. Council Executive Officer, Ms Jenny O'Callaghan (telephone: 9489 2818) or Deputy Executive Officer Dr Nyaree Jacobsen (telephone: 9489 2819) are able to provide assistance with these matters.

Yours sincerely

CA Michael AO
Chair Reproductive Technology Council 3 March 2010

APPENDIX 6

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

The general functions of the Reproductive Technology Council are covered in section 14 of *the Human Reproductive Technology Act 1991*, which in effect set its Terms of Reference.

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:

S. 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 in the HRT Act -

11. Annual report on reproductive technology

(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.]

APPENDIX 7

POLICY ON EMBRYO STORAGE AND APPLICATIONS TO EXTEND STORAGE BEYOND TEN YEARS

AND

EMBRYO STORAGE BROCHURE

POLICY ON EMBRYO STORAGE AND APPLICATIONS TO EXTEND STORAGE BEYOND TEN YEARS.

REPRODUCTIVE TECHNOLOGY COUNCIL

Based on recommendations from the Embryo Storage Committee.

February 2010

CONTENTS

GLOSSARY

ART- assisted reproductive technology/ies

Authorised storage period - see Directions under the HRT Act: Interpretation
'Authorised storage period' in respect of embryos or eggs undergoing fertilisation means the shorter of-

a) any period of time specified in the consent to store the embryo or egg;
b) a period of 10 years or such longer period as approved by the Council under section 24(1a) of the Act.

Council - Reproductive Technology Council of Western Australia

Directions - Directions given by the CEO of Health (Director General) under the HRT Act

Effective Consent - see section 22 of the HRT Act:
Section 22(8) For the purposes of this Act a consent to the use or keeping of any human gametes, a human egg undergoing fertilisation or a human embryo shall not be taken to be effective unless-

a) it is given in writing;
b) any condition to which it is subject is met;
c) it has not been withdrawn;
d) those gametes are, or that egg or embryo is, kept and used in accordance with the consent.

Embryo storage extension - an extension to an authorised storage period

FSA- Fertility Society of Australia

HRT Act- *Human Reproductive Technology Act 1991*

Initial storage period – a period of up to 10 years from the first day of storage of a human embryo or egg in the process of fertilisation, as authorised under section 24(1) of the HRT Act

IVF- in vitro fertilisation procedure as defined in section 3 of the HRT Act

NHMRC- National Health and Medical Research Council

NHMRC Ethical Guidelines - Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, June 2007

RTAC- Reproductive Technology Accreditation Committee

Stored - see section 3 of the HRT Act
In relation to human gametes, a human egg undergoing fertilisation or a human embryo a reference in this Act-

a) to keeping, includes storing, whether by cryo-preservation or in any other way, in such a state as temporarily arrests or suspends metabolic function; and
b) to any human gametes which are or a human egg or embryo which is, **"stored"** means kept in such a state,
and **"store"** and **"storage"** shall be construed accordingly

INTRODUCTION

The process of in vitro fertilisation (IVF) involves the creation of embryos for the purpose of assisting eligible people to conceive a child or children. In Western Australia, regulation of the practice of IVF and other assisted reproductive technologies (ART) is provided by the *Human Reproductive Technology Act 1991* (the HRT Act) and Directions under the HRT Act (Directions). In addition to this, both the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia, and the National Health and Medical Research Council (NHMRC) have set out guidelines that underpin the provision of ART services in Australia.

Under the HRT Act, it is a condition of holding a licence to provide ART services that service providers be accredited by RTAC. In order to gain and retain accreditation, service providers must comply with the RTAC Code of Practice, which in turn also requires compliance with the NHMRC Ethical Guidelines. As such, the HRT Act, (including its subsidiary legislation), the RTAC Code of Practice and the NHMRC Ethical Guidelines regulate ART practice in this State. The HRT Act prevails over the RTAC Code and the NHMRC Ethical Guidelines. Compliance with provisions of the HRT Act is mandatory for licensees. Nothing in this policy document is intended to be, or should be construed as being, inconsistent with the HRT Act, RTAC Code of Practice or NHMRC Ethical Guidelines. Any reference to sections in legislation in this policy refers to sections of the HRT Act.

The HRT Act allows the creation of human embryos only for the purpose of achieving pregnancy in a woman. Most embryos are utilised in the pursuit of creating a child for individuals and couples seeking to create or expand their family. However, in some cases embryos created in vitro will not be used. Some embryos may be considered sub-optimal when an embryo is being selected for implantation in a woman, others may become excess to the IVF needs of individuals or couples if they have completed their IVF treatment. These embryos may be stored until they are used, donated or ultimately allowed to succumb.

The HRT Act permits the storage of embryos for a period of up to ten years. This storage period was increased in 2004, from an initial period of three years. To extend storage beyond ten years duration, an application for an extension of the authorised storage period must be sought from the Reproductive Technology Council (Council). Under the HRT Act, an extension to an authorised storage period beyond ten years *may* be granted *only if there are special reasons for doing so in a particular case*. Furthermore, the primary purpose in the consent to the storage of an embryo must relate to the probable future implantation of the embryo, or its probable future use under an NHMRC research licence. Indefinite storage of embryos is arguably not ethical, and does not assist participants, many of whom are repeat applicants, to resolve their issues concerning their stored embryos.

To this end, Council encourages participants to make a decision about how their embryos are to be dealt with well prior to expiry of the authorised storage period. Further, where this is their intention, participants are encouraged to take steps prior to expiry of the storage period to consent to donate their embryos to other eligible person/s or for research.

The ‘Policy on Embryo Storage and Applications to Extend Storage Beyond Ten Years’ sets out Council policy to guide decision-making regarding embryo storage extensions, and the responsibilities under the legislation of Council, licensees and participants.

ETHICAL CONSIDERATIONS OF EMBRYO STORAGE ISSUES

There are many complex ethical and emotive issues associated with embryo storage, embryo donation and allowing embryos to succumb. As an example, many people express different views as to when human life begins. For some, life begins at conception, for others it is at the time of implantation, or at the time of fetal brain development. Some people hold the view that human life begins at birth, reflecting the perspective that legal rights begin at the birth of a child. These diverse views and the experiences and outcomes of their fertility treatment will impact on how participants approach end of storage decision-making.

Council is aware that many people find it difficult to reach a definitive decision regarding their stored embryos: some participants understandably consider that they are entitled to determine how their embryos are dealt with. While this position is respected and understood by Council, to store embryos indefinitely is not considered appropriate by the legislature or by Council. Reflecting a similar position, the 2007 NHMRC Ethical Guidelines state that it is not desirable to leave embryos in storage indefinitely, and that licensees must have clear policies that limit the duration of storage of embryos.

In addition, under the HRT Act, the prospective welfare of any child born as a result of an IVF or ART procedure must also be properly taken into consideration. This influences policy on matters such as on-donation of embryos created using donor gametes. In on-donation the potential for genetic confusion and the psychosocial impact on children that may be born following donation has to be weighed up against the potential gift that a donor embryo may represent. This and many other factors underpin the legislation, policy, and decision-making about end of storage issues for embryos.

A summary of the legal and ethical principles determining this Embryo Storage Policy follows.

1.0 EMBRYO STORAGE POLICY – DETERMINING FACTORS

The primary legal and ethical principles underpinning the Embryo Storage Policy follow:

1.1 In WA an embryo must not be stored for more than ten years except where this has been approved by Council (s24(1)).

1.2 An embryo storage extension beyond a ten year period may be granted by Council only if it considers there are special reasons for doing so in a particular case (s24 (1a)).

1.3 The primary purpose of storage of an embryo must relate either to its probable future implantation or its probable future use under an NHMRC licence (s24(1)(a)).

1.4 Where storage is for probable future implantation, compliance with the IVF eligibility requirements of the HRT Act (s23) will be taken into consideration.

1.5 The options for embryos in storage include:

- future use by the participants;
- donation to other eligible participants;
- donation to research as an excess ART embryo; and
- being allowed to succumb.

Indefinite storage is not an option.

1.6 Any extension to storage must only be in accordance with consent given by those with a right to consent (s22).

1.7 To facilitate participant decision-making about their embryos, ongoing communication between licensees and participants during the initial storage period outlining options and responsibilities will be important. Licensees will be required to undertake this communication, and ensure clinic policies incorporate counselling on embryo storage.

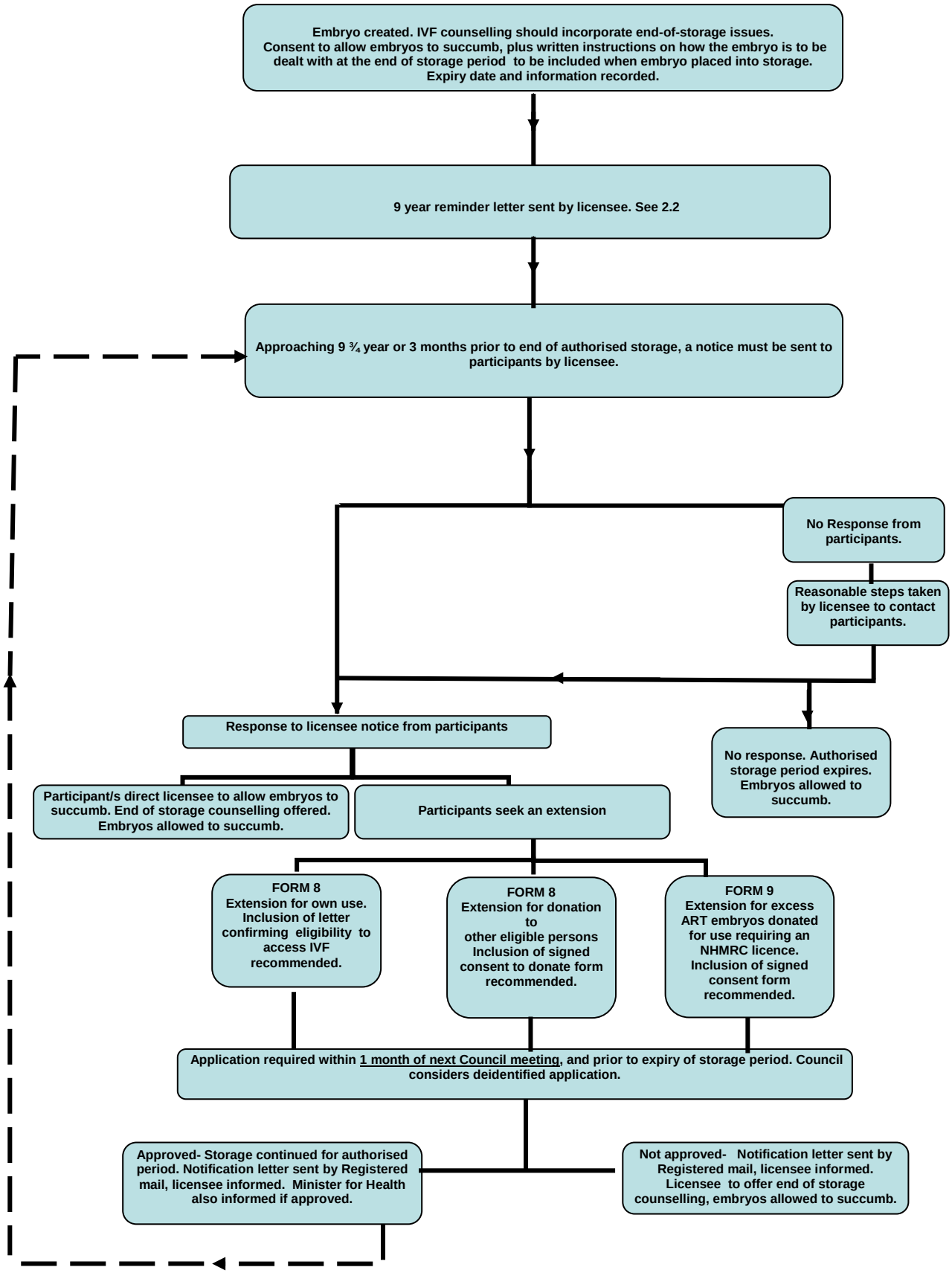
1.8 The HRT Act provides that where the initial storage period comes to an end and no application has been made to extend the storage period, the licensee (having taken reasonable steps to notify participants of the impending expiry in accordance with s24(3)) may allow the embryo to succumb and will not be liable for doing so. In such circumstances, at the end of an authorised storage period, an embryo must be removed from storage and allowed to succumb (s24(4), s33(3)(d), Direction 6.11). The RTAC Code of Practice and NHMRC Ethical Guidelines also support this practice.

1.9 The prospective welfare of any future child must be taken into consideration in matters associated with reproductive technology, including embryo storage (s4(1)(d) iv)).

1.10 Consideration of the welfare of the persons requesting an extension to the storage period should be given and their decisions respected, subject to compliance with the Act.

1.11 Any decision to extend storage must take into account equity, welfare and general standards prevailing in the community.

EMBRYO STORAGE - FLOW CHART FOR INITIAL STORAGE PERIOD (MAXIMUM TEN YEARS) AND ONGOING APPLICATIONS



2.0 LICENSEE INFORMATION

2.1 LICENSEE EMBRYO STORAGE POLICY AND PROTOCOLS

The provision of regular information regarding embryo storage issues is considered vital to ensure participants are well prepared to make decisions about their stored embryos.

2.1.1 Licensees must develop a protocol that covers their methods for informing participants about embryo storage, consent renewal, options for the future of embryos and the process for situations where there are difficulties notifying participants.

2.1.2 Licensees should incorporate embryo storage issues in their counselling policy.

2.2 TIME-LINE FOR LICENSEE INFORMATION FOR INITIAL STORAGE PERIOD (MAXIMUM TEN YEARS)

As set out in the Flowchart, the provision of written information by licensees after 9 years of storage is recommended *in addition* to the required notification of expiry 3 months prior to the expiry date. It may be licensee practice to send additional information to participants during an authorised embryo storage period, for example, some licensees send biannual invoices for storage. In this case, the recommended reminder letter below may be included at an appropriate time convenient to clinic practice. Example letters from the Council have been included in Appendix 5. Clinics may opt to send these, or develop their own reminders. The importance of participants providing updated contact details should also be included with reminders.

2.2.1 Information on embryos storage matters to be provided with initial IVF counselling. Storage payment fee letters should include reminders about responsibility to update contact details for both participants.

2.2.2 9 years of storage- reminder letter should be sent.
This aims to encourage participants that may be approaching the completion of their ART treatment to consider all options for their embryos. For those who may have difficulties in allowing any unused embryos to succumb, the options of donation to other eligible participants or as excess ART embryos for research should be considered, so that the donation process can be underway before the initial storage period has expired. Counselling may be beneficial for participants who remain uncertain of their intended actions. An Embryo Storage Brochure has been developed by Council, and aims to assist in the provision of relevant information. See Appendix 4.

2.2.3 9 3/4 years storage or 3 months prior to expiry - Notice to be sent.
Three months before the expiry of the authorised storage period, the licensee must take reasonable steps to notify participants of the impending expiry. This action is required by legislation (s24(3), d6.12), and aims to notify participants:

a) of the impending expiry of the authorised storage period
b) that further instructions are being sought from the participants on how the embryo/s is to be dealt with
c) that the licensee is unable to keep an embryo for a period longer than the authorised storage period
d) where the authorised storage period was less than ten years, that effective consent to continue storage will be required
e) where the authorised storage period was for ten years and it is a 9 ¾ year notice, that participants are aware that they may apply to Council for an extension (Form 8), and that such an application

must be received by the Council at least one month before the Council meeting that precedes expiry of the storage period; the due date (one month before the relevant Council meeting) should be included in this notification. This may be calculated from Council meeting dates available on the RTC website www.rtc.org.au/

f) that the licensee is required to provide assistance with completion of the Form 8 if necessary
g) that an extension to an embryo storage period may be granted where Council considers there are *special reasons* for doing so
h) that supporting documentation (such as the inclusion of signed consent forms to donate) will assist Council in determining that the basis for approval meets this criterion (g)
i) that Council is unable to approve an extension to the storage period once the authorised storage period has expired
j) that if approval for a storage extension by Council is not received, it is a legislative requirement that the embryos be allowed to succumb

2.2.4 An End of Storage Information Sheet (to be developed by Council) aims to assist participants who are unable to use, or who do not intend to use or donate their embryos, but who find it *difficult* to allow their embryos to succumb. It will set out options for the process of allowing embryos to succumb; for example, when a ceremony may be of benefit to participants. It also will encourage participants to undertake counselling.

2.3 CONSENT ISSUES AND PATIENT INFORMATION

To avoid difficulties near the end of an authorised storage period, it is important that licensees inform participants of their legislative requirements at the outset and throughout storage. Where the authorised storage period was for a period less than ten years, renewed effective consent to continue storage will be required from participants. NB: When Council approval to extend the authorised storage period beyond ten years has been granted, renewed effective consent to continue storage will also be required.

2.3.1 The patient information provided to participants at the time of giving consent to store embryos -

a) should advise that participants may only consent to a maximum of ten years for embryo storage
b) should advise that embryos cannot be stored indefinitely
c) should advise that consent must be renewed for storage beyond ten years and that Council may only approve an application by an eligible person for a longer embryo storage period where it considers there are special reasons for doing so
d) should advise that Council is unable to approve an extension after expiry of the authorised storage period
e) should advise that after expiry of the authorised storage period an embryo must be removed from storage and allowed to succumb, and that consent for this must be given at the time of consenting to store (see 2.3.2 (d), direction 3.6).

2.3.2 The patient consent forms to store embryos -

a) must specify the maximum period of storage, being the initial storage period of up to ten years;
b) must state the storage period required by the participants or determined by the licensee (which may be less than ten years) See 2.3.3

c) must state that the primary purpose of storage relates to the probable future implantation of the embryo, or its use under an NHMRC research licence (s24(1)(a))
d) must include consent to allow embryos to succumb at the end of the authorised storage period (Direction 3.6)
e) should indicate that 3 months prior to expiry of the authorised storage period reasonable steps will be taken to notify the participants. An application to extend an authorised storage period beyond ten years may only be approved by Council where there are special reasons for doing so (s24(3), Direction 6.12)
f) should seek written instructions on how embryos are to be dealt with at the end of authorised storage
g) must seek instructions on what is to be done with an embryo in storage if one or both parties die or are unable by reasons of incapacity to vary the terms of the consent or to withdraw this. The consent may specify conditions upon which the embryos are to remain in storage (s22 (6)(b))
h) should inform participants in advance of their terms regarding any storage fees and any conditions that apply in the event of ongoing unpaid storage fees, in particular where the licensee has lost contact with or is otherwise unable to obtain any further instructions from the participants.

2.3.3 Licensees are to notify each person for whom the embryos are being stored 3 months prior to the expiry of the authorised storage period in accordance with s24 (3), even though that storage period may be less than 10 years.

2.3.4 Consent to donate embryos to other recipients or for research must be effective consent (see glossary) under the HRT Act. The licensee must ensure that prior to donation of an embryo-

a) effective consent to the donation is given by the person for whom the embryo was developed and
b) any person who donated gametes to create the embryo and the spouse or de-facto partner of the gamete provider (if any) have given their effective consent to the use at the time donation was made (though see 3.3.7 re on-donation)

2.3.5 Each person on whose behalf an embryo was developed (or is being kept or is to be kept) has the right to decide, during the authorised storage period, how the embryo is dealt with, or disposed of.

2.3.6 The donors of an embryo may withdraw consent or vary consent up to the commencement of implantation of an embryo in the woman receiving the embryo (s26(1)).

2.3.7 Counselling requirements for donation of embryos where the recipient is known to the donor are set out in the Schedule 4, Part 2 of the Directions. These requirements include a minimum of 3 hours counselling in three individual sessions during which the recipient (and spouse or de-facto spouse, if any) and donor (and spouse or de-facto spouse, if any) should be seen separately and then together. There is then a requirement for a minimum *3 month cooling off period,* before the embryos may be used in an artificial fertilisation procedure.

2.3.8 Counselling is also strongly encouraged prior to donation of embryos where the recipient is not known to the donor (Direction 5.7).

2.3.9 For couples seeking embryo storage extensions, any *one* member of the participant couple may apply for an extension. For donation or a directive for embryos to be allowed to succumb before the expiry of the authorised storage period, *both* members of the participating couple must give consent (see 4.1.3).

2.4 NON-RESPONSE BY PARTICIPANTS TO LICENSEE CONTACT

Regular contact with participants by a licensee during the course of the authorised storage period (including issuance of embryo storage fees, and through the reminder at 9 years and notice at 9 ¾ years) aims to remind participants of their responsibility to provide updated contact information and to make a decision about their embryos in storage.

However, when participants do not respond to reminders or licensee prompts regarding decision-making for their embryos in storage, it may eventuate that an authorised storage period for these embryos may expire *without* the participants directing licensees to allow their embryos to succumb. Licensee responsibilities in these circumstances are set out below:

2.4.1 Under s24 (3) of the HRT Act, three months before the end of an embryo storage period, licensees are required to take reasonable steps to notify each person for whom the embryo is being stored that the storage period is due to expire.

2.4.2 The note to Direction 6.10 sets out that "reasonable steps" may include-

a) writing to the person at the last known address
b) writing to the person at an address obtained from an electoral roll search
c) telephoning or contacting the person's general practitioner
d) telephoning or contacting any other suitable third party.

2.4.3. Where embryos have been donated to a recipient/s, in the event that the recipient/s does not respond despite licensee reminders about impending storage expiry and where reasonable steps to contact have been made, the licensee may then take reasonable steps to contact the donor/s to give them the opportunity to vary or withdraw the consent given, or apply for an extension of storage prior to the expiry of the authorised storage period.

2.4.4 Under s24(4) of the HRT Act, if a period of storage comes to an end, no application has been made for the extension of the storage period, AND the requirements under s24(3) above have been met, licensees may allow the embryos to succumb and will not be liable to anyone for so doing.

2.4.5 Direction 6.11 states that the licensee must ensure that at the expiry of the authorised storage period for an embryo or egg undergoing fertilisation, the embryo or egg is removed from storage and allowed to succumb. Compliance with s24(3) should be ensured and documented *before* the step to allow an embryo or embryos to succumb is taken. Documentation demonstrating compliance with s24(3) may be taken into account in determining whether the requirements have been met.

2.4.6 Council is unable to approve an embryo storage extension after the expiry of an authorised storage period.

3.0 EMBRYO STORAGE EXTENSIONS

3.1 GENERAL MATTERS

3.1.1 Council approval for the extension of an embryo storage period beyond ten years is required under s24(1) of the HRT Act.

3.1.2 Where an embryo is intended for use in an IVF procedure an eligible person may apply for an extension to the storage period on a Form 8: 'Application for extension of frozen embryo storage period for use in IVF procedure'. A Form 8 application may be made by -

a) a person/s for whom the embryo was developed, or
b) the recipient/s, if this responsibility has been passed on to a recipient/s following donation (see 2.4.3)

3.1.3 Where an embryo is intended for use in research an eligible person may apply for an extension to the storage period on a Form 9: 'Application for extension of permitted storage where excess ART embryos have been donated for a use requiring a licence from the NHMRC'. A Form 9 application may be made by -

a) the participant/s for whom the embryo was developed
b) the storage licensee or
c) a person with an exemption to a storage licence issued under s28A.

3.1.4 Council will only consider an extension to an authorised storage period if it considers there are "special reasons for doing so in a particular case". Part B of Form 8 requests participants to briefly explain their reasons for seeking an extension. Some examples of circumstances that may, and may not be considered by Council as warranting an extension are set out in 3.2 and 3.3.

3.1.5 De-identification: Forms containing participant information received by the Executive Officer of the Council will be de-identified before being presented to Council for consideration, in order to comply with confidentiality obligations under the HRT Act.

3.1.6 In general, extensions will be initially considered by the Embryo Storage Committee of Council, and a recommendation regarding the application will be then made to Council.

3.1.7 The length of any approved extended storage period will be at the discretion of Council. An application should demonstrate the need for an extension and, if a specific time period is requested, the reason for this specified extension period.

3.1.8 Supporting documentation such as medical confirmation of eligibility to use the embryos and 'consent to donate' forms will assist Council to determine whether the basis for an extension can be considered a "special reason". Accordingly, such documentation, where appropriate, should be included with the extension application.

3.1.9 Section 24(1) states that the primary purpose of storage must relate to the probable future implantation of that embryo, or its probable future use under an NHMRC licence. Applications made for "own treatment at a later time" therefore are underpinned by participant eligibility for IVF under s23 of the HRT Act. Section 23(d) requires that the reason for infertility is not age. In cases where participant age may raise uncertainty about eligibility, medical

confirmation that a participant is not infertile by reason of age (that is, not post menopausal at the usual time) will be required.

3.1.10 Where there appears to be insufficient grounds on which to grant an extension, participants may be requested to supply further information to support their application. In this event, the request from Council will be sent by registered mail, and set out the date by which the participants must respond in order for their embryo storage extension application to be considered. As per Part B of Form 8: if a participant consents, the Executive Officer may use phone contact if further information is required in a short time frame**.**

3.2 WHEN APPROVAL MAY BE CONSIDERED.

An application to extend an authorised storage period may be considered by Council if there are *special reasons* for doing so. The following may assist Council in making a decision as to the special reasons for the application-

3.2.1 Participant/s stated intent to continue with infertility treatment in an attempt to conceive a child. Medical confirmation should be provided in support of the person/s ongoing eligibility to access IVF under the HRT Act (see 3.1.9).

3.2.2 Participant/s have one or more live births as a result of treatment, and wish to have additional children. Medical confirmation should be provided in support of the person/s ongoing eligibility to access IVF under the HRT Act (see 3.1.9).

3.2.3 Participants or (following donation and consent) recipient/s may have an existing child from the use of embryos formed with donor gametes and wish to have further children with the same genetic background. Medical confirmation should be provided in support of the person/s ongoing eligibility to access IVF under the HRT Act (see 3.1.9).

3.2.4 Participant/s have stored embryo/s for later use where a serious medical condition and/or its treatment may make the person infertile at a later date. Where practicable, medical confirmation should be provided in support of the person/s ongoing eligibility to access IVF under the HRT Act (see 3.1.9).

3.2.5 Participant/s wish to pursue a surrogacy arrangement in an attempt to conceive a child. Medical confirmation should be provided in support of the person/s eligibility to access IVF under the HRT Act (see 3.1.9) and/or evidence of the surrogacy arrangement being in progress.

3.2.6 Participant/s state their intent to donate their embryo to an eligible recipient/s. Either a 'consent to donate' form signed by all responsible persons or licensee confirmation that pre-donation counselling for donation has been initiated should be attached with the application for an extension for donation. This is to assist Council in the decision making process. Suitable recipients may have already been selected to receive the donor embryos, but this is not necessary for approval.

3.2.7 Participant/s state their intent to donate their embryos for research purposes or other purposes authorised under the Act. Section 24(1) states that the primary purpose of storage must relate to the probable future implantation of that embryo, or its probable future use under an NHMRC licence. A Consent to Donate Embryos for Research under an NHMRC Licence Form, signed by all responsible persons, should accompany the application to assist Council

to determine that the primary purpose of storage will relate to the probable future use under an NHMRC licence.

3.3 WHEN APPROVAL WILL NOT BE CONSIDERED

The following circumstances will not generally be considered by Council as "special reasons" to extend an authorised storage period beyond ten years.

3.3.1 The authorised storage period has expired and no extension has been sought. In this event, Council is unable to approve an embryo extension.

3.3.2 Participants cannot be located after reasonable steps have been taken by a licensee, and the authorised storage period has expired. In this event, Council is unable to approve an embryo extension.

3.3.3 Participants, who are no longer eligible for IVF treatment, remain undecided about their intended use of an embryo. (This does not rule out a brief extension approved by Council to allow the participants to access counselling etc where they are having difficulty in making a decision).

3.3.4 Where an embryo in storage has been donated by a couple, and that couple withdraw their consent to the donation/use (see 2.3). (This does not preclude an application being made by the donor couple for an extension and Council may give approval where there are special reasons for seeking an extension).

3.3.5 Participant/s wish to keep an embryo in storage indefinitely, or wish to be buried with the embryo.

3.3.6 Participant/s wish to keep an embryo in storage where the basis for the application is a proposed use that is not authorised under the HRT Act. This (under current legislation) includes future use as a source of stem cells.

3.3.7 In general, where recipient/s of a donated embryo (or an embryo created using a donated gamete or gametes) are applying for a storage extension in order to donate the embryo (on-donation) to another eligible person/s, Council approval will not be given: NHMRC Ethical Guideline 7.2 states that clinics should not facilitate on-donation as this may increase difficulties in tracing genetic parents and have possible effects on the long-term psychosocial welfare of persons born from embryos that have undergone serial donations.

In addition, at the present time it is likely that the gamete donor will not have consented to the provision of identifying information to any child born when they reach 16 years of age. For embryos created before December 2004, Direction 8.5 requires licensees to take reasonable efforts to contact any gamete donor involved in the creation of an embryo to obtain his or her consent to the provision of identifying information before using an embryo created with donor gametes in an artificial fertilisation procedure.

The inclusion of a copy of a signed consent form (verifying that the gamete donor agrees to the provision of identifying information) with the application may be considered by Council as a *special reason* by which to consider an embryo storage extension for on-donation.

4.0 DONATION OF EMBRYOS

4.1 DONATION TO OTHER ELIGIBLE PERSONS FOR PROBABLE FUTURE IMPLANTATION.

4.1.1 Donation to unknown recipient/s: where participant/s have decided to donate an embryo/s to anonymous recipient/s (where a cooling off period is not a requirement)

a) a copy of a Consent to Donate Embryos for Treatment form signed by all responsible persons, or
b) licensee confirmation that pre-donation counselling for donation has been initiated

attached with the application for an extension to the authorised storage period will assist Council in the approval process.

4.1.2 Donation to known recipients: where participant/s have decided to donate an embryo/s to known recipient/s (where a cooling off period is a requirement),

a) a copy of a 'consent to donate' form signed by all responsible persons, or
b) licensee confirmation that pre-donation counselling for donation has been initiated

attached with the application for an extension to the authorised storage period, will assist Council with the approval process.

4.1.3 An application for a storage extension can be made by one member of an eligible couple. However, consent to donate an embryo to other participant/s must include the effective consent of -

a) any person on whose behalf the embryo was developed;
b) any person who donated gametes used to develop the embryo (see 3.3.7) and
c) the spouse or de facto partner of the gamete provider.

4.1.4 Where an intention to donate is indicated, a 'consent to donate' form attached with an application for extension to storage, or evidence that pre-donation counselling has been initiated, will assist Council in the approval process. Where no 'consent to donate' form is included with the application, it is recommended that both participants (male and female) complete and sign the application for an embryo storage extension.

4.1.5 Licensees must maintain a clear procedure for the transfer of responsibility for an embryo at each stage (NHMRC Ethical Guideline 7.3)

4.1.6 If an embryo donor has not specified a recipient for the embryo, licensees should keep or place the embryo in storage until a suitable recipient/s is found (subject to the authorised storage period). Any application to extend an authorised storage period must still be made by the donating participants on a Form 8 and cannot be made by the licensee.

4.1.7 Where recipient/s of a donor embryo/s apply for an extension to the storage period for probable future implantation, the Form 8 application should provide that these embryos are donated, and specify what, if any, specified time period is requested for the purpose of the recipient/s undergoing IVF treatment and that the recipients are eligible for IVF under the HRT Act.

4.1.8 See 3.3.7 regarding extension of storage periods and donation of embryos created using donor material, or donation of donor embryos.

4.2 COUNSELLING

4.2.1 A licensee must ensure that all IVF participants have access to an approved counsellor, and that cost of one counselling session is included in each IVF cycle that is begun. Licensees should ensure participants who may not have utilised this paid-for session are informed that they may be able to access this counselling session to discuss end-of storage issues.

4.2.2 If embryos are to be donated to an unknown recipient/s, counselling should be offered and information regarding donation be provided as set out in the HRT Act (see Directions 4.1, 4.2 and 5.7).

4.2.3 If embryos are to be donated to a known recipient/s, psychosocial counselling (with cooling off period) and information must be provided, as set out in the HRT Act (see Schedule 4, Part 2, directions 4.1, 4.2 and 5.8).

4.3 DONATION OF EXCESS ART EMBRYOS FOR RESEARCH

Participants may donate their embryos for the purpose of research. Section 53T(2) of the HRT Act provides that each relevant person may determine in writing that an embryo is excess to their needs and give written authority for use of an embryo for a purpose other than relating to their ART treatment. However, the embryo may only be used for a purpose authorised under WA legislation, which will therefore be limited to research permitted under the HRT Act. This may also have implications for embryos intended to be exported for research outside of Western Australia, as embryos must not be exported for a use not allowed under the HRT Act (see 8.5, Direction 6.4).

For excess ART embryos donated for research under an NHMRC licence, NHMRC Ethical Guidelines require the researcher to obtain consent to donate for research under an NHMRC licence and also consent to the specific proposed research. This is set out in NHMRC Ethical Guidelines 15.7, 17.10 and 17.17.

NB: At present as the licensing system for excess ART embryo research is inoperative under the HRT Act and such, a licence may only be issued to certain entities under the Commonwealth *Research Involving Human Embryos Act 2002*.

Use of embryos declared to be excess ART embryos may be an “exempt use” (that is, exempt from requiring an NHMRC licence) if the use consists only of-

a) storage
b) removal from storage
c) transport
d) observation
e) allowing the embryo to succumb,
f) diagnostic investigations for the benefit of the woman for whom the embryo was created, and that the embryo is not fit for implantation. In this case, Council approval for the diagnostic investigation must be granted. (See p2 of the Policy on Approval of Diagnostic Procedures involving Embryos, Council website, www.rtc.org.au/)
g) use by a licensee for the purpose of achieving pregnancy in a woman other than the woman for whom it was created. See s 53W (2)

5.0 WHERE PARTICIPANTS DISAGREE

5.1 When an embryo developed on behalf of a person or on whose behalf the embryo is being kept or is to be kept in storage, each such person has the right to decide how the embryo is dealt with, or how it may be disposed of (s26(1)), and may review, vary or withdraw consent for storage.

5.2 If a couple in whom the rights to an embryo are vested disagree about the embryo's use or continued storage, a member of the couple can apply to the CEO of Health (Director General), to direct the licensee to continue storage. On receiving such an application, the CEO of Health must direct the storage licensee to ensure that storage is continued. This will be subject to the storage fees being paid, any limitation on the storage period under s24(1)(b) of the Act, and any order made by a Court of relevant jurisdiction.

6.0 DEATH OF PERSON/S WITH RIGHTS TO AN EMBRYO

6.1 In the event of the death of one member of a couple in whom the rights to an embryo are vested, the responsibility and right to decide how an embryo is dealt with or disposed of remains with the surviving member (s26(1)(b)).

6.2 In the event that both members of a couple (who have provided gametes to create an embryo) die, the licensee should act in accordance with any written consent of the couple as to how the embryo is to be dealt with. There is no prohibition on the posthumous use of *embryos,* provided that it is a use otherwise permitted under the HRT Act. NHMRC Ethical Guideline 8.7.2 also provides that in such circumstances any reasonable, clearly expressed and witnessed directive from the couple should be followed. NB. As at Jan 2010 Direction 8.9 prohibits a licensee from knowingly using or authorising the use of *gametes*, but not embryos, in an artificial fertilisation after the death of the gamete provider).

6.3 With regard to 6.2, a directive may include a lawful donation to another couple, or use in research.

6.4 In the absence of a reasonable or lawful directive for the future of any embryos stored for a participant couple who have died, licensees should arrange for the disposal of the embryo/s (NHMRC Ethical Guideline 8.7.2).

7.0 ALLOWING EMBRYOS TO SUCCUMB

7.1 The HRT Act requires that embryos be allowed to succumb on the premises licensed under the HRT Act. Participants are not able to take their live embryos home to succumb.

7.2 NHMRC Ethical Guidelines 8.5 and 8.9 outline that licensees must provide information about the removal of embryos from storage to participants, and have protocols in place for the respectful disposal of embryos.

7.3 The HRT Act does not appear to expressly prohibit a person (in whom rights to an embryo were formerly vested) taking an embryo that has been allowed to succumb off the licensed premises for disposal. However, other regulation

(of biological materials etc) may apply. For this reason, licensees should seek their own legal advice upon receiving such a request.

7.4 Participants may wish to consider providing consent to the use of their embryos for training purposes, once the embryos have been allowed to succumb. The use of non-living embryos for licensee training does not require an NHMRC licence, although licensees must receive general Council approval to use non-living embryos for training or research purposes (s20(2)).

8.0 IMPORT AND EXPORT OF EMBRYOS

8.1 Where a licensee seeks to import embryos created from donated human reproductive material from outside of Western Australia, information about the donor embryo/s required for the Reproductive Technology Registers must be available to the licensee, or waived by Council (Direction 6.2).

8.2 If the information (including donor identifying information) is not available, Council may waive this requirement on application, based on compassionate grounds (Direction 6.3).

8.3 A licensee must not permit or facilitate the export of a donated embryo or an embryo created from donated gametes from Western Australia without the prior approval of Council (Direction 6.5).

8.4 The approval to export a donated embryo is dependant on the recipient of the embryo/s undertaking to provide the WA licensee with information required for the RT Registers. Form 10 sets out this requirement (Appendix 3).

8.5 The export of embryos for a use that is prohibited in Western Australia is not permitted (Direction 6.4).

8.6 A licensee accepting an embryo from another person for storage is responsible for the reporting requirements for that embryo (Direction 2.12).

9.0 ENQUIRIES REGARDING EMBRYO STORAGE MATTERS

Form 8 and Form 9 applications should be marked ‘Confidential’ and returned to the ‘Executive Officer, Reproductive Technology Council, PO Box 8172, Perth Business Centre, Perth WA 6849.

When an application is received by the Executive Officer directly from participants, the Executive Officer or Deputy Executive Officer will notify the licensee storing the embryos that an application has been received. Following a decision by Council, participants will be notified of Council’s decision by registered mail. Licensees will be informed and the Minister for Health notified as per s24(1d).

Licensee enquiries regarding embryo storage may be directed to the Executive Officer or Deputy Executive Officer by email, or telephone. Current contact details are available on the RTC website www.rtc.org.au , or by telephoning the Department of Health on (08) 9222 4222. Queries may also be sent to the above postal address.

APPENDICES

Appendix 1: FORM 8

Appendix 2: FORM 9

Appendix 3: FORM 10

Appendix 4: EMBRYO STORAGE BROCHURE

Appendix 5: EXAMPLE LETTERS TO PATIENTS FOR 9 AND 9 ¾ YEARS

Appendix 6: RELEVANT LEGISLATION AND GUIDELINES

CONFIDENTIAL

FORM 8: APPLICATION FOR EXTENSION OF FROZEN EMBRYO STORAGE PERIOD FOR USE IN IVF PROCEDURE

INSTRUCTIONS

- **Application can only be made by eligible participants ie those for whom the embryo was developed or, if consent for receipt after donation has been completed, the recipient(s).**
- **Both Part A and Part B of the application should be completed.**
- **Applications should be received by the Executive Officer of the Reproductive Technology Council at least one month prior to the meeting of the council preceding expiry of the current storage period.**
- **Approval for extension of storage cannot be granted if the storage period has already expired. Embryos are required to be removed from storage if the storage period expires and no extension has been granted.**
- **Please mark your envelope 'Confidential' and return this application to: Executive Officer, Reproductive Technology Council, Health Dept of WA, 189 Royal Street, East Perth WA 6004 Ph: (08) 9489 2818**

PART A Licensee to Complete:

1. Have these embryos been granted a previous extension? **yes** ☐ **no** ☐

2. Storage details:

Date of expiry of current storage period ☐☐ **day** ☐☐ **month** ☐☐ **year** **10 years from date embryos placed in storage in WA, or date of expiry of any later current extension**

Date of Completion by Licensee ☐☐ **day** ☐☐ **month** ☐☐ **year** **Licensee number:** ☐☐☐

3. Treatment cycle details:

Participant ID Code **Female :** ☐☐☐☐☐☐☐☐ **Partner** (if any): ☐☐☐☐☐☐☐☐

Treatment unit ID ☐☐☐

Treatment cycle codes **Cycle ID :** ☐☐☐☐☐☐☐☐☐☐ **Fertilisation :** **F** ☐☐☐☐☐☐☐☐

Date cycle commenced : ☐☐ **day** ☐☐ **month** ☐☐ **year**

Date of storage in WA ☐☐ **day** ☐☐ **month** ☐☐ **year**

Female DOB : ☐☐ **day** ☐☐ **month** ☐☐ **year** **Partner DOB :** ☐☐ **day** ☐☐ **month** ☐☐ **year**

Number of embryos affected by this expiry: ☐☐

Also indicate Participant ID codes of donor/s here if applicable:

Female : ☐☐☐☐☐☐☐☐ **Male:** ☐☐☐☐☐☐☐☐

Health Department use only: **Application Number :** ☐☐☐☐☐☐ - ☐☐☐ **Code** ☐☐

Date of expiry of extended storage period: ☐☐ **day** ☐☐ **month** ☐☐ **year**

Chairman, RTC _____

CONFIDENTIAL

PART B

Eligible Participant(s) to complete:

Date of Application ☐☐ ☐☐ ☐☐
day month year

Eligible Participant Name:	**Female**	**Partner** (if any)
name:	**Family name** _____	**Family name** _____
	Given name _____	**Given name** _____

Signature: _____ _____

Address: _____

Postcode: ☐☐☐☐ **Phone Number:** _____

You will be contacted by mail for notification of the outcome of your application or should we require further information in order to process your application. Your phone number will only be used to contact you if further information is required within a short time frame, we do not anticipate this happening in the majority of cases. Should we attempt to contact you discretion will be used and we will only speak to the participant or their partner.

Please indicate if there are any restrictions to the way in which you would like us to contact you.

_____

1. Who is applying?:

- **(a)** ☐ **Both members of the eligible couple.**
- **(b)** ☐ **One member only of the eligible couple.**
- **(c)** ☐ **Eligible single person.**

2. Are you seeking an extension with the intention of:

- **(a)** ☐ **Using the embryos for your own treatment at a later time.**
- **(b)** ☐ **Donating the embryos to an eligible recipient/s.**
- **(c)** ☐ **Other**

3. Briefly explain your reasons for seeking an extension:

_____

_____

_____

_____

4. When do you plan to use or dispose of your embryos?

5. Signature of applicant(s) _____

_____

CONFIDENTIAL

FORM 9

APPLICATION FOR EXTENSION OF PERMITTED STORAGE PERIOD WHERE EXCESS ART EMBRYOS HAVE BEEN DONATED FOR A USE REQUIRING A LICENCE FROM THE NHMRC

INSTRUCTIONS

- **Application may be made by:**
  - **The participant(s) for whom the embryo was developed**
  - **Storage licensee**
  - **Holder of an exemption under section 28A of the *Human Reproductive Technology Act 1991* (HRT Act)**
- **Applications should be received by the Executive Officer of the Reproductive Technology Council at least one month prior to the meeting of the council preceding expiry of the current storage period.**
- **Approval for extension of storage cannot be granted if the storage period has already expired.**
- **Embryos are required to be removed from storage if the storage period expires and no extension has been granted.**
- **Please mark 'Confidential' and return to Executive Officer, Reproductive Technology Council, Health Dept of WA 189 Royal Street, East Perth WA 6004 Ph: (08) 9489 2818 or**

1. Who is applying?

(a) ☐ **Participant(s) for whom the embryo is being stored**

(b) ☐ **Licensee**

(c) ☐ **Holder of exemption under section 28A of the HRT Act**

2. Have these embryos been granted a previous extension? **yes** ☐ **no** ☐

---

3. Storage details:

Date of expiry of current storage period ☐☐ **day** ☐☐ **month** ☐☐ **year** **10 years from date embryos placed in storage in WA, or date of expiry of any later current extension.**

Licensee number ☐☐☐

---

4. Treatment cycle details:

Participant ID code **Female** ☐☐☐☐☐☐☐☐ **Partner** (if any) ☐☐☐☐☐☐☐☐

Treatment unit ID ☐☐☐

Treatment Cycle Codes **Cycle ID** ☐☐☐☐☐☐☐☐☐☐ **Fertilisation** **F** ☐☐☐☐☐☐☐☐☐

Date cycle commenced ☐☐ **day** ☐☐ **month** ☐☐ **year**

Date of embryo storage in WA: ☐☐ **day** ☐☐ **month** ☐☐ **year**

FemaleDOB: ☐☐ **day** ☐☐ **month** ☐☐ **year** **Partner DOB:** ☐☐ **day** ☐☐ **month** ☐☐ **year**

Number of embryos affected by this expiry: | | |

5. Briefly explain reasons for seeking extension.

_____

_____

_____

_____

_____

Signature of applicant(s)

_____

_____

Health Department use only: **Application number** **9-200** - | | | | | **Code** | |

Date of Expiry of Extended Storage period | | **day** | | | **month** | | | **year**

Chairman, RTC

_____

FORM 10 - UNDERTAKING

EXPORT OF DONATED HUMAN REPRODUCTIVE MATERIAL FROM WESTERN AUSTRALIA (WA):

Formal undertaking between a person seeking the approval of the Reproductive Technology Council to receive this material and the WA licensee who is to export the donated human reproductive material.

This is to certify that I, ...

.....
(full name, title and occupation)

of .....
(full address)
.....

do undertake:

1. To provide the WA licensee

.....
(Full name of licensee who is to provide the material)

within a reasonable time, with all the information that would be required if any assisted fertilisation procedure that I carry out or authorise with the donated human reproductive material were carried out in Western Australia (ie recipient code, type of treatment, date of treatment and outcome at 8 weeks after the procedure);

2. To provide to the WA Donor Register, when requested by Register staff, recipient identifying information as required under the Act;

3. To provide the recipient and their spouse/partner with all relevant information, especially regarding the Registers which have been established, prior to obtaining their consent to the procedure as set out under the Act.

I understand that if I fail to provide the required information to the licensee or the Register within a reasonable time and without good cause, the approval of Reproductive Technology Council for me to receive further material from the licensee may be withdrawn.

..... (Date) .....
(Signature of applicant)

TO OBTAIN APPROVAL THE APPLICANT FOR APPROVAL SHOULD RETURN THE SIGNED ORIGINAL OF THIS UNDERTAKING TO THE RELEVANT WA LICENSEE. THE LICENSEE SHOULD THEN CONTACT THE REPRODUCTIVE TECHNOLOGY COUNCIL SEEKING ITS APPROVAL, IN WRITING, TO EXPORT THE MATERIAL TO THE APPLICANT, ENCLOSING A COPY OF THIS UNDERTAKING.

Reproductive Technology Council

EMBRYO STORAGE BROCHURE

In vitro fertilisation (IVF) involves the creation of embryos outside of a woman's womb for the purpose of assisting people to conceive a child. In Western Australia, regulation of IVF and other assisted reproductive technologies (ART) is provided by the *Human Reproductive Technology Act 1991* (the HRT Act). This Act also determines matters on embryo storage.

Most embryos created through IVF will be used with the aim of creating a child. However, those embryos that are not used will remain in storage. Individuals or couples can be faced with making what can be a difficult decision about the future of these embryos at the end of their permitted storage period.

How long can I store my embryos?

The current law allows licensed clinics to store embryos for a maximum of ten years. Under the law, the Reproductive Technology Council (the Council) may approve the storage of embryos for a period of time beyond the ten years. However, this approval must be given on a case-by-case basis and only for special reasons.

How do I know when my embryo storage period is due to expire?

Your clinic will make contact with you about any storage fees and consent matters during the storage of your embryos. Your clinic will also send you further information after 9 years of storage to help you consider your options as the end of the ten year storage period approaches.

In addition, the law requires that your clinic takes *reasonable steps three months* before the end of the authorised storage period to notify you that the storage period is coming to an end for your embryo/s. For this reason, it is important that you keep your clinic updated with any changes to your contact details.

What are our options at the end of our embryo's storage period?

Individuals, or if a couple, both members of the couple may choose to allow their embryos to succumb (or expire) at the end of their storage.

Other possibilities include:

a) seeking to keep your embryos for your own use at a later date
b) donating them to others undergoing fertility treatment - this option may depend on your clinic, and whether donated gametes were already used to create these embryos
c) donating your embryos for approved research under a National Health and Medical Research (NHMRC) Licence.

For any of these reasons, an embryo storage extension must be granted by the Council before the authorised storage period ends.

Aren't they our embryos to make decisions about?

Some people understandably consider that they have a right to determine how their embryos are dealt with. While this position is understandable, it does not include the right to hold embryos in storage indefinitely. The law requires that any extension to the storage of embryos can only be granted by Council for *special reasons.*

What special reasons can be approved by Council?

The law requires that consent to the storage of embryos must relate to the *probable future use* (implantation) of an embryo, or *probable donation for research* under an NHMRC licence.
There will be a wide variety of reasons for seeking to store embryos beyond ten years. To assist the Council in determining that these conditions are being met, and the *special reasons* for your application, it is recommended that the reason for your storage extension is clearly described on the application form. Documents supporting your extension request should be included with your application.

- If you are seeking to extend the storage for your own use of your embryos, it is

suggested that you include a medical report supporting that you are still eligible to access IVF.

- If your intention is to donate your embryos for use by another person or couple or to the clinic for research, it will help the application process to include documents supporting this intention to donate. This may include a signed 'consent to donate embryos' form, or verification that you have started the counselling process prior to donation.

The law requires that the Council receives any embryo storage extension at least one month before it is due to meet next. In addition to this, your embryo storage period must still be valid at the time the Council meets to discuss this matter. For this reason, it is important that you have given some consideration to your situation and what you wish to do with your embryos- it can be very difficult to have to make a hurried decision.

If you wish to seek an extension of your embryo storage period, your clinic can provide help to ensure that your application meets the requirements under the HRT Act.

Who has the responsibility to apply for an extension?

If you intend to store your embryos for your own use at a later date, or if you are intending to donate your embryos but a recipient has not yet been selected, you will need to apply for an extension. Your clinic is not able to do this on your behalf.

If you have donated them to another person or couple, you may have agreed to give this person or couple the responsibility of applying to the Council for any ongoing storage extensions.

Clinics can only apply for embryo storage extensions if you have declared your embryos to be excess to your needs (they are then considered "excess ART embryos") and have donated your embryos to the clinic for approved NHMRC research purposes.

What happens if I don't apply for an extension?

It is illegal for clinics to continue to store your embryos beyond ten years unless you are granted a storage period extension. If you have *not* made an application to extend the storage time to the Council and the authorised storage period expires, your clinic will have to allow these embryos to succumb. Under the law, Council is unable to approve an embryo storage extension once the authorised storage period has expired.

What if we can't decide what to do with our embryos?

Some people find it very difficult to reach a decision regarding their stored embryos. Every person or couple needs to consider their particular situation.

People facing these decisions are encouraged to have counselling with an 'Approved Counsellor' to discuss their options and to assist with decision-making. Counselling will be required if you wish to donate your embryos to someone you know, but also can benefit anyone who is considering what to do with their embryos in storage. Talking about these issues with other couples who have undergone IVF has also helped many people facing this difficult decision.

What if we can't agree, or our circumstances change?

In the situation where a couple is in disagreement, one of the couple must apply, before the end of the storage period, to the Director General of the Department of Health WA. The Director General may instruct the clinic to store the embryos until resolution of the disagreement, or a Court order is issued regarding this matter.

Where do I get more information about embryo storage?

Your clinic is able to provide you with assistance in completing an application and discussing your embryo storage issues.
You can also visit the **RTC website** http://www.rtc.org.au for further information,
or contact the RTC Executive Officer, on
rtc@health.wa.gov.au

Reproductive Technology Council

Storage of embryos at *Fertility clinic*

Dear IVF participant

This letter serves as a reminder that the embryos created from your in vitro fertilisation (IVF) treatment at _____ have now been in storage for more than nine years.

You may be aware that in 2004, the maximum time for embryos to remain in storage in Western Australia was increased from three years to ten years. This increase aimed to provide enough time, in general, for people to complete their fertility treatment. Embryos may be stored beyond ten years. However, this requires an application to the WA Reproductive Technology Council (Council). In order to grant an extension under the *Human Reproductive Technology Act 1991*, the Council must consider that your application is for a *special reason*.

At this point in time, you may be still undergoing fertility treatment at your clinic and wish to keep your embryos in storage for this purpose. If the embryos are to be used for your own treatment, you must still be eligible to undertake IVF treatment- your clinic can assist you with this. However, if you are reaching completion of your treatment, or no longer wish to use your embryos for your own treatment, you are encouraged to give some consideration to your future options.

Many people will choose to allow their embryos to succumb when they no longer wish to keep them for their own treatment. Another option is to donate embryos to another person or couple, or donate embryos for research purposes. Donation to other people who are seeking infertility treatment can be a very generous act, though there are important issues that will require consideration. For this reason, if you are considering donation, you will be asked to see a clinic counsellor before consenting to this. If your embryos were created using donated gametes, it may not be possible to on-donate your embryos- this matter can also be discussed with your clinic or counsellor.

Your clinic is required to take reasonable steps to contact you three months before the end of the authorised storage period to notify you that your embryo storage period is coming to an end. The law does not allow Council to consider applications once the authorised storage period ends. For this reason, it is important that you keep your clinic updated with any changes to your contact details, and that you respond promptly to the clinic notification in the event that you do wish to apply for an embryo storage extension.

If you would like further information on embryo storage matters, please contact your clinic. Information is also available on the Reproductive Technology Council website http://www.rtc.org.au/. If you are uncertain about your future intentions or have any other issues of concern, discussing these issues with a clinic counsellor before the ten year end of storage approaches can also be very beneficial.

Yours faithfully

Ms Jenny O'Callaghan
Executive Officer
Reproductive Technology Council

Reproductive Technology Council

Storage of embryos at *Fertility clinic*

Dear IVF participant

This letter is to remind you that the ten year authorised storage period for the embryos created through your in vitro fertilisation (IVF) treatment at is soon to expire. Your clinic is required to inform you that if you wish to keep your embryos in storage beyond this time, you will need to apply to the Reproductive Technology Council (Council) to extend your embryo storage period.

Under the *Human Reproductive Technology Act 1991* (HRT Act), Council is able to approve such an extension to an authorised storage period. However, the HRT Act requires that Council consider that there are *special reasons* for approving an extension. Another requirement of the law is that the future use of an embryo must relate to the probable future implantation of the embryo, or its probable future use under a national research licence.

At this point in time, you may be still undergoing fertility treatment at your clinic and wish to keep your embryos in storage for this purpose. If the embryos are to be used for your own treatment, you must still be eligible to undertake IVF treatment.. Eligibility for IVF requires that the reason for infertility is *not* age, and therefore women who have undergone menopause (where it is not considered a premature menopause) are unfortunately no longer eligible for IVF. Written support from your IVF specialist that you are still eligible for IVF (which includes the embryo transfer process) will assist your application.

If you have completed your treatment, or no longer wish or are able to use your embryos for your own treatment, it is hoped that you have given some consideration to the other options available to you.

If you have decided to donate your remaining embryos to another person or couple, or for research, then the inclusion of supporting documents with your embryo storage application will assist your application for an embryo storage extension. For example, including a copy of the completed 'consent to donate' form with your application will enable Council to consider that the extension is for a *special reason*, and that the storage of the embryos is for probable implantation or for research purposes. Alternatively your clinic may be able to verify that you have started the counselling process as an indication of your intention to donate.

Donation of embryos can be considered to be a generous act, but it is not for everybody. If your embryos were created using donated gametes, it may not be possible to on-donate your embryos- this matter can also be discussed with your clinic or counsellor.

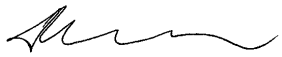
Many people will choose to allow their embryos to succumb when they no longer wish to keep them for their own treatment. This is a very personal decision - if you are uncertain about your future intentions or have any other issues of concern, discussing these issues with a clinic counsellor before the ten year end of storage approaches can be very beneficial.

Whatever your intention, the law does *not* allow embryos to be stored indefinitely, and you will need to take action before the expiry of your embryo storage period if you do not wish your embryos to succumb at the end of this period as the HRT Act does not allow Council to consider applications once the authorised storage period ends. Your clinic can assist you with the application, but cannot undertake the extension application for you unless embryos have been donated for research to the clinic.

The law also requires the application to be received one month before the next Council meeting. **For this reason, it is important that you keep your clinic updated with any changes to your contact details, and that you respond promptly to the clinic notification in the event that you do wish to apply for an embryo storage extension.**

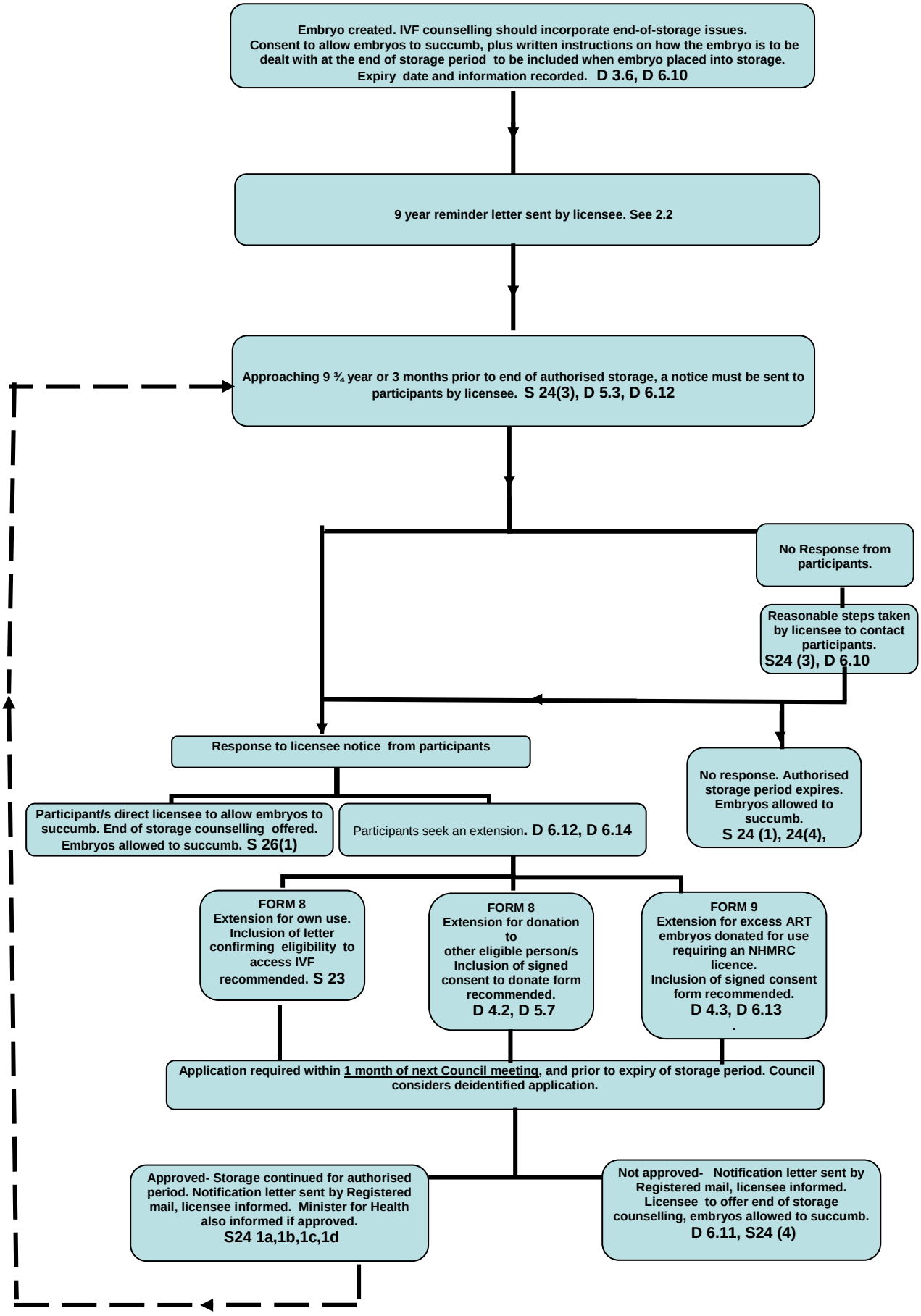
You will be notified of the outcome of your embryo storage extension application. If you would like further information on embryo storage matters, please contact your clinic. Information is also available on the Reproductive Technology Council website http://www.rtc.org.au/.

Yours faithfully



Ms Jenny O'Callaghan
Executive Officer
Reproductive Technology Council

APPENDIX 6- RELEVANT LEGISLATION AND GUIDELINES



Appendix 4: Relevant Legislation and guidelines on embryo storage

EXCERPTS FROM LEGISLATION CONCERNING EMBRYO STORAGE

HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

3A. Meaning of "human embryo"

(1) In this Act —

"human embryo" means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.

(2) For the purposes of the definition of "human embryo" in subsection (1), in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

6. Unlicensed practices

(1) No person shall cause or permit —

(a) any procedure to be carried out related to the storage of —

(i) a human egg intended for use in an in vitro fertilisation procedure;

(ii) a human egg undergoing fertilisation; or

(iii) a human embryo;

(b) human sperm, having been obtained from different men, to be kept;

(c) an artificial fertilisation procedure, other than an artificial insemination to which section 28(3) applies, to be carried out; or

(d) any other use, outside the body of a woman, of a human embryo, if the use is not for a purpose relating to the reproductive technology treatment of the woman,

except pursuant to a licence or exemption by which it is authorised under this Act.

(2) A person who contravenes subsection (1) commits a crime and is liable to imprisonment for 5 years.

Summary conviction penalty: Imprisonment for one year.

7. Offences relating to reproductive technology

(1) A person, whether or not a licensee, must not cause or permit —

(a) research to be conducted upon or with a human egg undergoing fertilisation, or any embryo, not being research in respect of which the Council has already granted relevant approval or all requisite specific prior approvals have been sought and obtained under section 20; or

(b) a diagnostic procedure to be carried out upon or with a human egg undergoing fertilisation, or any embryo, not being a procedure which is —

(i) authorised by the Code; or

(ii) specifically approved by the Council.

(2) A person who contravenes subsection (1) commits a crime and is liable to imprisonment for 5 years.

Summary conviction penalty: Imprisonment for one year.

[(3), (4) repealed]

(5) A person who —

(a) being a licensee, keeps or uses human gametes, a human egg undergoing fertilisation or a human embryo in contravention of this Act; or

(b) being a person to whom a licence applies or applied, fails to comply with a direction given for the purpose of section 30(4)(a),

commits an offence.

Penalty: 2 years imprisonment.

14. Functions of the Council

(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).

20. Principles applicable to projects of research

(1) A licence shall not be capable of authorising any research contravening the condition referred to in subsection (3).

(2) No licensee shall carry out, or authorise or facilitate or become involved in the carrying out of, any project of research —

(a) upon or with —

(i) human gametes obtained in the course of an in vitro fertilisation procedure or intended for use in an artificial fertilisation procedure; or

(ii) a human egg undergoing fertilisation or a human embryo whether or not live;

or

(b) involving any person who is a participant in an artificial fertilisation procedure,

unless general or specific approval relevant to that project has already been granted by the Council, or unless specific prior approval from the Council for that particular project

of research is sought for in such manner as may be required by the Code or directions, and if the Council so requires is also sought from a specific Institutional Ethics Committee recognised by the Council, and is obtained.

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

22. Consents, generally

(1) For the purposes of the licence condition referred to in section 33(2)(e) —

(d) where the development of an egg undergoing fertilisation or a human embryo was brought about by an in vitro fertilisation procedure it shall not be kept in storage unless —

(i) there is an effective consent, by each person from whose gametes the egg or embryo was derived, to the storage; and

(ii) the egg or embryo is stored in accordance with that consent;

(e) where the development of a human egg undergoing fertilisation or a human embryo was brought about by an in vitro fertilisation procedure, it shall not be used for any purpose, or for such a purpose be received by a licensee or participant, unless —

(i) there is an effective consent, by each person from whose gametes the egg or embryo was derived, to the use for that purpose;

(ia) in the case of a use outside the body of a woman, there is an effective consent to the use for that purpose by the woman on whose behalf it is being developed and her spouse or de facto partner, if any;

(2)Where a consent is given in general terms to the use or storage of human gametes separately, whether human eggs or human sperm, that consent shall be taken to relate to the use or storage of any of those eggs or sperm, and also to any human egg undergoing fertilisation or human embryo derived from the use of the human gametes, for any purpose, save that —

(a) any such consent may be given subject to specific conditions in its terms; and

(b) notwithstanding subsection (4) or that a human egg undergoing fertilisation or a human embryo, may have developed which is derived from the use of human gametes the subject of any particular consent, in so far as it relates to any human egg or human sperm that has not been used that consent may be varied or withdrawn,

but where a human egg in the process of fertilisation, or a human embryo, has been developed from any human gametes the consent thereafter to be required is not a consent to the use of those human gametes but a specific consent relating to that particular egg undergoing fertilisation or embryo only.

(6) A consent to the keeping of any human gametes, a human egg undergoing fertilisation or a human embryo must —

(a) specify the maximum period of storage, if that is to be less than such limit as may be prescribed or may be determined in accordance with section 24(1)(b); and

(b) give instructions as to what is, subject to this Act, to be done with the gametes, the egg or the embryo if the person who gave the consent is unable by reason of incapacity or otherwise to vary the terms of the consent or to withdraw it,

and may specify conditions subject to which the gametes, or the egg or embryo, shall or shall not remain in storage.

(7) Before a licensee gives effect to a consent given for the purposes of this Act the licensee shall ensure that each participant has been provided with a suitable opportunity to receive —

(a) proper counselling about the implications of the proposed procedures; and

(b) such other relevant and suitable information as is proper or as may be specifically required by the Code or directions,

including an explanation of the effect of subsection (3) and subsection (4).

(8) For the purposes of this Act a consent to the use or keeping of any human gametes, a human egg undergoing fertilisation or a human embryo shall not be taken to be effective unless —

(a) it is given in writing;

(b) any condition to which it is subject is met;

(c) it has not been withdrawn; and

(d) those gametes are, or that egg or embryo is, kept and used in accordance with the consent.

23. When procedures may be carried out

An in vitro fertilisation procedure may be carried out where —

(a) it would be likely to benefit —

(i) persons who, as a couple, are unable to conceive a child due to medical reasons;

(ia) a woman who is unable to conceive a child due to medical reasons; or

(ii) a couple or a woman whose child would otherwise be likely to be affected by a genetic abnormality or a disease;

(b) each of the participants required to do so has given an effective consent;

(c) the persons seeking to be treated as members of a couple are —

(i) married to each other; or

(ii) in a de facto relationship with each other and are of the opposite sex to each other;

(d) the reason for infertility is not age or some other cause prescribed for the purpose of this paragraph; and

(e) consideration has been given to the welfare and interests of —

(i) the participants; and

(ii) any child likely to be born as a result of the procedure,

and in the opinion of the licensee that consideration does not show any cause why the procedure should not be carried out,

but not otherwise.

24. Storage

(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.]

26. Control, dealing and disposal in relation to an egg in the process of fertilisation or an embryo

(1a) This section 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).

(1) Subject to section 24(4), in relation to rights to the control of, or power to deal with or dispose of, any human egg undergoing fertilisation or human embryo that is outside the body of a woman —

(a) each person on whose behalf it is developed or is being or is to be, kept has, subject to section 53Q, the right to decide how a human egg undergoing fertilisation or a human embryo is to be dealt with or disposed of, so that —

(i) such a person shall have, while storage continues, the right to review the decision to store from time to time and may withdraw consent or vary the terms of any consent; and

(ii) any question as to the nature or extent of the respective rights or powers may, subject to subsection (2), be referred to a court of competent jurisdiction;

(b) in the event of the death of one member of a couple in whom the rights are vested, those rights vest solely in the survivor;

(c) where from any human gametes, a human egg undergoing fertilisation or a human embryo is developed, whether or not with effective consent, the individual rights of a human gamete provider or person to whom the human gametes were provided and of a licensee cease at the moment fertilisation begins and the rights thereafter vest jointly in the couple on whose behalf that egg or embryo was developed, or vest in the woman on whose behalf that egg or embryo was developed;

(d) where a human egg undergoing fertilisation or a human embryo has been developed on behalf of a couple or a woman and is no longer required for that purpose, the egg may be used if all the participants in a proposed procedure give an effective consent; and

(e) on the commencement of an implantation procedure the rights in a human egg undergoing fertilisation or a human embryo vest in the woman receiving it, whether or not —

(i) that recipient was eligible to undergo the procedure; or

(ii) any consent required was given or, if given, was effective.

(2) Where rights in relation to a human egg undergoing fertilisation or a human embryo are vested in a couple and the couple disagree about its use or continued storage, the CEO shall, on application by a member of that couple, direct the licensee storing the egg or embryo to ensure that the storage is maintained subject to —

(a) payment of the proper charges of the licensee for the storage;

(b) any limitation as to the time of storage prescribed or determined in accordance with section 24(1)(b); and

(c) any order made by a court of competent jurisdiction which otherwise requires.

[Section 26 amended by No. 3 of 2002 s. 76; No. 17 of 2004 s. 20; No. 18 of 2004 s. 7; No. 28 of 2006 s. 270(1).]

27. Licences, and the person responsible

(2) In accordance with its terms a storage licence may authorise the licensee to carry out any procedure related to —

(a) the storage of —

(i) any human egg intended for use in an in vitro fertilisation procedure;

(ii) any human embryo; or

(iii) any human egg undergoing fertilisation;

(b) the keeping of human sperm, having been obtained from different men; and

(c) any project of research related to such storage and approved under section 20.

33. Conditions applicable to all licences and exemptions

(3) Every storage licence is subject to the conditions —

(a) that human gametes, a human egg undergoing fertilisation or a human embryo shall be stored only if received or acquired from —

(i) a person to whom a licence applies; or

(ii) a person who satisfies the licensee that they can give an effective consent to that storage;

(b) that a human egg undergoing fertilisation or a human embryo the development of which was brought about by an in vitro fertilisation procedure, otherwise than under the authorisation conferred by a practice licence held by the same licensee, shall be stored only if received or acquired from —

(i) another person to whom a licence applies; or

(ii) a person who satisfies the licensee that they can give an effective consent to that storage;

(c) that human gametes, human eggs undergoing fertilisation or human embryos which are or have been stored shall not be supplied to a person unless that person is a person to whom a licence or an exemption applies, or the supply has been otherwise authorised under this Act; and

(d) that no human gametes, human egg undergoing fertilisation or human embryo shall be stored for longer than this Act authorises.

49. Confidentiality

(1) A person shall not divulge, or communicate to any other person, any information disclosed or obtained by reason of this Act respecting the identity of —

(a) a donor of human gametes, a human egg undergoing fertilisation or a human embryo;

(b) a participant in any procedure involving reproductive technology; or

(c) a child born as a result of any artificial fertilisation procedure,

unless subsection (2) applies.

(2) Information to which subsection (1) applies may be divulged or communicated —

(a) for a purpose necessary to the carrying out of any procedure, or the conduct of any research, to which this Act applies;

(b) for the purposes of and in the course of the administration of this Act, or pursuant to a request of the Minister made for the purposes of section 5;

(c) as may be authorised or required by the Code or the regulations;

(d) subject to subsections (2a) to (2c), with the consent of each donor, participant or child in question or other person whose identity may be disclosed in so far as it does not identify any person who was a participant in the relevant procedure and who has not given such consent; or

(e) under an authorisation conferred by another written law.

51. Supervision

(2)It shall be the duty of the licence supervisor to secure —

(c)that proper arrangements are made for the keeping of human gametes, human eggs undergoing fertilisation and human embryos and for the disposal of any such gametes, eggs or embryos that succumb;

53Q. Offence — commercial trading in human eggs, human sperm or human embryos

(1)A person commits a crime if the person gives or offers valuable consideration to another person for the supply of a human egg, human sperm or a human embryo.

(2) A person commits a crime if the person receives, or offers to receive, valuable consideration from another person for the supply of a human egg, human sperm or a human embryo.

(3) A person who commits an offence against this section is liable to a fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

(4) In this section —

"reasonable expenses" —

(a) in relation to the supply of a human egg or human sperm includes, but is not limited to, expenses relating to the collection, storage or transport of the egg or sperm; and

(b) in relation to the supply of a human embryo —

(i) does not include any expenses incurred by a person before the time when the embryo became an excess ART embryo; and

(ii) includes, but is not limited to, expenses relating to the storage or transport of the embryo;

"valuable consideration", in relation to the supply of a human egg, human sperm or a human embryo by a person, includes any inducement, discount or priority in the provision of a service to the person, but does not include the payment of reasonable expenses incurred by the person in connection with the supply.

[Section 53Q inserted by No. 18 of 2004 s. 8.]

53T. Definitions

"excess ART embryo" means a human embryo that —

(a) was created, by assisted reproductive technology, for use in the assisted reproductive technology treatment of a woman; and

(b) is excess to the needs of —

(i) the woman for whom it was created; and

(ii) her spouse or de facto partner (if any) at the time the embryo was created;

"proper consent", in relation to the use of an excess ART embryo, means —

(a) consent obtained in accordance with the *Ethical Guidelines on Assisted Reproductive Technology* (1996) issued by the NHMRC;

(b) if other guidelines are issued by the NHMRC under the *National Health and Medical Research Council Act 1992* of the Commonwealth and prescribed by the Commonwealth Human Embryo regulations for the purposes of paragraph (b) of the definition of "proper consent" in section 8 of the Commonwealth Human Embryo Act — consent obtained in accordance with those other guidelines, rather than the guidelines mentioned in paragraph (a); or

(c) where an intended use is to provide a human embryonic stem cell line, the uses to which the human embryonic stem cell line may be put must have been disclosed and explained;

"responsible person", in relation to an excess ART embryo, means —

(a) each person who provided the egg or sperm from which the embryo was created;

(b) the woman for whom the embryo was created, for the purpose of achieving her pregnancy;

(c) any person who was the spouse or de facto partner of a person mentioned in paragraph (a) at the time the egg or sperm mentioned in that paragraph was provided; and

(d) any person who was the spouse or de facto partner of the woman mentioned in paragraph (b) at the time the embryo was created;

"State" includes the Australian Capital Territory and the Northern Territory.

(2) For the purposes of paragraph (b) of the definition of "excess ART embryo", a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if —

(a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or

(b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.

53W. Offence — use of excess ART embryo

(1) A person commits a crime if the person uses an excess ART embryo, unless —

(a) the use by the person is authorised by a licence; or

(b) the use by the person is an exempt use as defined in subsection (2).

Penalty: A fine of 300 penalty units or imprisonment for 5 years or both.

Summary conviction penalty: A fine of 60 penalty units or imprisonment for 12 months or both.

(2) A use of an excess ART embryo by a person is an **"exempt use"** for the purposes of subsection (1) if —

(a) the use consists only of —

(i) storage of the excess ART embryo;

(ii) removal of the excess ART embryo from storage; or

(iii) transport of the excess ART embryo;

or

(b) the use consists only of observation of the excess ART embryo;

(c) the use consists only of allowing the excess ART embryo to succumb;

(d) the use is carried out by a licensed ART centre, and —

(i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created where the suitability of the embryo is determined only on the basis of its biological fitness for implantation; and

(ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created;

(e) the use is carried out by a licensed ART centre and is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created; or

(f) the use is of a kind prescribed by the Commonwealth Human Embryo regulations for the purposes of section 10(2)(f) of the Commonwealth Human Embryo Act.

53ZE. Licence is subject to conditions

(1) A licence is subject to the condition that before an excess ART embryo is used as authorised by the licence —

(a) each responsible person in relation to the excess ART embryo must have given proper consent to that use;

Directions under the *Human Reproductive Technology Act 1991*

***2.12 Transfer of responsibility to report to the Commissioner of Health**
A licensee, including the holder of an exemption under section 28A of the Act, who accepts gametes or an embryo from another person for storage, is responsible for the provision of any report required in respect of those gametes or that embryo.

2.15 Reporting on excess ART embryos donated for research
A storage licensee must provide to the Commissioner of Health for inclusion in the registers, information set out in Part 3 of the Data Structure in Schedule 2 that is relevant to each excess ART embryo that has been donated for research.

2.16 Copies of reports to NHMRC Licensing Committee to be provided to Council
A licensee, including the holder of an exemption under section 28A, must provide the Council with a copy of any report provided to the NHMRC Licensing Committee in connection with an NHMRC licence held by the licensee.

1.6 Standards for an exemption for storage of excess ART embryos (holder of an exemption under section 28A of the Act)
The holder of an exemption from the requirement to hold a storage licence authorising the storage of an excess ART embryo under section 28A of the Act must ensure that.
(a) as a minimum, standards for practice, equipment, staff and facilities comply with good laboratory practice;
(b) any relevant conditions of the NHMRC licence are complied with; and
(c) any requirements established under the Act are complied with.

1.7 Application for renewal of a licence
A licensee who is the holder of a storage or practice licence must apply for renewal of a licence no later than 3 months before its expiry.

1.8 Renewal in relation to an exemption under section 28A of the Act
The holder of an exemption under section 28A of the Act must apply for a new exemption in relation to each NHMRC licence held.

1.9 Notification in relation to an exemption under section 28A of the Act
The holder of an exemption under section 28A of the Act must notify the Commission of Health of any change to the NHMRC licence for which the excess ART embryos are being stored.

3.4 Consent to use of embryo or egg undergoing fertilisation
Prior to the donation of an embryo or egg undergoing fertilisation for use in an artificial fertilisation procedure, any person to whom the licence applies must ensure that.
(a) effective consent to the donation and use is given by the person(s) for whom the embryo or egg was developed; and
(b) any person who donated gametes used to develop the embryo or egg, and the spouse or defacto partner of the gamete provider (if any) gave effective consent to the use at the time the donation was made.

3.5 Donors and recipients of gametes, embryos and eggs undergoing fertilisation to be aware of *Artificial Conception Act 1985
Any person to whom the licence applies, including an exempt practitioner, who proposes to use donated gametes, embryos or eggs undergoing fertilisation in an artificial fertilisation procedure must ensure that the donor(s) and recipient(s) are aware of the impact of the *Artificial Conception Act 1985* on the legal parentage of a child born as a result of the procedure.

3.6 Consent to allow an embryo to succumb
The licensee must ensure that any consent to storage of an embryo or egg undergoing fertilisation includes consent to remove the embryo or egg from storage and allow it to succumb at the end of any authorised storage period.

3.8 Consent for the use of excess ART embryos
The license supervisor must ensure that no embryo is provided for use in connection with an NHMRC licence unless.
(a) the embryo has been declared to be an excess ART embryo by the woman for whom it was created and her spouse or de facto partner (if any); and
(b) proper consent to the use of the embryo for the purposes authorised under the NHMRC licence has been given by each responsible person.

3.9 Donors of excess ART embryos for research to be informed that further, specific consent may be required
The licensee must ensure that donors of excess ART embryos for research are informed that further specific consent for use of the embryo in a particular project may be required in the future and that they may refuse to give such consent.

3.10 Donors of excess ART embryos for research to be informed of eligibility to apply for an extension of storage period
The licensee must ensure that donors of excess ART embryos for use in providing treatment to another person or couple are informed that they may be eligible to apply for an extension of the storage period of an embryo that has not yet been used. The donors should be given the option of indicating whether they want to be contacted in accordance with the provisions in section 24(3) of the Act if the embryo is still in storage.

***4.2 Additional information to be given in relation to the use of donated reproductive material**
The licensee must ensure that, prior to consent being given for the donation or use of donated human reproductive material in an artificial fertilisation procedure, all donors and recipients are given oral explanations, supported by relevant written information in a form approved by Council, including information about.
(a) the effect of the *Artificial Conception Act 1985*;
(b) information that is included on the registers in relation to the donated material, its use and the biological parentage of any child born as a result of the use;
(c) rights of donors, participants and children born as a result of the donation to access identifying and non-identifying information in accordance with the Act;
(d) the medical and social implications in relation to donation and for children born as a result of the donation;
(e) the need to refrain from unprotected sexual intercourse during the course of treatment to avoid confusion about the biological parentage of any child born;
(f) limitations on the storage periods permitted for the reproductive material and requirements of the Act in relation to seeking extension of the storage period.

4.3 Information to be given in relation to the use of donated embryos for a use requiring an NHMRC licence
The licensee must ensure that, prior to consent being given, persons wishing to donate excess ART embryos for a use which requires an NHMRC licence are given oral explanations, supported by relevant written information in a form approved by Council, including information about.
(a) procedures under Part 4B of the Act and the *Research Involving Human Embryos Act 2002* (Cth) for obtaining consent to the use of an excess ART embryo for a specific NHMRC licence, including advice that consent for a specific use may be requested at some future date and that the person has the right to refuse to give that consent;
(b) rights to place conditions on the uses to which the embryo may be put;
(c) rights to withdraw consent prior to use of the embryos; and
(d) limitations on the storage period for embryos, including advice that the licensee may apply for approval to extend the storage of an embryo unless the person who is donating the embryo has advised that they wish the embryo to be removed from storage at a specified time.

5.3 Cost of treatment to include time with approved counsellor
The licensee must ensure that the overall cost of treatment includes the cost of at least one consultation with an approved counsellor for each IVF cycle begun. The licensee must not provide a discount to a participant on the basis that the participant chooses not to use the counselling included in the overall cost of treatment.

5.5 IVF participants must be provided with information as to counselling entitlements
The licensee must ensure that participant/s proposing to undergo an IVF procedure is/are provided with information about their entitlements to counselling and the options that available in relation to how and when and if to take up the entitlement and that they are strongly encouraged to undertake such counselling.

5.7 Information about counselling to be provided to donors of eggs, embryos or eggs undergoing fertilisation where recipient is unknown to the donor
The licensee must ensure that where the recipient is unknown to the donor, the donors of eggs, embryos or eggs undergoing fertilisation, are provided with adequate information, in a form approved by the Council, that.
(a) strongly encourages the donor to seek assistance with decision making and counselling from an approved counsellor and provides a list of approved counsellors;
(b) sets out the availability of and entitlement to, counselling through the licensed practice; and

(c) provides information about the possible impacts of becoming a donor, including medical, social, secrecy and disclosure implications of donation.

6.10 Records of period of storage of embryos and eggs undergoing fertilisation
The licensee must ensure that.
(a) records are maintained to accurately reflect the expiry date of the authorised storage period for each embryo and egg undergoing fertilisation; and
(b) a system is in place to identify embryos or eggs undergoing fertilisation that are nearing the expiry of the authorised storage period and to notify persons on whose behalf those embryos or eggs are being stored.
Note: The licensee has a potential liability to the persons for whom the embryo or egg undergoing fertilisation is stored if the notification requirements in section 24(3) of the Act have not been complied with before the embryo is removed from storage. To avoid such liability it is in the interests of the licensee to ensure that the steps they have taken to notify the persons of the expiry of the storage period are reasonable. Such steps may include writing to the person at the last known address, writing to the person at an address obtained from an electoral roll search, or telephoning or contacting the person.s general practitioner or any other suitable third party.

6.11 Embryo or egg undergoing fertilisation must be allowed to succumb
The licensee must ensure that at the expiry of the authorised storage period for an embryo or egg undergoing fertilisation, the embryo or egg is removed from storage and allowed to succumb.

6.12 Extension of storage period for embryos and eggs undergoing fertilisation for use in an artificial fertilisation procedure
Note: The licensee cannot apply for an extension of the storage period for an embryo or egg undergoing fertilisation that is to be used in an artificial fertilisation procedure.
The licensee must ensure that.
(a) information is provided to persons on whose behalf an embryo or egg undergoing fertilisation is being stored for use in an artificial fertilisation procedure, about the possibility that the person may apply to the Council, using Form 8 in Schedule 1, for an extension of the storage period, and that such an application must be received by the Council at least one month before the Council meeting that precedes the expiry of the storage period;
(b) if required, assistance with completion of Form 8 is provided to a person who wishes to seek an extension to the authorised storage period.

6.13 Extension of storage period for excess ART embryos donated for research
The licensee or the person(s) for whom the embryo was developed may apply to the Council using Form 9 in Schedule 1 for approval to extend the storage of an excess ART embryos that have been donated for a use requiring an NHMRC licence.

6.14 Time for applications for approval to extend storage period of excess ART embryo
The licensee must ensure that an application for approval to extend the storage period of an excess ART embryo that has been donated for research is received by the Council at least one month prior to the meeting of the Council that precedes the expiry of the storage period.

***8.5 Restrictions on use of reproductive material donated prior to 1 December 2004**
A licensee must ensure that reproductive material donated before the commencement date of the *Human Reproductive Technology Amendment Act 2004* (1 December 2004) is not used in an artificial fertilisation procedure unless.
(a) each donor has been given information about the changes to the Act in relation to the rights of donor offspring who has reached 16 years of age to be given identifying information about the donor, and the donor has given consent after 1 December 2004 to the use of the donation in an artificial fertilisation procedure; or
(b) donated gametes are stored for a woman who wishes to have a full sibling for an existing donor child, and.
(i) the licence supervisor has not been able to contact the donor(s) to obtain his or her consent to the provision of identifying information to a future donor offspring who has reached 16 years of age despite reasonable efforts to do so; or
(ii) the donor(s) has been asked to consent to the provision of identifying information to a future donor offspring who has reached 16 years of age and has refused;
or
(c) an embryo was created before 1 December 2004, and.
(i) the licence supervisor has not been able to contact each person who provided gametes used in the creation of the embryo to obtain his or her consent to the provision of identifying information to a future donor offspring who has reached 16 years of age despite reasonable efforts to do so; or
(ii) each person who provided gametes used in the creation of the embryo donor(s) has been asked to consent to the provision of identifying information to a future donor offspring

who has reached 16 years of age and has refused;
or
(d) the conditions set out in section 49(2e)(b)(ii) of the Act have been complied with in respect of the donation.

SCHEDULE 5.PROTOCOL MANUALS
PART 1 REQUIREMENTS FOR PROTOCOL MANUALS

4.2 Protocols relating to data collection and reporting, including.
Protocols for maintenance of clinic Database/reporting to RTAC/RT Register and Annual Reporting requirements;
Protocols for database of gamete and embryo storage/ for managing embryo extensions

The law requires that the Council receives any embryo storage extension at least one month before it is due to meet next. In addition to this, your embryo storage period must still be valid at the time the Council meets to discuss this matter. For this reason, it is important that you have given some consideration to your situation and what you wish to do with your embryos – it can be very difficult to have to make a hurried decision.

If you wish to seek an extension of your embryo storage period, your clinic can provide help to ensure that your application meets the requirements under the Act.

Who has the responsibility to apply for an extension?

If you intend to store your embryos for your own use at a later date, or if you are intending to donate your embryos but a recipient has not yet been selected, you will need to apply for an extension. Your clinic is not able to do this on your behalf.

If you have donated them to another person or couple, you may have agreed to give this person or couple the responsibility of applying to the Council for any ongoing storage extensions.

Clinics can only apply for an embryo storage extension for you if you have declared your embryos to be excess to your needs (they are then considered “excess ART embryos”) and have donated your embryos to the clinic for approved NHMRC research purposes.

What happens if I don’t apply for an extension?

It is illegal for clinics to continue to store your embryos beyond ten years unless you are granted a storage period extension. If you have not made an application to extend the storage time to the Council and the authorised storage period expires, your clinic will have to allow these embryos to succumb. Under the law, Council is unable to approve an embryo storage extension once the authorised storage period has expired.

What if we can’t decide what to do with our embryos?

Some people find it very difficult to reach a decision regarding their stored embryos. Every person or couple needs to consider their particular situation.

People facing these decisions are encouraged to have counselling with an ‘Approved Counsellor’ to discuss their options and to assist with decision-making. Counselling will be required if you wish to donate your embryos to someone you know, but also can benefit anyone who is considering what to do with their embryos in storage.

Talking about these issues with other couples who have undergone IVF has also helped many people facing this complex decision.

What if we can’t agree, or our circumstances change?

In the situation where a couple is in disagreement, one of the couple must apply, before the end of the storage period, to the Director General of the Department of Health WA. The Director General may instruct the clinic to store the embryos until resolution of the disagreement, or a Court order is issued regarding this matter.

Where do I get more information about embryo storage?

Your clinic is able to provide you with assistance in completing an application and discussing your embryo storage issues.

You can also visit the Reproductive Technology Council website www.rtc.org.au for further information and for Council meeting dates, or contact the Reproductive Technology Council Executive Officer, on rtc@health.wa.gov.au

This document can be made available in alternative formats such as computer disc, audio tape or Braille, on request.

Reproductive Technology Council

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Government of **Western Australia**
Department of **Health**

Embryo storage

Delivering a **Healthy WA**

In vitro fertilisation (IVF) involves the creation of embryos outside of a woman's body to assist the conception of a child. In Western Australia, IVF and other assisted reproductive technologies (ART) are regulated through the *Human Reproductive Technology Act 1991* (Act). This Act also regulates matters regarding embryo storage.

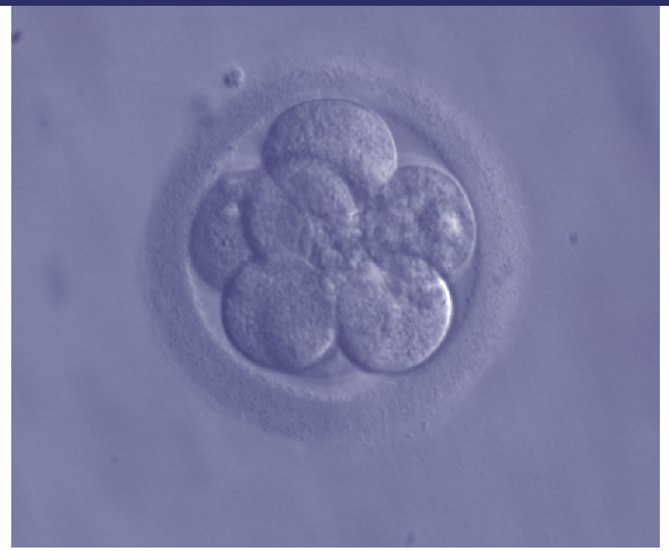
Most embryos created through IVF will be used with the aim of creating a child. However, those embryos that are not used will remain in storage. Individuals or couples can be faced with making what can be a difficult decision about the future of these embryos at the end of their permitted storage period.

How long can I store my embryos?

The current law allows licensed clinics to store embryos for a maximum of ten years. Under the law, the Reproductive Technology Council (Council) may approve the storage of embryos for a period of time beyond the ten years. However, this approval must be given on a case-by-case basis and only for special reasons.

How do I know when my embryo storage period is due to expire?

Your clinic will make contact with you about any storage fees and consent matters during the storage of your embryos. Your clinic should also send you further information after nine years of storage to help you consider your options as the end of the ten year storage period approaches.



In addition, the law requires that your clinic takes *reasonable steps three months* before the end of the authorised storage period to notify you that the storage period is coming to an end for your embryo/s. For this reason, it is important that you keep your clinic updated with any changes to your contact details.

What are our options at the end of our embryo's storage period?

Individuals or both members of a couple may choose to allow their embryos to succumb (or expire) at the end of their storage.

Other possibilities include:

a) seeking to keep your embryos for your own use at a later date;

b) donating embryos to others undergoing fertility treatment – this option may depend on your clinic and whether donated gametes were already used to create these embryos; or

c) donating your embryos for approved research under a National Health and Medical Research Council (NHMRC) Licence.

For any of these reasons, an embryo storage extension must be granted by the Council before the authorised storage period ends.

Aren't they our embryos to make decisions about?

Some people reasonably consider that they have a right to determine how their embryos are dealt with. While this position is understandable, the law does not include the right to hold embryos in storage indefinitely. The law requires that any extension to the storage of embryos can only be granted by Council for *special reasons*.

What special reasons can be approved by Council?

The law requires that consent to the storage of embryos must relate to the *probable future use* (implantation) of an embryo, or probable *donation for research* under an NHMRC licence.

There will be a wide variety of reasons for seeking to store embryos beyond ten years. To assist the Council to determine if these legal requirements are being met and that there are special reasons for your application, it is recommended that the reasons for your storage extension are clearly described on the application form. Documents supporting your extension request should be included with your application.

- If you are seeking to extend the storage for your own use of your embryos, it is suggested that you include a medical report supporting that you are still eligible to access IVF.
- If your intention is to donate your embryos for use by another person or couple or to the clinic for research, it will help the application process to include documents supporting this intention to donate. This may include a signed 'consent to donate embryos' form, or verification that you have started the counselling process prior to donation.