

WESTERN AUSTRALIA'S
HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991
and
HUMAN REPRODUCTIVE TECHNOLOGY
AMENDMENT ACT 1996

SUMMARY

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CONTENTS

Introduction.....	1
Administration of the Act	2
Offences.....	3
The Western Australian Reproductive Technology Council	4
Membership.....	4
Functions.....	5
Code of Practice.....	5
Eligibility Criteria for an IVF Procedure.....	6
Rights to decide over the disposition of Gametes and Embryos	6
Licensing	7
Registers	8
Framework of the Human Reproductive Technology Act	9

INTRODUCTION

The process of development of the policies in the Human Reproductive Technology Act took over six years from 1983 onwards. It involved three Government initiated committees, including a multi-party **Select Committee of the Legislative Assembly**, as well as a major demographic, clinical and economic **evaluation** of IVF in Western Australia. The Bill passed through both Houses of Parliament by August 1991 and came into full operation on April 8 1993. There was extensive **public consultation** during this process, including public submissions made on draft legislative proposals circulated in December 1989. The Human Reproductive Technology Act represented the culmination of this long and detailed process.

Most importantly this Act helps promote the **safe** and **beneficial** treatment of those who need to resort to reproductive technology in order to have a child, and ensures that they have adequate **counselling** and **objective information** to guide their decision-making. However it also ensures that the **wider community** is kept **informed** and **involved**, as the policies relating to the regulation of these technologies continue to evolve.

In 1996 the Act was amended by passage of the Human Reproductive Technology Amendment Act 1996 to allow, for special reasons, case by case extensions to the 3 year limit to embryo storage set by the principal Act.

This document is to introduce these Acts to you. There are separate information booklets by the Reproductive Technology Council for licensees and participants, and to indicate how others may participate in decision making under the Act. If you need more detailed information you are urged to acquire copies of the Acts and to seek advice, for example from the Executive Officer of the Reproductive Technology Council or a lawyer. This document is no substitute for that advice.

Also available from the Executive Officer is a compiled text of the Code of Practice.

ADMINISTRATION OF THE ACT

The Human Reproductive Technology Act is administered by the **Commissioner of Health**, subject to the **Minister for Health**. Extensive interpretation sections define important details, such as what is meant by the term "embryo", and who is the person responsible for a licensed practice.

The **Commissioner of Health** acts as the **Licensing Authority**, and grants licences for the practice of reproductive technology and the storage of human eggs, sperm and embryos. The Commissioner is to keep registers of information, that are vital for adequate monitoring and evaluation of the technology. The Act provides for reasonable inspection powers to persons authorised by the Commissioner of Health.

The Commissioner has power to: -

- give **directions** to a licensee, subject to the Act;
- **act as the Council** in taking decisions, but only with Ministerial approval, and if this is necessary in the interests of public health and the Council is unable to make the decision;
- require **advice** from the Council.

The **Reproductive Technology Council** established by the legislation is responsible for drafting a **Code of Practice** that sets both Rules for those who are licensed, and guidelines to assist in keeping the Rules. The Council is to submit an **Annual Report**, via the Commissioner to the Minister, on its own activities and those of the licensees, and this is to be tabled in Parliament.

The **Minister** has power to give directions to Council (except in relation to a particular licensee), provided these directions comply with the objects of the Act. If Council considers a direction to be outside the objects of the Act, it may report its disagreement with the Minister to Parliament, and all directions given by the Minister are to be included in the Annual Report of the Council.

The objects of the Act are:

- to **regulate** and **guide** the use of reproductive technology, by making sure that standards set by and under the Act are adhered to by licensees;
- to ensure that artificial fertilisation procedures are used only on participants eligible under the Act itself, with consideration of their welfare and the welfare of any child likely to be born as a result, and after participants have been adequately assessed medically as to the need for these procedures and informed and counselled as to their implications;
- to require that **equity, welfare** and **general community standards** are considered in any decisions about reproductive technology;
- to promote **public debate** on reproductive technology on an informed basis; and
- to allow **beneficial developments** in reproductive technology to take place.

OFFENCES

Offences in the Act include practising reproductive technology, or running a storage facility without a licence. These are needed to **enforce the licensing system**.

The Act also establishes a number of offences related to **IVF embryos**. It is an offence to carry out **research** involving a human embryo or to perform a **diagnostic test** on an embryo without Council approval. This approval may only be given for research or tests that are intended to be therapeutic and current scientific and medical knowledge demonstrate to be unlikely to harm the embryo. Offences also prohibit keeping a human embryo **beyond 14 days** of development, selling human reproductive material, **embryo flushing, cloning, genetic engineering** of embryos and procedures that create **hybrids**.

Other offences enforce the strict **confidentiality** provisions in the Act.

The Governor has the power to make **regulations** to give effect to the objects of the Act, and in that way could create further regulatory offences. Penalties for these offences include fines, and in the case of certain offences, fines or imprisonment or both.

THE WESTERN AUSTRALIAN REPRODUCTIVE TECHNOLOGY COUNCIL

This Act has established the **WA Reproductive Technology Council**.

Membership

The Council has **10 nominated members**, and an Executive Officer who is an employee of the Health Department. The Governor appoints the Council on the recommendation of the Minister, and for the majority of members (7) the Minister's recommendation is to be based on nominations made by organisations, four of which are named in the Act.

The nominating organisations named in the Act are:

the **Australian Medical Association**;

the **Royal Australian College of Obstetricians and Gynaecologists**;

the **Department for Family and Children's Services**; and

the **Law Society of Western Australia**.

Three other nominating organisations are to be selected by the Minister to represent interests relevant to the Act. The members, as far as possible, are to represent all the relevant interests in the community, with experts in **reproductive technology, ethics and public health**, and representation of **women's** interests, the interests of **parents, consumers of reproductive technology** and the interests of **children born of reproductive technology**.

The Minister is required, as far as possible, to recommend appointment of approximately equal numbers of men and women.

FUNCTIONS

The functions of the Council are to:

- formulate and review a **Code of Practice** to govern the use of artificial fertilisation and storage procedures carried on by licensees;
- **advise the Commissioner of Health** on the suitability of applicants, and compliance of licensees with conditions of their licences;
- make sure that any **research** carried out by or on behalf of a licensee on eggs, sperm, or participants, has general or specific approval of Council;
- **advise the Minister for Health** on matters related to reproductive technology;
- encourage and facilitate research into the **causes** and **prevention** of all types of human **infertility** and on the social and public health implications of reproductive technology; and
- to promote **informed public debate** and education on these issues.

CODE OF PRACTICE

The Act outlines in detail matters and **principles** to be considered by the Council in the development of the Code of Practice for licensees.

Licensing is dependent on compliance with this Code of Practice, which is to be in 3 parts -

- **Rules** - which establish standards binding on licensees;
- **Guidelines** - to assist licensees in complying with the Rules;
- Other notices and papers.

The Rules may refer to conditions of licence imposed by the licensing authority, either in general as required by the Act, or for individual licensees. Rules only become binding after Parliament has had an opportunity to review and disallow them, and a Rule will override any conflicting direction from the Commissioner. Directions from the Commissioner may also set standards of practice for licensees which must be complied with.

ELIGIBILITY CRITERIA FOR AN IVF PROCEDURE

The Act limits eligibility for an IVF procedure, so that only **heterosexual couples**, who are married or have been living together for five years and who are **infertile**, or whose child would otherwise likely to be affected by a **genetic abnormality** or disease, are eligible. The Act also states that the reason for the infertility must not be age. In addition the licensee must consider the welfare and interests of the participants and of any child likely to be born in decisions about whether or not to carry out a procedure.

The Act is silent about eligibility for artificial insemination.

RIGHTS TO DECIDE OVER THE DISPOSITION OF GAMETES AND EMBRYOS

The Act sets out who must **consent** to the keeping or use of gametes (eggs and sperm), eggs in the process of fertilisation and embryos, and who will have rights of control over them.

Gamete providers have rights of control over their own gametes, and must consent to any storage or use of the gametes they have provided, until they are used to create an egg in the process of fertilisation or embryo. When this occurs the rights transfer to the couple for whom this is carried out. Gametes may be donated, in which case these rights are passed on to the licensee or other recipient, who may only use those gametes as the Act allows.

Embryos or **eggs in the process of fertilisation** may only be created for implantation into a particular woman. Both members of the couple of whom the woman is a member must consent to any storage or use of an egg in the process of fertilisation or embryo. However,

- if the couple **disagree** over the use or continued storage of an egg in the process of fertilisation or an embryo, the Commissioner of Health shall, on the application of either member of the couple, direct the continued storage of the egg or embryo, until the issue is resolved by Court order or agreement;
- if **one member** of the couple **dies**, rights in respect of an egg in the process of fertilisation or an embryo vest in the survivor;
- **if both die**, the Commissioner of Health must, subject to the Act, direct that the egg in the process of fertilisation or embryo be made available for treatment of another woman, unless a Court directs otherwise; and

- the egg in the process of fertilisation or embryo may only be **donated** by the couple to another couple for the purpose of being implanted into the other woman, thus excluding donation for research purposes.

LICENSING

The Commissioner of Health has the power to grant a **licence** for the following activities:

- **artificial fertilisation procedures** such as **IVF** and **GIFT**; and
- the **storage** of human eggs, sperm or embryos.

The normally permitted storage period for embryos is 3 years, but an extension to this period may be sought from the Council on a case by case basis.

Neither of these licences directly authorises **research** on gametes, eggs in the process of fertilisation, embryos or participants: that requires Council approval.

The Act permits registered medical practitioners to apply for an **exemption** from the licence requirement for the purpose of performing **artificial insemination**. This is subject to certain conditions. Regulations specify others who may perform artificial insemination and yet be excluded from any requirement for a licence or exemption, and these are people, such as nurses, acting under the direction of a licensee.

Licenses may be **granted** by the Licensing Authority (Commissioner of Health) on the recommendation of the Council provided:

- the applicant is **suitable** and able to comply with terms or conditions of licence and the standards in the Act and Code of Practice; and
- the activity authorised by the licence is required to fulfil a **genuine social need**.

Licence and exemption holders are required to observe the **Rules** of the Code of Practice and comply with any **conditions** of licence or exemption and directions from the Commissioner, or face disciplinary proceedings. This may result in loss of, or restrictions on, licences or exemptions.

Provisions in the Act establish procedures for:

- **disciplinary hearings** by the Reproductive Technology Council; and
- **appeals** to a Judge of the Supreme Court against a decision as to licence or exemption compliance, or a failed application for a licence or exemption.

REGISTERS

The Act provides for the establishment and maintenance of **registers** by the Commissioner, containing prescribed information about participants, procedures and any children born as a result of treatment. The Code, directions or conditions of licence also detail specifications for **records** to be kept by licensees, and details to be provided by them, on request, in the form of reports to the Commissioner of Health. There are extensive provisions for the **confidentiality** of the information obtained in the administration of the Act which are backed up by penalties.

The registers must:

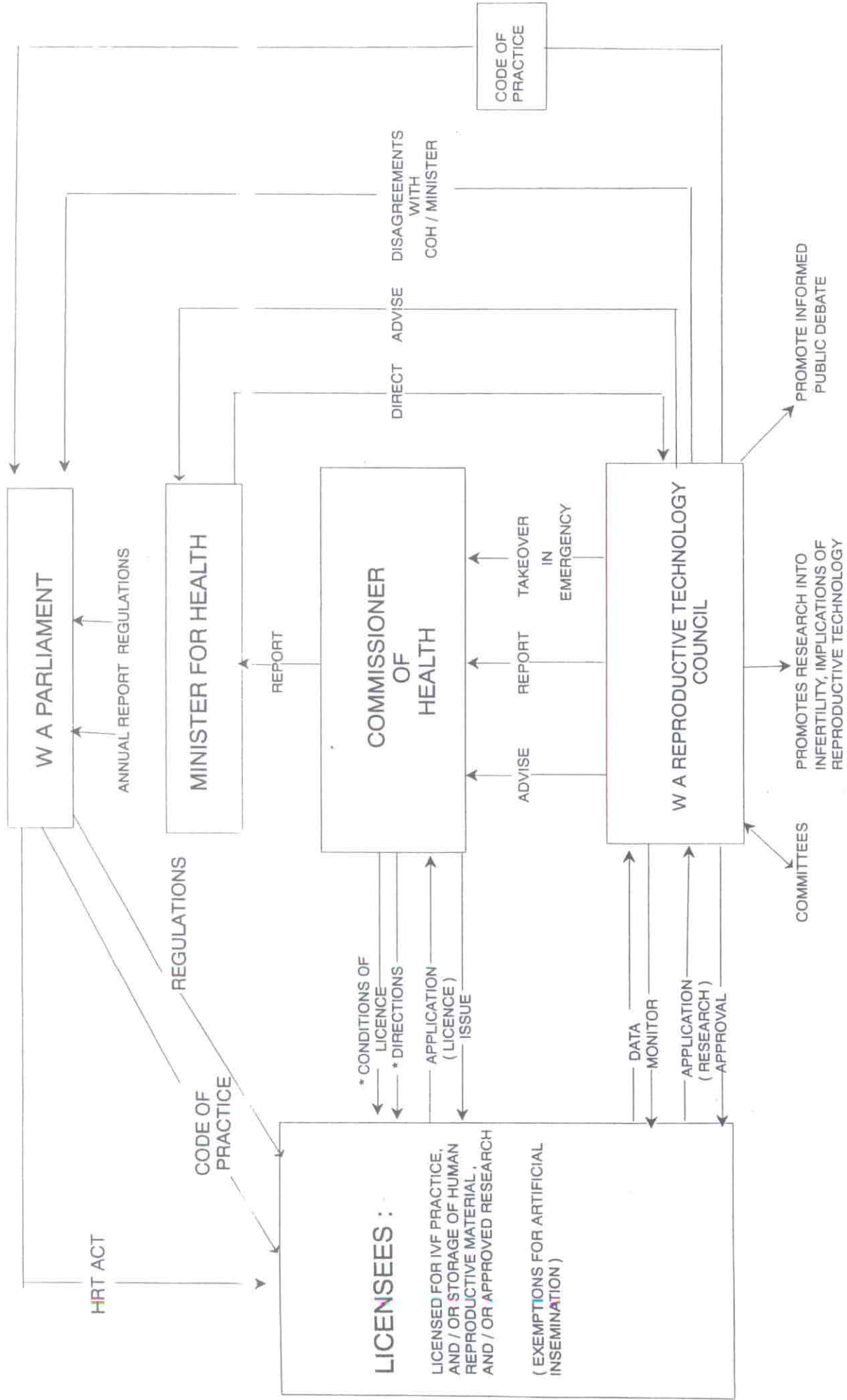
- record the identities of children born through artificial fertilisation procedures, as well as the identities of the biological parents of each child, and other relevant clinical information; and
- record the identities of all participants in the procedures, with required demographic and clinical information.

The registers will assist in the **monitoring** and **evaluation** of the practices and procedures covered by the Act, and facilitate **long term follow-up** of participants and children to document the safety, or otherwise, of the procedures.

It should be noted that, although this Act allows for the access by children of gamete donors to **non-identifying** information about their biological parents, it does not allow for their access to identifying information, and it is silent on the issue of **surrogacy**. These issues are to be covered in separate legislation, approved by Cabinet in April 1989 and to be administered by the Department for Family and Children's Services.

The Human Reproductive Technology Act (1991) received Royal Assent on 8 October 1991 and came into full operation on April 8 1993. There is to be a compulsory review after 5 years, which ensures that any developments in the technology, or the community at large, may be accommodated, if necessary, by the review.

FRAMEWORK OF THE HUMAN REPRODUCTIVE TECHNOLOGY ACT



* DIRECTIONS OR CONDITIONS FROM COMMISSIONER OF HEALTH CANNOT OVERWRITE RELEVANT SECTIONS OF THE CODE OF PRACTICE.