

**WESTERN AUSTRALIA'S  
REPRODUCTIVE TECHNOLOGY COUNCIL:  
MEMBERSHIP, POWERS AND DUTIES**

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*For further information please contact*  
The Executive Officer  
**Reproductive Technology Council**  
189 Royal Street  
**EAST PERTH WA 6004**  
Tel (08) 9222 4260 Fax (08) 9222 4236

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## 1. INTRODUCTION

The Human Reproductive Technology Act (1991) establishes the Western Australian Reproductive Technology Council, which has a central role in the regulation of artificially assisted human conception and related research in Western Australia.

This Council consists of 10 nominated members, with an additional *ex officio* member as its Executive Officer. The membership is broadly representative of all those in the community with interests in reproductive technology and the issues surrounding it. Fundamental functions of the Council are to compile a Code of Practice for those licensed to carry out reproductive technology, to monitor compliance with this and to consider applications, and where appropriate grant approval, for research carried out by these licensees. However, the Council has important roles as an advisory body to the Minister and Commissioner of Health on matters related to reproductive technology and in promoting informed public debate and consultation on issues relating to infertility and reproductive technology and their widest ramifications.

This paper elaborates in detail on the membership and proceedings of Council, its functions and responsibilities.

## 2. MEMBERSHIP, RELATIONSHIPS AND PROCESSES

### 2.1 Membership [S.8,9]

The Council is to consist of **10 nominated members** with an **ex officio** member, an employee of the Health Department, as its **Executive Officer**. The **Chairman of Council** is appointed by the Governor on the recommendation of the Minister, from among the nominated members of Council [Sch.1]. Council itself must appoint a **Deputy Chairman** from its membership, and if neither Chairman or Deputy Chairman is present at a meeting, must then select a Chairman for the proceedings.

The 10 nominated members are appointed by the Governor, on the recommendation of the Minister. **Seven** of these recommendations are to be made from panels of two or more names **submitted by organisations named in the Act itself or regulations**. Organisations named in the **Act** are:

- the Royal Australian College of Obstetricians and Gynaecologists;
- the Australian Medical Association;
- the Law Society of Western Australia; and
- the Minister for Community Services.

The Minister for Health in his second reading speech, undertook to name in **regulations** organisations representing the interests of reproductive technology practitioners, participants and women. The relevant bodies are named in the WA Reproductive Technology Council (Nominating Bodies) regulations 1992. The remaining **three** nominations will be made by the **Minister**.

In making all recommendations the Minister is to endeavour to ensure that there are approximately **equal numbers of men and women** on the Council, and representation of the interests of **women, of parents, of the children born of reproductive technology, of participants and that there is expertise in reproductive technology, relevant experience in public health matters and relevant ethical guidance among the membership.** Members are generally appointed for up to three years and may be reappointed. However, one-half of the nominated members on the inaugural Council are to hold office for only 18 months to allow some continuity at the initial turnover of membership [Sch.3].

Limitations to be imposed are that no one person is to be the sole representative of more than one interest specified in the Act and there is to be no more than one member of Council at any one time who is a licensee or who has a pecuniary interest in the practice of a licensee [S.9(2)(d)(ii)]. The Minister has an important role in directing whether or not a member has a direct personal or pecuniary interest in a matter before Council, such that they would be ineligible to vote [Sch.6].

Thus the Council has a broad range of expertise and interests from its own membership, rather than, for example, being a body with membership predominantly representing the interests of those directly involved in reproductive technology as practitioners and participants. However, the Council may appoint **committees**, consisting of its own members and others, to provide it with specialist advice as may well be necessary for it to carry out its duties properly [S.10]. The Minister is to approve the constitution of a Committee, its terms of reference and the conditions of appointment of non-Council members, but otherwise the Council may instruct the Committee and decide on its membership [S.10], and obtain a written report from the Committee as it requests [Sch.9].

The Minister may appoint **deputies** to act, when necessary, as members. These appointments are generally based on the nominations of the various organisations where this is relevant [Sch.2], although in certain circumstances, such as when a deputy cannot act or there is no nominated deputy, the Minister may appoint a person representative of the appropriate interest. The Council can also resolve to **delegate** certain of its responsibilities, other than its function to advise the Commissioner on disciplinary matters [S.11]. It may delegate to a Council member, one of its committees, the Commissioner of Health, a public authority with a relevant legal duty or power or approved by the Minister, or, if approved by the Minister, to some other person engaged in the administration or enforcement of the Act. If delegation is not to a member or committee of Council the Commissioner of Health has to be satisfied with the delegate and the matter published in the Gazette [S.11(2)]. The Council may also, if further approved by the Minister, authorise a delegate to further delegate any function [S.11(3)].

## **2.2 Meeting Processes**

The office of a nominated member becomes vacant if that member resigns, dies, is absent without leave of Council from three consecutive meetings of Council, becomes bankrupt etc., or is removed from office by the Governor on the recommendation of the Minister for misbehaviour, neglect of duty, or incompetence, etc. [Sch.5]. Whether or not a member has a direct personal or pecuniary interest in a matter arising before Council may need to be decided by the Minister [Sch.6(6)], and having such an interest that is undisclosed may amount to "misbehaviour".

Six members eligible to vote constitute a **quorum** for a meeting. The Chairman has a deliberative vote and if a vote is tied may have a casting vote, but only at a subsequent meeting where the same issue is voted upon. The Executive Officer cannot act as Chairman of a meeting, but can vote [Sch.7].

### 2.3 Funds and Staffing

A member and any person appointed to a committee, or requested to attend a meeting of the Council or a committee, is entitled to receive **sitting fees** if not a member of the Public Service, or other allowances as determined by the Minister [Sch.4].

**No detailed provisions in the Act specify funding or staffing levels** for the implementation of the Act and Council activities. However, the Council may make arrangements with the Minister and the Public Service Commissioner to use the services of employees or facilities of the Public Service or a State Agency. The Council may also, with prior Ministerial approval, engage consultants as it considers necessary. Where staff are appointed to carry out activities necessary for the administration of the Act, they will hold office under the Public Service Act 1978 [S.58].

### 2.4 Relationship of the Council to the Minister

The **Council** is to act as an **advisory body to the Minister** on reproductive technology matters [S.12]. It must also consider proposals made by the Minister about its own affairs, reporting to the Minister on its functions or information it holds if requested by the Minister or the Commissioner [S.5(7)]. If required by the Commissioner, it must also consult with the Minister on major new initiatives. The Minister may request access to Council minutes [Sch.7(9)], and has an important role in determining whether or not a member has a personal pr pecuniary interest in a matter under consideration by Council [Sch.6].

Furthermore, the Minister may **give instructions** to the Council and the Council must carry these out. There are, however, limitations as to these instructions. They must be in line with the objects of the Act, not relating to an individual licensee and are to be included in the Annual Report to Parliament. If the Council and the Minister cannot agree that the instructions are within these limits, the Council may report the disagreement to each House of Parliament, so discouraging intervention by the Minister for simply political reasons. The Minister is to approve any arrangements made by Council to use staff or facilities in the public sector and any contracts made with consultants [S.58(1),(2)]. The Minister is also to approve how and where registers are to be kept [S.45(1)].

The Minister can recommend the making of **regulations** concerning any matter that may be dealt with by the Code of Practice, and these may override the Code. However these must be required urgently or for public health reasons [S.5(4),13(2)], and are to be in line with the objects of the Act [S.60(1)].

Rules Part 1 of the Code of Practice, are normally to have effect as subsidiary legislation [S.15(1)(a)] if Gazetted and laid before each House of Parliament and brought into operation on a date later also Gazetted [S.16]; but can be brought into immediate effect if Regulations specifically so provide.

## 2.5 Relationship of the Council to the Commissioner of Health

The **Commissioner of Health** is responsible for the **issuing of licences** under this Act [S.27]. The Council has a vital **advisory role** to the Commissioner, in relation to reproductive technology matters in general and specifically in relation to the licensing of applicants and evaluating and monitoring their compliance with requirements for licensing [S.13].

**Directions** may be given by the Commissioner and are not subject to the appeal procedure, but the power is very limited in that -

- (a) the **Council** is not required to enforce a direction by disciplinary action [S.14(3)] unless it is -
  - (i) consistent with the Code; or
  - (ii) not inconsistent with existing ethical guidelines or professional criteria for the time being brought into force by Regulation and as laid down by the National Health and Medical Research Council or established by the Fertility Society of Australia,

and is also consistent with the principles set out in the Act;

- (b) a direction does not have effect at all, to the extent that it is inconsistent with the Regulations or the Code [S.5(5) and S.31(2)];
- (c) the Commissioner is required to give due regard to the principles set out in the Act [S.31(2)]; and
- (d) the Commissioner is required to give reasons [S.13(8)] and a reasonable opportunity to show cause why the direction should not have effect.

In spite of the power of the Commissioner of Health to issue directions, the **Council** and its **Code of Practice** maintain a role of pivotal importance in the implementation of this Act, owing to the ability of provisions of the Code to override directions [S.31(2)]. In practice directions issued by the Commissioner of Health may be as advised by Council.

In certain circumstances the Commissioner can act as the Council in taking decisions. The position is that if the Council can agree and does make Rules that Parliament does not disallow, those Rules are paramount. But if the Council can not agree or does not make Rules, or Rules made are disallowed, then the Minister may instruct the Commissioner to discharge the function of the Council [S.12(2)]. The Minister has jurisdiction over disputes between the Council and the Commissioner, and in so doing is answerable to Parliament [S.13(3) and (6)]. Given time, the Commissioner could make Rules and lay them before Parliament, as though the Commissioner had been the **delegate of the Council** [S.13(2)]. In fact, and where time does not so permit, the Commissioner would probably proceed by way of directions. In either event, once Rules are in place the power to give directions would probably only be used in an administrative context.

However, when a decision is urgently needed in the interests of public health and Council has not time to, or cannot, make a decision, the Commissioner, with written instruction from the Minister, can make the decision and instruct the Council to carry it out. If the decision is not then discharged by the Council, the Commissioner of Health may carry it out. Any disagreement between Council and Commissioner is to be decided by the Minister [S.13(2)]. In all cases where this intervention occurs the matter must be included by the Commissioner of Health in the annual report to Parliament, again maintaining the public accountability of any intervention into Council's activities.

Council is to provide the Commissioner with this annual report, which the Commissioner of Health is to hand on to the Minister who is to lay it before both Houses of Parliament [S.5(6),Sch.11]. Details of what is to be reported are covered in the Schedule.

### **3. FUNCTIONS: OVERVIEW**

#### **3.1 Advisory function to Minister and Commissioner of Health**

As already stated the Council is to advise the Minister on reproductive technology matters [S.14(1)(a)] and to advise the Commissioner in particular on matters relating to licensing, administration and enforcement under the Act [S.14(1)(b)]. These issues are discussed in detail later in this paper. Most importantly, prior to full proclamation of the Act, the Council is to advise the Commissioner on terms or conditions that are to be imposed on the licences and on the suitability of any applicant for a licence. This is of urgent importance for those with current practices requiring licensing.

#### **3.2 Compilation of the Code of Practice**

Council is responsible for the compilation of the Code of Practice, its publication and review [S.14(1)(c)], after consultation with those in the community with relevant expertise or interest in the issues involved.

#### **3.3 Consideration and approval for research proposals**

Council is to consider applications for, and where appropriate grant approval to, research carried out by or on behalf of licensees and involving any human egg, any gametes intended for use in an artificial fertilisation procedure, any egg in the process of fertilisation or embryo or any participant. Details of this approval process and its guidelines are covered in detail later in this paper.

#### **3.4 Public duties**

Council is to encourage and **facilitate research into the causes, prevention of treatment of all types of infertility and into the social and public health implications of reproductive technology** [S.14(1)(d)]. It is also to promote **informed public debate and consultation** on the "ethical, social, economic and public health issues" that arise from reproductive technology [S.14(1)(g)]. The Annual Report submitted by the Council to the Commissioner, and then via the Minister to Parliament, ensures that details of the activities of licensees and any significant developments or trends relating to reproductive technology are available to the public [S.5(6)]. At all times in carrying out these public duties Council should be guided

by the Objects of the Act [S.4], and attempt to ensure that beneficial progress is encouraged, unsuitable practices discouraged or prohibited and that the welfare of all participants, children born and the wider community are considered.

There is no further elaboration of these public duties in this paper, other than in relation to the need to consult on the Code. This is not because they are not of vital importance, rather that the responsibilities are less well defined and constant.

### **3.5 Collaboration and communication with other similar bodies in Australia and elsewhere [S.14(1)(h)]**

## **4. COUNCIL'S ROLES IN THE LICENSING PROCESS**

### **4.1 Setting the standards to be adopted as terms or conditions of licence**

Council develops and reviews standards for licence conditions, some guidelines for which are set out in the Act, and has arranged for regulations to prescribe the format of licences etc.

This subject is further discussed in the "Guide to the Duties and Powers of the Minister and Commissioner of Health under the Human Reproductive Technology Act".

### **4.2 Assessing applicants**

Council assesses the suitability of applicants and advises the Commissioner of this. The process is also discussed in the "Guide to the Duties and Powers of the Minister and Commissioner of Health under the Human Reproductive Technology Act".

### **4.3 Monitoring compliance**

**Council is responsible for monitoring of compliance of licensees with provisions of the Act, terms or conditions of licence and directions from the Commissioner.**

The **extent of any monitoring and evaluation** is determined by Council, subject to fulfilling its functions and the availability of a suitable budget and staffing [S.59(1)]. The annual report required from Council [Sch.11] must contain statistical information on the activities of licensees for the previous financial year, and details of their research. Whether this information is to be reported by licensees [S.47(1), S.46(4)] or collected by an officer authorised by the Commissioner of Health [S.3(1), 54] from records kept by licensees may vary [S.44(3)(c),(6)].

In all its administrative or monitoring activities Council has a duty to maintain the **confidentiality** of any identifying information it deals with [S.49]. Although it may require access to identifying information to carry out its duties, as far as possible it should handle information without the inclusion of identifying information [S.49(4)].

### **4.4 Disciplinary action**

#### **4.4.1 Complaints for an offence**

All proceedings for an offence under this Act are to be instituted in the name of the Commissioner of Health [S.56(1)] but the Council may have a role in initiating this process in its advisory capacity.

#### **4.4.2 Disciplinary proceedings for breaches of licence conditions, etc**

##### **(i) Overview**

When a licensee breaches a condition of licence or a direction this is not an offence unless special regulations specify that it should be, however it may constitute grounds for disciplinary action against the licensee [S.34]. A number of matters may be subject to

**disciplinary proceedings** against licensees and Council has several clear cut roles in these proceedings, as well as its continuing advisory role to the Commissioner.

If the licensed practice is not properly conducted in accordance with the licence, or the person contravenes a requirement of the Act, or is convicted of an offence [S.39] a person to whom the licence applies may be liable. The Commissioner of Health can impose penalties ranging from a reprimand to cancellation of a licence [S.40], but there are several provisions which may mitigate the penalties. If it could be proved that the licensee could not reasonably have been aware of any contravention, the licensing authority cannot impose certain penalties, such as cancellation of licence [S.40(3)]. Rather similar restraints appear at S.52(3) and S.53(1)(b) where the liability is vicarious.

Where a person appears to the Commissioner to be liable to a relatively minor penalty [S.40(1)(a) to (f)], the Commissioner may make an immediate decision and issue a warning or impose the penalty. A written notice of the proposed decision must be given to the person liable if that is practicable, or published in the Gazette if not, and the person said to be liable must be given a specified period to respond and the penalty will only be imposed if the person consents [S.37(3)]. If that person does not consent to the determination or if the person appears liable to a more serious penalty, the matter must be referred to Council. Council may then establish a committee of inquiry into the matter, or must do so if the Commissioner requires this [S.38].

**Disciplinary** action may be commenced by way of either of two processes -

the first process is a **summary determination** made by the Commissioner and reported to Council [S.37]; and

the second process is a hearing before a **committee of inquiry** appointed by **Council** and reporting to the **Council**, which in turn advises the Commissioner who then makes a determination in accordance with that advice [S.38].

## (ii) **Summary determination**

This **summary determination** process is designed to save time and costs in minor matters or those not disputed. The distinctive features are -

- (a) it requires that the Commissioner give written notice setting out the reasons why it is proposed that a warning or penalty should be imposed and giving the person concerned a chance to respond [S.37(2)];
- (b) the person concerned can accept the proposed warning or penalty, or can try and convince the Commissioner not to impose it [S.37(3)];
- (c) the only penalty which can be imposed is of the minor kind set out in S.40(1)(a) to (f);
- (d) if the person concerned does not consent, a penalty can only be imposed if the Commissioner reports the matter to the **Council** and, after a committee of inquiry has

looked into it, the **Council** advises the Commissioner to impose a penalty - which then could be of a more severe kind as set out in S.40.

**(iii) Committee of inquiry**

The **committee of inquiry** process has also been designed to save time and costs, but is intended for use where the matter alleged is of a serious nature or is disputed. The distinctive features are -

- (a) the final determination remains with the Commissioner, acting on advice of the **Council**;
- (b) the committee is appointed by the **Council**, and makes its recommendations in writing to the **Council**;
- (c) the function of advising the Commissioner can not be delegated to the committee, but remains with the **Council** [S.11(1)];
- (d) persons who are not members of the **Council** may be appointed to a committee, but there must be some members on it [S.10(1)];
- (e) personal or pecuniary interests must be disclosed, [Sch.Cl.6] and any person who has such an interest may be excluded [Sch.Cl.7(7)], otherwise a committee may determine its own procedures [Sch.Cl.9] unless regulations otherwise provide [S.38(9)];
- (f) findings are made on the balance of probabilities [S.38(1)(a)]. The criminal test of proof beyond reasonable doubt would be unrealistic given the nature of medical matters;
- (g) a hearing may be dispensed with and the matter dealt with by written submissions, if the person concerned agrees [S.38(2)(a)];
- (h) if it goes to hearing -
  - (i) the committee may be assisted by a lawyer appointed by the **Council** [S.38(2)(b)(ii)]; and
  - (ii) the person concerned may be represented, by a lawyer or anyone else suitable [S.38(2)(b)(iii)], and may not even need to be present [S.38(2)(b)(iv)];
- (j) a committee may summons witnesses, and examine on oath [S.38(2)(f)] but must afford the person concerned the right of cross-examination, calling witnesses and making submissions [S.38(2)(b)(i)];
- (k) a committee may require a person appearing before it, and others whose conduct becomes relevant, to answer questions [S.38(2)(g)] and such a person will not be excused from the requirement merely to avoid self incrimination but the evidence given has restricted admissibility [S.38(3)] and the person giving it is afforded

protection [S.38(4)]. If it were not so, matters within the exclusive personal knowledge of, say, the surgeon operating or a person performing a laboratory procedure, could not be brought out in evidence;

- (l) the committee may take into account findings made in other proceedings, so is not required to go over the same ground again [S.38(5)]; and
- (m) the proceedings may be in camera [S.38(9)].

#### **4.5 Appeals - Council's role**

Appeals against various decisions of the licensing authority lie with a Judge of the Supreme Court [S.42]. Council has no direct involvement in any Appeal. However, the Executive Officer may need to be involved in providing written details to allow the appeal to be considered, and the Council must give effect to the decisions of the Judge [S.42(5)].

#### **4.6 Compiling, reviewing, publishing the Code of Practice**

##### **4.6.1 Overview**

The **Code of Practice** is central to the licensing system established by the Human Reproductive Technology Act, [S.39(2)] and sets out the **Rules and standards of practice** for licensees. Council has the function of **compiling, reviewing and publishing** this Code [S.14(1)(c)], which is to be in three parts.

**Part 1** - will set out **Rules** which, once ratified by Parliament, must be complied with by licensees. These Rules may refer to conditions imposed on a licence by regulations or directions, or by specific endorsement on a licence.

**Part 2** - will contain **guidelines** to set out the **ethics and relevant professional information**, to assist a licensee interpret and keep the Rules.

**Part 3** - contains **notices** and other information authorised for circulation by Council.

While Part 1 should be in language understandable to those not medically qualified, Part 2 may be quite technical [S.15(2)]. The Code may refer to other printed texts [S.15(2), 60(3)]. Basically the Rules of the Code are of fundamental importance and a licensee must comply with these or be liable to disciplinary action. However, whether or not the licensee followed the guidelines may assist in establishing whether or not the licensee was liable for disciplinary action [S.15(4)], or whether as an applicant for a licence that person is suitable. Of fundamental importance in its compilation of the Code is that Council must consult with experts and those interested members of the community.

The Code of Practice will come into operation after its ratification by Parliament. This ratification process may be passive, as it will occur automatically if neither House of Parliament passes a resolution disallowing any proposed Rule within 14 sitting days of the Code being laid before them [S.16(2)]. Rules are then to be published in the Gazette [S.16(2)]. A compiled text of the Code and any relevant texts referred to in it, must be

available from the Council, and the Executive Officer must ensure that new Rules or guidelines are brought to the attention of licensees [S.16(5)].

The guidelines will deal with ethical and medical concepts not readily communicated in the language of the law. That is why a Rule may be brought into effect by way of Regulations rather than as a Regulation. Whether the Rule is brought into effect by way of a Regulation (the Regulation itself being subject to disallowance under S.42 of the Interpretation Act) or is Gazetted and then laid before Parliament and not disallowed [S.16(3)], is material only as to timing. Either way Parliament may examine and disallow the proposal - but in the case of a Rule laid before the House it can not be amended or substituted by that House [S.16(2)(b)]. This is because of the technical, probably medical, nature of the subject matter.

Conditions not originally contained in a licence may be introduced generally by the Rules or specifically in relation to that licence may be imposed by the Commissioner. Any condition imposed by the Commissioner can only have effect if notice of it is given [S.42(1)] and no appeal to a Judge of the Supreme Court is made within time.

#### **4.6.2 What the Council must include in the Code of Practice**

The Council, in compiling its Code, must "have regard to" principles set out in Sections 17, 22-26 of the Act. These sections give some detailed instructions as to how and when these principles are to apply.

The Council is specifically directed by the Act to prohibit mixing of reproductive material in a single artificial fertilisation procedure and so creating confusion as to the biological parentage of any child born. It is also specifically directed to prohibit the development of any egg in the process of fertilisation or embryo other than "with a view to its future implantation into a particular woman" [S.17].

The Act elaborates on a number of situations where consent is to be given, in relation to keeping and use of human reproductive material and its storage [S.22]. Guidance to the Code aims to ensure that any consent given is "effective". This guidance includes instructions on how the consent is to be given and that the Code must provide the opportunity for the participant to receive "proper" counselling [S.22(7),(8)].

The Act directs the Code in some detail as to who is eligible to be treated by IVF. However, certain considerations balancing the welfare and interests of the participants and any child likely to be born, remain to be weighed up by the licensee before carrying out the procedure [S.23].

The Code must ensure that the primary purpose of storage of any egg in the process of fertilisation or embryo is its "probable future implantation", and that for an egg in the process of fertilisation or embryo the maximum time of storage is to be three years. The Code must also be compiled such that it is clear who, under any particular circumstances, has the right to make decisions about what should be done with gametes, eggs in the process of fertilisation or embryos [S.25,26].

#### **4.6.3 What the Council may include in the Code of Practice**

A wide range of power is given in the Act for the Code to potentially regulate a variety of practices and procedures [S.18, 20, 21]. Details of record-keeping and reporting by licensees could be in the Code, or in directions from the Commissioner of Health [S.31, 44]. In relation to research the Code may set out how general or specific approvals may be applied for, and when given including a role for an Institutional Ethics Committee in the granting of approval [S.18(h),20,21(k),(n)].

The potential exists for the Code to elaborate in great detail on assessment of participants including donors, counselling, the keeping of records, transfer and storage of human reproductive material and treatment itself [S.18,21].

#### **4.7 Council's role in setting enforceable standards of practice prior to implementation of the Code**

Until the Code of Practice has been compiled by the Council and ratified by Parliament, Council must ensure that **Interim Provisions** are in place. These provisions are to be put in place by directions from the Commissioner of Health, and may relate to NH&MRC or RTAC guidelines as set out in regulations [S.14(3)] or to the principles spelled out in various sections of the Act [S.19.2]. There are also registers of information and record-keeping standards that have been established by directions from the Commissioner of Health and these will later be continued under the Code of Practice. Directions from the Commissioner are usually based on the advice of Council. On ratification of the Code its provisions would, however, override any conflicting directions from the Commissioner of Health [S.31(2)].

#### **4.8 Records and registers**

##### **4.8.1 What the Act says: Council's role**

The Commissioner must establish the **registers under the Act**, but the **Council has a vital advisory role** as to their content, uses, etc. Through the directions and the Code of Practice Council has a role of central importance in decisions as to what records are to be kept by licensees and what information provided from these records for registers.

Interpretation of the Act shows that basically any information about artificial fertilisation procedures or participants, including identifying information, must be included in these registers, if the Act requires this in the form of subsidiary legislation, such as the Code of Practice.

The establishment of a number of registers is required by the Act, and their maintenance and effective use is fundamental to the fulfilment of the Objects of the Act and for Council to credibly carry out its required functions. However, the Act also places on those maintaining the registers strong provisions for their *confidentiality* [S.49]. Furthermore, as far as possible, any activities of Council should be carried out without identifying information [S.49(4)].

There appears to be increasing community concern over identifying information being kept in central registers. However, with passage of the Act, the need for ongoing monitoring and evaluation of the procedures and the need to balance public and private interests in reproductive technology has effectively been endorsed by Parliament. Council has then a pivotal role in balancing these interests and implementing the requirements of the Act.

The Act states that **beneficial** developments in reproductive technology should be allowed, and that the standards of the technology practised should be "**proper and suitable**". Council must promote informed public debate, on matters including public health issues that arise from the technology. Council must also monitor the compliance of licensees with their licence conditions and the Code of practice. Data collected from effective registers is an essential element of the research needed for Council to comply adequately with these provisions of the Act.

Under the requirements of the Act the **identity** of participants, donors of reproductive material or children born is included in the information stored in the registers [S(45(1)(a))]. The IVF and Donor Registers that have been established include identifying information, on donors of reproductive material and their offspring, as well on all participants. The details specified for registration on these registers may be set out in Regulations, Directions given by the Commissioner or the Rules of the Code of Practice.

#### **4.8.2 Why the Registers are being kept.**

At least **three** fundamentally different reasons **for** the maintenance of registers can be distinguished, and a variety of different issues are raised in relation to different types of registers. The Registers facilitate the management and implementation of the licensing process, allow long term public health studies on participants or children born, and store information related to donors and their children. With regard to the Donor Registers, under the Act there is a right of access only to non-identifying information.

Effective **long-term studies** of outcome after IVF, necessary to provide information on the long-term safety of the procedures. To date no long-term studies of IVF have been carried out, although following a 1990 consultation on the place of IVF in infertility care, **the WHO has recommended that such studies should be carried out, particularly in relation to ovulation induction.** These studies would add information to the vital question posed in the Objects of the Act, as to whether or not the procedures are beneficial. Registers containing identifying information facilitate this type of research into the outcomes of IVF, by allowing linkage of IVF data directly with other valuable data bases, such as the Cancer registry or the Maternal and Child Health Data Base. Also, WA IVF data could also be used to contribute to larger National or multi-national studies, using the State data-base to collect information that can only be collected locally from such linkage to other local data.

The Minister of Health, as required by the Act, in 1993 gave instructions as to how and where the Registers were to be kept. These instructions include details of strict confidentiality provisions, that are in addition to the confidentiality provisions in the Act itself.

## **5. COUNCIL'S ROLE IN RELATION TO RESEARCH AND DIAGNOSTIC TESTS**

### **5.1 Assessing projects of research**

One of Council's most important roles is to **assess**, and where appropriate **grant approval for, research** conducted or facilitated by a licensee. Independent research, not facilitated by

a licensee, is not subject to restriction by this Act, but otherwise a licensee planning any research involving human eggs, gametes intended for use in IVF or DI, any egg in the process of fertilisation or embryo or any participant, must have the approval of Council to be carried out [S.20(2),(3), 27(2),(3)].

However Council may, as is to be detailed under the Code, grant **general approval** for research of certain types [S.20(4), 21(m)] and recommend general standards and ethics applicable to research [S.20(5)(c)] and criteria for assessment of applications to carry out research [S.20(m)].

Of vital importance is that Council has (as enabled under the Act), made provisions for inclusion in the Directions or the Code to ensure adequate standards for **counselling** and the obtaining of "**effective consent**" from participants. This includes consent for research to be carried out involving them or their gametes, eggs in the process of fertilisation or embryos [S.20(5)(b)].

Council may officially recognise an **Institutional Ethics Committee** that is to have an important role in granting approvals [S.18(1)(h)]. In particular it may recommend writing into the Code or directions a provision that the approval of such an IEC is necessary prior to introduction of any particular practice or research [S.21(n)]. Also, any decision or report from the IEC relating to a particular research project must be considered by the Council, which may in fact adopt the IEC's decision as the basis for its own decision on the project [S.20(6)]. Council is to establish how licensees are to seek research approval and report to an IEC or Council [S.20(5)].

With regard to **human embryo research** there are a number of limitations set by the Act to what research or experiments Council may approve. In particular it is to be an offence for a person, whether or not a licensee, to carry out research on an egg in the process of fertilisation or embryo without Council approval [S.7(1)(a)]. And Council is given the difficult responsibility of ensuring that the only research it is to approve is that intended to be therapeutic for the egg or embryo and, based on existing scientific and medical knowledge, is unlikely to be detrimental to the wellbeing of any egg in the process of fertilisation or embryo [S.14(2)]. The inclusion of an egg in the process of fertilisation in these restrictions and instructions elsewhere in the Act to the Council to prohibit the creation of an egg in the process of fertilisation or embryo other than with a view to implantation [S.17(b)], mean that experiments involving early phases of fertilisation can probably not be given Council approval.

## **5.2 Granting approval for diagnostic procedures involving an egg in the process of fertilisation or embryo**

Council is to be involved in decisions as to which types of **diagnostic procedures** are to be allowed under the Act, and which will break the law. As for embryo experimentation, it is to be an offence for a person to carry out a diagnostic procedure involving an egg in the process of fertilisation or embryo that is not authorised by the Code or specifically approved by Council [S.7(1)(b)]. This **approval is limited** again to tests intended to be **therapeutic** to the egg or embryo and not likely to harm the "wellbeing" of any egg in the process of fertilisation or embryo -based on existing scientific and medical knowledge [S.14(2)]. Again, however, the potential is given for the Code compiled by Council to elaborate on which types of

diagnostic procedures in general may be authorised by the Code [S.21(k)], so opening the way to **general approval** of certain types of diagnostic tests.

As for research approval, in giving approval to any diagnostic procedure Council is to be aware that "no detrimental effect on the well-being of any egg in the process of fertilisation or embryo is likely thereby to occur" [S.14(2)]. This requirement, read with definitions of "embryo" and "parthenogenesis", may limit the use of tests such as embryo biopsy even when they are not likely to harm the embryo upon which they are performed, if there is the potential for the cells removed from the embryo to themselves develop into a parthenogenetic embryo.

## **6. DUTIES OF THE EXECUTIVE OFFICER**

### **6.1 General duties**

A number of duties for the Executive Officer are specified in the Act, apart from generally understood duties to coordinate the Council, assist the Commissioner in licensing, etc., assist the Minister as required and perhaps as an "authorised officer" in monitoring compliance of licensees.

### **6.2 Council activities specified in the Act**

The Executive Officer is appointed by the Minister to Council "ex officio", and is to be an employee of the Health Department. The Executive Officer is not eligible to be appointed as Chairman or Deputy Chairman of Council, but is a voting member [S.8(3)]. The term of office may be specified in relation to the position held in the Department or as determined by the Minister [Sch.(3),(4)].

Where there is a unanimous resolution by the Council without a meeting, the Executive Officer is to report this at the next meeting of Council [Sch.8(2)].

The Minister may ask Council to provide a report on Council activities or any information it possesses, for parliamentary purposes or public business, and the Executive Officer is authorised to ensure compliance with this request [S.5(8)]. Although not specified in the Act, in effect it is the Executive Officer who must coordinate the preparation of the Annual Report. This is to be submitted by Council to the Commissioner in time for the Commissioner to pass it on to the Minister by 30 September each year and relates to the preceding financial year [S.5(7), Sch.11].

### **6.3 Role in implementation of the Code specified in the Act**

In the course of implementation of the Code, the Executive Officer must ensure that when any proposed Rule is to be laid before Parliament it is accompanied by a copy, certified by the Executive Officer as correct, of any relevant text referred to in the guidelines [S.16(2)(a)]. The Executive Officer must ensure that a compiled text of the Code is always available from Council, including any relevant texts referred to in it. The Executive Officer must also, as soon as possible, try to bring any new Rules or changed guidelines to the attention of licensees affected [S.16(5)].

### **6.4 Role in disciplinary action and appeals specified in the Act**

There are several statutory duties for the Executive Officer in the course of disciplinary action. A Committee of Enquiry may summons a person, but this is to be in the prescribed form and signed by the Executive Officer [S.38(2)(e)]. The Executive Officer may then administer any oath or affirmation required by the Committee that the person will truly answer all relevant questions [S.38(2)(f)]. Following disciplinary proceedings the Commissioner of Health must make known the reasons for the decision reached and the Executive Officer must be prepared, if possible, to provide the person liable with greater details if asked for this within 7 days. This is to provide the detail necessary for any appeal [S.38(7)].

When the licensing authority refuses an application for a licence or exemption or for interim authorisation to carry on a practice, or varies a condition of licence or cancels or suspends it, this may be subject to an Appeal to a Judge of the Supreme Court. The applicant or licensee concerned may ask the Executive Officer for reasons for the decision and the Executive Officer must try to provide, in writing, sufficient detail to enable the question of an appeal to be considered.

### **6.5 Role as authorised officer**

When the Executive Officer is acting as an "authorised officer" there are a number of powers and responsibilities [S.54,55,59]. Confidentiality provisions must be complied with [S.49], but there may be access to information in records kept by licensees or in the registers [S.44,45]. The officer must have a certificate of identity as prescribed and be suitably qualified. To have access to identifying information the officer must also be specifically authorised by the Commissioner of Health.

### **6.6 Role as Coordinator of activities of Minister and Commissioner of Health under the Act**

Although specific duties for the Executive Officer in relation to the licensing process, disciplinary matters, etc. are not specified in the Act, it is likely that the Executive Officer will have a vital role in coordinating these activities of the Commissioner of Health and the Minister. These responsibilities for the Executive Officer are best understood by referring to the respective duties of the Minister and Commissioner of Health under the Act.