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**Assisted reproductive technology**

by

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## EXECUTIVE SUMMARY

Interest in assisted reproductive technologies (ART) has grown with events such as the birth of the cloned sheep Dolly (see Part 7, page 63) and a court in Victoria allowing a doctor to remove sperm from a woman's deceased husband for the purposes of artificial insemination (see Part 4.7, page 32) ensuring the issues remain in the media. The NSW Health Department produced a discussion paper in October 1997 which addressed the need for legislation on the subject in NSW. The technologies available to infertile couples are constantly increasing. From when the world's first IVF baby was born in England in 1978, procedures such as Gamete IntraFallopian Transfer, IntraCyttoplasmic Sperm Injection and Cryopreservation of sperm, embryos and ovum have become commonplace. It is estimated that approximately one per cent of all live births in Australia are as a result of assisted reproductive technologies. The technologies most commonly employed are discussed in Parts 3.1-3.9 (pp 4-10).

There are many ethical questions surrounding assisted reproductive technology. The most fundamental question concerns access to the technology (Part 4.1, p 11). For example, in Victoria and Western Australia, access is restricted to married or de facto heterosexual couples. In South Australia, the legislation has not been interpreted so restrictively, enabling single women and lesbian women who are medically infertile to gain access to the technologies. Controversy centres around members of same sex couples, single women and women who have passed their natural child-bearing age. Other ethical issues include parentage of children born as a result of assisted reproductive technologies, and consequent rights and responsibilities towards the child (Part 4.2, p 16), record keeping and disclosure of identifying information about donors (Part 4.3, p 18) and storage of embryos, eggs and sperm (Part 4.4, p 26). Questions relating to embryo experimentation are examined in Part 4.5 (p 28) and posthumous use in Part 4.7 (p 32). The issue of the costs associated with assisted reproductive technology, and particularly whether or not the community (Medicare) or individuals seeking treatment should pay for the procedures is looked at in Part 4.6 (p 31). As an indication of the costs involved, Schedule 2 contains a table of indicative costs of ART procedures from one private Sydney clinic. The issues of surrogacy and human cloning are particularly controversial, and are discussed in Parts 6 and 7 (pp 58 and 70).

As in any area of rapidly developing technology, the law has been slow in catching up with scientific developments. In Australia, Victoria, Western Australia and South Australia are the only states which have legislated in this area (Parts 5.2-5.4). The other states, including NSW, rely on a combination of common law principles and the application of the National Health and Medical Research Council *Ethical Guidelines on Assisted Reproductive Technologies* (Part 5.1.2, p 38). These comprehensive guidelines do not have the force of legislation, and a failure to comply with them will not result in any penalty being imposed. In NSW, the *Human Tissue Act 1983* also applies (Part 5.1.1, p 36). This Act regulates the supply of semen by requiring authorisation of businesses engaged in the collection and supply of semen, and requiring certification from semen donors pertaining to the potential contamination of the semen. The options for regulation are many, and vary across the States as well as internationally. The most common approaches focus on licensing practitioners and clinics, and the prohibition of certain practices, such as mixing human and non-human

gametes, surrogacy or human cloning. A comparison of legislative and other regulation in all Australian states is included in Part 5.5 (p 49). The regulatory schemes of the United Kingdom, Canada, New Zealand and Spain are discussed in Part 5.6 (p 54).

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## 1.0 INTRODUCTION

Artificial reproduction technologies (ART) were initially developed in the 1970s when adoption as a viable alternative for infertile couples became more difficult. The number of babies being offered for adoption fell, as social acceptance of single parenthood and financial allowances increased.<sup>1</sup> Since that time the technology of ART has expanded rapidly, with many different options now available to infertile couples. As in many areas of rapidly developing technology,<sup>2</sup> the law has been slow in catching up. The importance of law keeping pace with technology has been outlined by Justice Michael Kirby:

Science and technology are advancing rapidly. If democracy is to be more than a myth and a shibboleth in the age of mature science and technology and more than a triannual visit to a polling booth, we need a new institutional response. Otherwise we must simply resign ourselves to being taken where the scientists' and the technologists' imagination leads. The path may involve nothing less than the demise of the rule of law as we know it. It is for our society to decide whether there is an alternative or whether the dilemmas posed by modern science and technology, particularly in the field of bioethics, are just too painful, technical, complicated, sensitive and controversial for our institutions of government.<sup>3</sup>

Interest in this subject has grown in response to the NSW Health Department's Discussion Paper, *Assisted Reproductive Technologies*, which was released in October 1997. The object of that Discussion Paper was to examine the idea that assisted reproductive technology is different to other kinds of medical treatment. The basis for this difference is that, unlike other medical treatment which only has consequences for the individual being treated, assisted reproductive technology has consequences for a third person, namely the child born as a result of the treatment. As such, assisted reproductive technology should be provided for and regulated, in a manner different to other forms of medical treatment.<sup>4</sup>

This paper will briefly outline the development of assisted reproductive technologies and continue by explaining the different technologies available. The paper will examine the ethical issues which must be addressed in any regulation of ART, and will look at the differences in regulation in those states which have enacted legislation in the area: South Australia; Victoria and Western Australia. New South Wales does not have any operating

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<sup>1</sup> K Dawson, *Reproductive Technology: The science, the ethics, the law and the social issues*, Melbourne, 1994, pp. 24-25.

<sup>2</sup> Telecommunications and the Internet are two other examples of areas where the law and technology have not developed at a similar pace.

<sup>3</sup> Michael Kirby, *Reform of the Law*, 1983, pp. 238-239, quoted in J Kennan, 'Science and the Law - Lessons from the Experience of Legislating for the New Reproductive Technology', *Australian Law Journal*, Vol 59, August 1985, p. 489.

<sup>4</sup> NSW Health, *Discussion Paper: Assisted Reproductive Technologies*, October 1997, p. 9.

legislation, but the situation is regulated by the National Health and Medical Research Centre Guidelines and the *Human Tissue Act 1983*, which regulates the collection and supply of semen. The specific issues surrounding surrogacy and human cloning as they relate to ART are examined in Parts 6.0 and 7.0.

A Glossary of Terms is included in Appendix 1. Words appearing in the Glossary are italicised the first time they appear in the text.

## 2.0 DEVELOPMENT OF REPRODUCTIVE TECHNOLOGY

*Artificial insemination* has a long history. It is reported that Jewish thinkers in the third century were discussing the possibility of human insemination by artificial means. There are accounts of Arabs practising artificial conception of horses in the 14th century. In 1777 an Italian priest and professor of the University of Pavia, Lazzaro Spallanzani, began experimenting with artificial conception of reptiles. In 1780 he successfully artificially inseminated a bitch that consequently produces three live pups.<sup>5</sup>

The first recorded attempts of human artificial insemination are said to have been made in London by Scottish physiologist and surgeon John Hunter (see Part 3.2, page 5 for more detail). Some claim that Hunter succeeded in making a woman pregnant by artificial insemination in 1785 and she gave birth to a child as a result.<sup>6</sup> Numerous scientific reports were published between 1850 and 1900 of human artificial insemination being practised successfully in England, Germany, France and the United States. In 1909 the first account of successful artificial insemination of a married woman by donor sperm was published in the United States, an event said to have taken place in 1884 in Philadelphia. This development produced a storm of protest at the time, perhaps setting the tone for reaction to future developments in the area? In 1954 the first successful pregnancies using frozen sperm were reported.<sup>7</sup>

The technique of *embryo transfer*, an essential component of *IVF* (In Vitro Fertilisation) treatment was first demonstrated in 1890 by Walter Heape. He showed that fertilised rabbit *ova* could be flushed from a doe's *fallopian tube* and transferred into a *surrogate mother*.<sup>8</sup> Fertilisation *in vitro* took longer to master. The first attempts to fertilise mammalian *ova in vitro* were made in 1878, but were unsuccessful. In 1934 Gregory Pincus claimed to have successfully fertilised rabbit *ova in vitro*, but the results of his experiments were inconclusive. It was not until 1947 that the first unambiguous *in vitro* fertilisation of

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<sup>5</sup> NSWLRC, *Human Artificial Insemination*, Artificial Conception Discussion Paper 1, November 1984, p. 3.

<sup>6</sup> Ibid.

<sup>7</sup> NSWLRC, n 2, p. 4.

<sup>8</sup> NSWLRC, *In Vitro Fertilisation*, Artificial Conception Discussion Paper 2, July 1987, p. 4.

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mammalian ovum took place.<sup>9</sup>

Research into IVF procedures in relation to humans began in the 1960s in Australia, England and the United States. The first major breakthrough was made in 1969 in England when Dr Bob Edwards and Dr Patrick Steptoe managed to fertilise human eggs in glass and keep them alive for a number of hours.<sup>10</sup> In 1975 they achieved pregnancy in a woman using IVF techniques, but the pregnancy was *ectopic* and unable to proceed. In 1978 they achieved success when the world's first "test tube" baby, Louise Brown, was born (see Part 3.3, page 6 for more detail). In Australia, the technique was pioneered by Professor Carl Wood. Australia's first IVF baby, Candice Reid, was born in 1980 at the Royal Women's Hospital in Melbourne. Since 1980 there have been more than 15,000 babies born as a result of reproductive technology techniques. In 1994 there were 2,715 births resulting from assisted reproductive technology in Australia, accounting for approximately one per cent of all births.<sup>11</sup> The first pregnancy from a frozen embryo was achieved by a Monash University team in 1983. In 1985 a technique for freezing and thawing ova instead of embryos was perfected in South Australia<sup>12</sup> (see Part 3.9, page 9 for more detail). The first pregnancy from a donated embryo was also achieved in Australia, with the child being born in early 1984.<sup>13</sup> The first *Gamete IntraFallopian Transfer* (GIFT) procedure was performed in 1984 in the United States (see Part 3.4, page 7 for more detail).

In 1991 the micro injection procedure was first successfully used in Melbourne's Monash University. Under this procedure between two and 10 sperm are treated with stimulants and injected into the outer membrane of the egg.<sup>14</sup> This procedure, called *Intra Cytoplasmic Sperm Injection* (ICSI) is discussed in more detail in Part 3.7 (page 8). In 1992, Royal North Shore Hospital in Sydney reported its first births from *cryopreservation* (freezing) of micro injection embryos. This procedure is discussed in Part 3.9, at page 9 below.

At 5pm on July 5, 1996, Dolly, the first *cloned* animal was born. This sheep was created by embryologist Ian Wilmut in Roslin, Scotland, from the genetic material from an udder cell of a six-year-old sheep. While Wilmut described the cloning of humans as "offensive",

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<sup>9</sup> Ibid.

<sup>10</sup> A Stuhmcke, 'Lesbian access to in vitro fertilisation', *Australasian Gay and Lesbian Law Journal*, Volume 7, October 1997, p. 18.

<sup>11</sup> P Lancaster et al, *Assisted Conception Australia and New Zealand 1994 and 1995*, Assisted Conception Series No 2, Australian Institute of Health and Welfare, Sydney, 1997, p. 1. Live birth was the outcome of 73.6% of the 2,254 clinical IVF pregnancies in 1994 (p. 7).

<sup>12</sup> D Morris (ed) 'IVF', *Contemporary Australian Issues*, vol 1 (1993), p. 115, at p. 120.

<sup>13</sup> D Cusine, *New Reproductive Techniques: a legal perspective*, Aldershot, 1988, p. 18.

<sup>14</sup> Morris, n 12, p. 119.



he also stated that “there is no reason in principle why you couldn’t do it”.<sup>15</sup> On 13 April 1998, Dolly gave birth to Bonnie, proving that despite her unusual origins, she can still reproduce. The technology and ethical implications of cloning are discussed in Part 7.0, at page 63 below. Australia’s first surrogate IVF baby was born on May 23, 1988 in Melbourne. The baby was born to a woman in whom her sister’s egg, fertilised by donor sperm, was implanted.<sup>16</sup> The practice and regulation of surrogacy in Australia is discussed in Part 6.0, at page 58 below.

### 3.0 REPRODUCTIVE TECHNOLOGIES

The number of available reproductive technologies is constantly expanding. With a greater understanding of the technology of cloning (see Part 7.1, page 65, below), the possibilities are even further extended. The most common causes of *infertility* are discussed below, as are the most widely applied reproductive technologies. A glossary of terms appears in Appendix 1.

#### 3.1 Infertility

In order to be eligible for any ART procedure, the couple must be deemed medically “infertile”. The definition most commonly used is *the inability to achieve pregnancy after one year of regular sexual intercourse without contraception*. The incidence of infertility among couples is difficult to ascertain, with estimates ranging from 10 to 20 per cent.<sup>17</sup> An estimate of approximately 15 per cent of couples actively but unsuccessfully trying to conceive is an appropriate one. The causes of infertility are many. They have been broken down into three categories: environmental, physical and psychological. In some cases there may be a combination of factors.<sup>18</sup> The “fault” lies with the male partner in about one third of cases, with the female partner in about one third of cases and with both partners also in about one third of cases. In about 25% of couples, no obvious cause can be found for their infertility.<sup>19</sup> The following table summarises the frequency of the different causes of infertility in couples seeking ART.<sup>20</sup>

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<sup>15</sup> G Kolata, *Clone: the road to Dolly, and the path ahead*, New York, 1998, p. 4.

<sup>16</sup> H Pitt, ‘A battle yet to come for IVF baby’, *Sydney Morning Herald*, 9 June 1998.

<sup>17</sup> For example, Douglas Cusine, in his book *New Reproductive Technologies* (n 13) That between 10 and 15 per cent of all marriages are infertile (page 5). Another estimate is given in G Macpherson (ed), *Blacks Medical Dictionary*, 38th ed (London, 1995), p. 252, that between 15 and 20 per cent of couples have difficulty conceiving.

<sup>18</sup> Cusine, n 13, p. 5.

<sup>19</sup> Macpherson, n 17, p. 252.

<sup>20</sup> Dawson, n 1, p. 25. Note that this may not be representative of all infertile couples, only those seeking ART..

	<b>Tubal</b>	<b>Male factor</b>	<b>Endo-metriosis</b>	<b>Other female</b>	<b>Multiple causes</b>	<b>Unexplained</b>
<b>Australia 1979-90</b>	44.1	9.9	5.7	unknown	26.3	10.1
<b>World 1991</b>	47.3	14.8	Unknown	8.9	18.7	10.3

Sources: *Assisted conception Australia and New Zealand 1990*, AIWH National Perinatal Statistics Unit, Sydney, 1992; and *World collaborative report 1991*, IWGROAR, 1993.

The 1996 National Perinatal Unit publication stated that “women conceiving after IVF in 1995 were more likely to have infertility due to male factors only or in multiple causes than in previous years (14.1% in 1979-93 and 30.0% in 1995, and 25.1% in 1979-93 and 34.9% in 1995 respectively), and were less likely to have tubal causes (39.9% in 1979-93 and 16.2% in 1995). All other causes of infertility have remained fairly constant over this period.”<sup>21</sup>

### 3.2 Artificial Insemination

Artificial insemination (AI) refers to the injection of semen from either the woman’s partner or a donor, by artificial means (usually a syringe) into a woman’s uterus for the purpose of achieving pregnancy.<sup>22</sup> Where sperm from a donor is used, the procedure is called *donor insemination*. It is estimated that more than 30,000 children are born as a result of donor insemination each year in the United States.<sup>23</sup> The procedure is undertaken either the day before or on the day of ovulation, and is normally undertaken on two or three successive days to increase the likelihood of pregnancy. The procedure is usually carried out in a hospital by a registered nurse,<sup>24</sup> but, because of its relative simplicity, may also be carried out privately in the home without professional assistance. Artificial insemination is employed in cases of male fertility. Donor insemination is also appropriate where the male partner is a carrier or victim of an inheritable disease. The woman is artificially inseminated and the normal process of *fertilisation* and pregnancy follows.

<sup>21</sup> T Hurst, et al, *Assisted Conception Australia and New Zealand 1996*, Assisted Conception Series Number 3, AIHW National Perinatal Statistics Unit, Sydney 1997, p. 8.

<sup>22</sup> L Bunney, ‘The status of human embryos’, *Australian Journal of Family Law*, volume 9, no 2, p. 123.

<sup>23</sup> S Klock & D Maier, ‘Psychological factors related to donor insemination’, *Fertil Steril*, 1991; 56, in E Durna et al, ‘Donor insemination: attitudes of parents towards disclosure’, *Medical Journal of Australia*, Vol 167, 1 September 1997, p. 256.

<sup>24</sup> NSWLRC, n 5, p. 3.

### 3.3 In vitro fertilisation

Colloquially, In Vitro Fertilisation (IVF) covers all technologies where fertilisation takes place outside the body of a woman. In comparison, *in vivo* fertilisation refers to fertilisation inside the woman's body (in the living situation). IVF was developed to overcome untreatable obstruction or absence (due to surgical removal) of the fallopian tubes.<sup>25</sup> IVF techniques are also employed to treat infertility problems including endometriosis, pelvic inflammatory disease (PID), when the cause of the couple's infertility can not be ascertained, or where the male partner has a poor sperm quality but where fertilisation has been shown to occur.<sup>26</sup> The basic IVF technique aims to duplicate the natural process of fertilisation and development that usually occurs within the fallopian tubes in the laboratory:

- Firstly, fertility drugs are used to stimulate the woman's ovaries to produce several mature eggs for ovulation (superovulation).
- These eggs are retrieved surgically, either by laparoscope or transvaginal ultrasound and placed in a dish which contains a special culture medium for two to three days. Sperm is added to effect fertilisation.
- If fertilisation is successful, the eggs are transferred to another dish and once the eggs reach the four cell stage (ie the eggs have divided twice), the doctor transfers the *blastocyst* through the cervix to the uterus of the female.
- If the transfer is successful the blastocyst attaches itself to the uterine wall and develops as if natural conception had occurred.

The success rate of IVF has been reported as the following:

- ▶ 85% of new patients get as far as egg pick-up;
- ▶ 75% of patients will have embryo transfer;
- ▶ 15% of patients will achieve a pregnancy, and
- ▶ 10% of patients will achieve a live birth.<sup>27</sup>

These statistics become particularly relevant when determining who should pay for the

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<sup>25</sup> Sydney IVF, *An Introduction to Infertility and IVF*, p. 4.

<sup>26</sup> Dawson, n 1, p. 32.

<sup>27</sup> *Ibid*, pp. 37-8. These figures, while illustrative, do not take into account the variance in success rates according to the age of the female. For example, a woman over 39 years of age, or who has significant infertility problems, has a greatly reduced chance of achieving a live birth. A woman under the age of 25 has, statistically, a 73% chance of achieving a live birth. This success rate reduces to 65.8% for a woman between 35 and 39 years of age, and further reduces to 52.9% for a woman over 40 years of age. The figures also do not reflect the effect of transferring more than one embryo, or the impact made by new technologies such as ICSI.

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treatment and the level of government and other funding which is made available to IVF clinics and patients.

### **Donor egg IVF**

Donor egg IVF allows women whose ovaries do not produce eggs to become the recipient of eggs donated by a friend, relative or volunteer donor. The donor eggs are fertilised in the laboratory with sperm from the husband/partner of the infertile couple. Resulting embryos are transferred to the infertile woman's uterus. Donor egg IVF has a higher success rate than regular IVF - 31% compared to 7.2% for women over 40 years of age being an example.<sup>28</sup>

The main side effect of IVF is the risk of ovarian hyperstimulation syndrome (OHSS), a result of ovarian stimulants taken to stimulate superovulation, producing a large number of cysts containing the eggs. Abdominal pain and bloating result. In its severest form, OHSS can result in hospitalisation and can even prove fatal, mainly due to blood clotting (thrombosis). Women who have had laparoscopies and ultrasound extraction procedures carried out have experienced nausea, abdominal pain, internal bleeding and infections. Certain ovarian stimulants may cause temporary blurred vision, nausea and dizziness, and there are also concerns about a possible link between ovarian hyperstimulation and later ovarian cancer. There is also concern that there may be greater chromosomal abnormalities in eggs collected after superovulation.<sup>29</sup>

### **3.4 Gamete IntraFallopian transfer**

Gamete IntraFallopian Transfer (GIFT) is an alternative to IVF when at least one fallopian tube is open. GIFT was developed in 1984 by Dr R Asche at the University of Texas Health Science Centre in Texas, USA. GIFT is similar to IVF in many ways. The fertility drugs given to the woman to induce ovulation, the daily blood testing and pelvic ultrasound are virtually identical. The male provides a semen specimen and it is prepared in a manner similar to that used in IVF. However, unlike IVF, both the *gametes* (sperm and egg) are introduced into the fallopian tube using a special catheter. Also unlike IVF, where fertilisation occurs in a test tube, in the GIFT procedure, fertilisation is allowed to occur naturally.<sup>30</sup> This means that GIFT involves an additional surgical procedure to IVF, which may be a disadvantage. However, because of the naturally occurring fertilisation, GIFT is acceptable to some religious groups that otherwise oppose IVF.

Other variations of the GIFT procedure are Pronuclear Stage Transfer (PROST) and Tubal

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<sup>28</sup> *Assisted Reproductive Technologies: A Range of Treatments to Fit the Needs of the Infertile Couple*, <http://www.ihr.com/westcoast/articles/art.html>.

<sup>29</sup> T Libesman & V Sripathy, *Your Body Your Baby, Women's Legal Rights from Conception to Birth*, Redfern Legal Centre Publishing, 1996, pp. 49-50.

<sup>30</sup> Atlanta Reproductive Health Centre, *Introducing the GIFT Procedure*, <http://www.ivf.vom/gift.html>.

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Embryo Stage Transfer (TEST). The essential differences are the stage of fertility at which the gametes or embryos are placed inside the woman's fallopian tubes.<sup>31</sup>

### 3.5 IntraUterine Insemination

*IntraUterine Insemination (IUI)* utilises the sperm preparation techniques from IVF (see Part 3.2 above) to concentrate the best sperm and place them high in the uterus. This increases the likelihood that the sperm will meet and fertilise the egg. In this sense it is also similar to artificial insemination (see Part 3.1 above), and natural conception occurs.

### 3.6 Zygote IntraFallopian Transfer

Zygote IntraFallopian Transfer (ZIFT), also called tubal embryo transfer, is appropriate where the woman has normal fallopian tubes but where there is a severe problem with the male and difficulties with fertilisation. ZIFT is a hybrid of IVF and GIFT techniques.<sup>32</sup> The eggs are retrieved and fertilised outside the body. Two days after fertilisation, the *zygote* is transferred directly into the fallopian tube, rather than into the uterus.

### 3.7 IntraCytoplasmic Sperm Injection

IntraCytoplasmic Sperm Injection (ICSI) was developed at the Centre for Reproductive Medicine at University Hospital, Brussels Free University, Belgium. In ICSI a single sperm is injected into the egg using a micro needle which punctures the outer layers and penetrates directly into the interior of the egg. After injection of the sperm, the eggs are incubated for 16-18 hours, then examined for possible damage and any evidence of fertilisation. If fertilisation has occurred, the fertilised egg can then be transferred back into the woman's uterus using traditional IVF or ZIFT techniques, or frozen to be used at a later time. There has been some concern over ICSI practices, based on the fact that ICSI "bypasses all natural sperm selection processes that have evolved to regulate vertebrate fertilisation, and the long-term implications for the life expectancy and fertility of the children are unknown".<sup>33</sup> However, ICSI allows fertilisation using the partner's sperm in situations where he may have an extremely low sperm count, for example. Previously, pregnancy could only be achieved using donated sperm.

### 3.8 Surrogate embryo transfer

Surrogate embryo transfer (also known as embryo flushing) is a highly controversial

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<sup>31</sup> Libesman, n 29, p. 50.

<sup>32</sup> Internet Health Resources, 'Assisted Reproductive Technologies', <http://www.ihr.com/bafertil/assistre.htm>, pp. 3-4.

<sup>33</sup> J Cummins and A Jequier, 'Concerns and recommendations for intracytoplasmic sperm injection (ICSI) treatment', <http://Numbat.murdoch.edu.au/spermatology/androl90s.html#RTFToC1>, p. 1 of 8.

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technique which has not been approved for use in Australia.<sup>34</sup> It involves fertilising a donor egg with a male partner's sperm inside a surrogate mother's body using artificial insemination procedures. The surrogate mother only carries the embryo for a short time after fertilisation - the resulting embryo is "flushed out" of the surrogate mother's uterus and transferred to the uterus of the male's partner who carries it to full term.<sup>35</sup>

### 3.9 Cryopreservation

Cryopreservation refers to storage by freezing. Freezing of sperm has been done successfully since 1953, the success of the procedures giving rise to a proliferation of sperm banks.<sup>36</sup> As a result of the fertility drugs given to a woman, and consequent superovulation, IVF and other ART procedures result in an average of 5 to 12 viable embryos per treatment cycle. It is not uncommon for an individual to have as many as 20 or more spare embryos at the completion of an ART process. Embryos may be frozen at the pronuclear stage (one cell) or at any stage after that and up to and including the blastocyst stage (up to 5 to 7 days after fertilisation). Embryos are cryopreserved by firstly removing water from the cells before freezing. If water is not removed, large ice crystals are formed during freezing which may damage the embryo. The embryos are then transferred to plastic straws containing cryoprotectants (solutions which lower the freezing point and protect cells) and are cooled slowly to a predetermined temperature below freezing. The straws are then plunged into liquid nitrogen and stored at  $-96^{\circ}\text{C}$  until thawing. To thaw the embryos, the straws are pulled out of the storage bank and warmed first at room temperature and then in a water bath at  $37^{\circ}\text{C}$ . The embryos are released from the straws and are incubated for 1-2 hours to determine whether they have survived the freeze-thaw process.<sup>37</sup>

The advantages of cryopreservation of embryos include:

- reduced risk of multiple gestation by replacing a few fresh embryos and freezing the excess (usually a couple will choose to replace three to four embryos during the retrieval cycle and freeze the rest);
- reduced cost of future replacement cycles, without additional egg retrievals if pregnancy does not occur after the initial fresh embryo replacement;
- enabling additional pregnancies and children without additional IVF or ICSI cycles,

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<sup>34</sup> Libesman, n 29, p. 52.

<sup>35</sup> Ibid.

<sup>36</sup> T Shannon & L Sowle Cahill, *Religion and Artificial Reproduction: an inquiry into the Vatican 'Instruction on Respect for Human Life'*, New York, 1988, p. 78.

<sup>37</sup> 'Embryo Preservation', <http://www.tcartonline.com/services/programs.ecp.html>, pp. 1-2 of 2.

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allowing an otherwise “natural” cycle to achieve pregnancy.<sup>38</sup>

As with any ART procedure, there are risks involved. Approximately half of all cryopreserved embryos will not survive. The survival rate is best for embryos which are frozen at the pronuclear stage or the 2-cell to 4-cell stage.<sup>39</sup> There is, however, no additional risk of abnormality using cryopreserved embryos.<sup>40</sup> The cost of cryopreservation is also a factor which must be considered: one article reports that it costs \$250 per year to “keep an embryo on ice”.<sup>41</sup> The cryopreservation of ova has presented scientists with greater challenges. Cryopreservation of eggs is not particularly successful. An article in the *Medical Journal of Australia*, in April 1997, reported that fewer than 2% of cryopreserved oocytes (*ovum*) are capable of producing a term pregnancy.<sup>42</sup> An alternative is to cryopreserve ovarian tissue. The procedure is a laparoscopic one, and involves removing one ovary (the *Medical Journal of Australia* refers to removing only a section approximately 2cm<sup>2</sup> from the ovary). The other ovary is left in place. The portion of the ovary containing the eggs is sectioned into thin tissue slices and cryopreserved at -196°C. When the woman wishes to attempt fertility, some of the ovarian tissue slices are thawed and replaced into the ovarian location, again by laparoscopy.<sup>43</sup> The above-mentioned article in the *Medical Journal of Australia* stated that “it has not yet been stated that cryopreserved ovarian tissue can restore fertility in humans” although in mice and sheep live young have been obtained.<sup>44</sup> Cryopreservation of ovarian tissue enables women who must undergo radiation or chemotherapy to attempt pregnancy once the treatment has been successful, and also enables women who have past the ‘normal’ child-bearing age to attempt pregnancy. The ethical issues involved in storage of sperm, eggs and embryos are discussed in Part 4.4, page 26, below.

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<sup>38</sup> ‘Human Embryo Cryopreservation (Embryo Freezing) and Frozen Embryo Transfer Cycles’, [http://www.givf.com/embryo\\_cryo1.html](http://www.givf.com/embryo_cryo1.html)

<sup>39</sup> ‘Embryo freezing: cryopreservation’, <http://www.advancedfertility.com/cryo.html>.

<sup>40</sup> ‘Embryo preservation’, n 37, p. 1 of 2.

<sup>41</sup> H Hawkes, ‘Labour Intensive’, *Vogue Australia*, July 1998, p. 128. See Appendix 2 for a schedule of costs for ART procedures, including cryopresertation, at a private Sydney clinic.

<sup>42</sup> C Wood, et al, ‘Cryopreservation of ovarian tissue: potential “reproductive insurance” for women at risk of early ovarian failure’, *Medical Journal of Australia*, vol 166, No 7, 7 April, 1997, p. 367. The article attributed such factors as the large volume of oocytes and their variable membrane permeability to the lack of success in cryopreservation.

<sup>43</sup> ‘Ovary cryopreservation (ovarian freezing, egg banking)’, <http://www.givf.com/ovar1.html>.

<sup>44</sup> Wood, n 42, p. 367.

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## 4.0 ETHICAL ISSUES

The introduction to the NHMRC's *Ethical Guidelines on Assisted Reproductive Technology* ("the Guidelines") highlighted a number of ethical and social values which the guidelines attempt to address on a practical level. The issues identified include:

- a serious regard for the long-term welfare of any fetuses brought into existence, and any children who may be born, as a result of the application of these technologies;
- a corresponding regard for the long-term welfare of the individuals, both women and men, who have recourse to these technologies;
- the recognition that any experimentation and research involved in these technologies should be limited in ways which reflect the human nature of the embryo, acknowledging that there is a diversity of views on what constitutes the moral status of a human embryo, particularly in its early stages of development; and
- a concern that the whole of society be well-served by the development and application of the technologies.<sup>45</sup>

These *Guidelines* are discussed in greater detail in Part 5.1.2, from page 38 below. These and other issues are examined in more detail in the following paragraphs.

### 4.1 Eligibility for assisted reproductive technology

The most fundamental question regarding ART is to whom should it be available? For example, the Victorian and Western Australian legislation restricts access to married or de facto, heterosexual couples.<sup>46</sup> In South Australia, the legislation has not been interpreted so restrictively, enabling females in a lesbian relationship or a single woman to gain access to ART services also, as long as they are medically infertile.<sup>47</sup> Generally, there are three areas

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<sup>45</sup> National Health and Medical Research Council, (NHMRC) *Ethical guidelines on assisted reproductive technology*, 1996, p. 1.

<sup>46</sup> Until mid-1997, Victorian legislation restricted access to ART to legally married couples. However, following a Human Rights and Equal Opportunity Commission decision in March 1997 which awarded three women almost \$30,000 compensation after being denied access to fertility programs, the Act was amended. The Commission found that the Victorian hospitals had breached the Federal *Sex Discrimination Act 1984* when they denied the women access because they were single. Section 6 of that Act prohibits discrimination on the grounds of marital status.

<sup>47</sup> *Pearce v South Australian Health Commission and Ors* (1996) 66 SASR 486. The case involved a woman who was refused access to IVF because she was separated from her husband, not falling within the category of persons eligible under section 13 of the *Reproductive Technology Act 1988* for reproductive technology services (legally married or in a de facto relationship of at least 5 years duration). The issue was whether or not that section was inconsistent with section 22 of the *Sex Discrimination Act 1984* (Cth), which prohibits discrimination in the provision of goods or services, by refusing to provide such



where the question of access to ART arises: marital status and the related issue of sexual orientation, and age (whether or not post-menopausal women should be allowed access to treatment).

As stated above, the Victorian and Western Australian ART legislation stipulates that only members of married or de facto heterosexual couples can gain access to ART procedures. This is a widely held view. For example, the Roman Catholic Church's *Instruction on Respect for Human Life* asserts that human procreation must take place within marriage: "the child has the right to be conceived, carried in the womb, brought into the world and brought up within marriage..."<sup>48</sup> The basis for this assertion is the Catholic Church's belief that it is only the promised stability and fidelity of marriage which provides an appropriate context for bringing up a child.<sup>49</sup> The Council of Europe also espouses this view, without the requirement of marriage, stating in its *Report on human artificial procreation*, that "the techniques of artificial procreation may be used for the benefit of a *heterosexual couple* when appropriate conditions exist for ensuring the well-being of the future child..."<sup>50</sup>

The NSWLRC discussed access to treatment in its 1988 Report on Artificial Conception. In it the Commission stated that:

Eligibility to be considered for treatment for infertility should not be restricted but should be regarded in the same way as eligibility for any other medical treatment. Thus, a person who is not affected by infertility of a type that can reasonably be treated by IVF, should not be able to compel the provision of IVF any more than a healthy person could compel a doctor to perform a pointless operation.<sup>51</sup>

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good or service, on the grounds of the person's sex, pregnancy or marital status. The Court held that the South Australian Act was inconsistent with the Federal Act, and was therefore invalid, according to section 109 of the *Australian Constitution*. The result is that a single woman or a woman who is a member of a lesbian couple can not be denied access to reproductive technology services on the basis of her marital status. However, the woman must still demonstrate medical infertility, for which the absence of a male sexual partner is not sufficient (whether or not this requirement is indirectly discriminatory is currently being examined in Queensland in the case *QFG & GK v JM*. See discussion on page 12, below, and n 56).

<sup>48</sup> *Instruction on Respect for Human Life in its Origin and the Dignity of Procreation: Replies to Certain Questions of the Day*, Congregation for the Doctrine of the Faith, Authorised Vatican Translation, Part II, section 1, <http://listserv.american.edu/catholic/church.vatican.giftlife.doc>, p. 10 or 16.

<sup>49</sup> G Gleeson, 'Ethical issues in reproductive technology: some Catholic insights', *Bioethics Outlook*, Vol. 9, No. 1, March 1998, p. 10.

<sup>50</sup> Council of Europe, *Report on human artificial procreation: principles set out in the report of the ad hoc Committee of experts on progress in the biomedical sciences*, principle 1, <http://www.coe.fr/oviedo/artif-e.htm>, pp. 1-2 of 7.

<sup>51</sup> NSWLRC, *Artificial Conception: In Vitro Fertilisation Report*, Report No. 58, July 1988, p. 67.

The corollary of this argument is that those who are infertile should not be refused treatment. The question then turns on an understanding of ‘infertility’. Robert Jansen, clinical professor at the University of Sydney, stated in relation to infertility:

Whereas infertility necessarily means childlessness, in my opinion not all childless states (voluntary or involuntary) equate with the medical disability of infertility. Some people would like to have and care for a child, but for many reasons, including their personal circumstances, can not. Biologically, being homosexual, being single, and growing old should all be recognised as normal states. The childlessness that accompanies these states should not necessarily constitute a medical abnormality that warrants publicly funded medical management.<sup>52</sup>

The Canadian Law Reform Commission identified three types of infertility: *physiological infertility*, where the persons are sterile, *social infertility*, which refers to persons who are unable or who do not wish to procreate through sexual relations with the opposite sex, and *genetic infertility*, referring to people who are likely to transmit a genetic disorder to their children.<sup>53</sup>

This question of what constitutes infertility was the central point in a case before the Queensland Anti-Discrimination Tribunal, in which a lesbian successfully challenged a Queensland fertility clinic’s refusal to allow her access to treatment. In the case of lesbians, some would argue that a lesbian woman is in fact infertile because she cannot conceive within that relationship (social infertility). Others would argue in response that both women in the relationship may in fact be biologically (medically) fertile, rendering the women ineligible for medical assistance.<sup>54</sup> Tribunal President Roslyn Atkinson based her finding on her interpretation of the facts - that the doctor had made a decision to deny the woman treatment on the basis that she was a lesbian engaged in “lawful sexual activity”. The doctor was thus in contravention of section 7(1) of the Queensland *Anti Discrimination Act 1991* which prohibits discrimination on the grounds of a number of “attributes”, including “lawful sexual activity”, and section 46(1) which states that “a person who supplies goods or services ... must not discriminate against another person ... by failing to supply goods or services”. Further, in her finding, President Atkinson said, referring to the notion of the best interests of the child, that “research evidence appears to indicate that there is no disadvantage to a child in being brought up in a homosexual household”.<sup>55</sup>

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<sup>52</sup> R Jansen, ‘Reproductive medicine and the social state of childlessness’, *Medical Journal of Australia*, Volume 167, 15 September 1997, p. 321.

<sup>53</sup> Canadian Law Reform Commission, *Medical Assisted Procreation*, working paper no 65, 1992, extracted in I Kennedy & A Grubb, *Medical Law: Text with Materials*, London, 1994, pp. 783-785.

<sup>54</sup> For a discussion of lesbian access to ART, see A Stuhmcke, n 10.

<sup>55</sup> S Powell, ‘IVF services provide fertile ground for discrimination’, *The Australian*, 17 February 1997.

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That decision was appealed against in the Queensland Supreme Court, where the Tribunal's finding of direct discrimination against the lesbian woman was set aside. In relation to the indirect discrimination by the doctor in providing specialised medical services only to those women considered medically infertile because they had failed to achieve pregnancy in the normal way (heterosexual intercourse), the Court remitted the matter to the Tribunal for re-hearing. In his reasons, in relation to the question of what constitutes infertility, Ambrose J stated that "... there is nothing in the evidence nor any finding to the effect that there was any explanation for the respondent's abstinence from heterosexual intercourse which would in the normal course of events produce a child other than the choice she made not to have heterosexual intercourse because of her homosexual preference".<sup>56</sup> The woman appealed to the Queensland Court of Appeal, which dismissed the appeal, finding that the President of the Anti-Discrimination Tribunal was wrong in her application of the legislation to the facts, in relation to direct discrimination, and upholding the decision of Ambrose J in relation to indirect discrimination, remitting the question back to the Tribunal for determination.<sup>57</sup>

The NSW Law Reform Commission listed a number of factors which should be taken into account when determining a person's eligibility for treatment:

1. Whether the woman is a member of a couple who are infertile, or whose children are likely to be affected by a genetic abnormality or disease;
2. The welfare and interests of any child born as a result of the IVF procedure;
3. The home environment and stability in which the child could live;
4. Whether or not counselling is desirable;
5. The prospective parent's physical and mental health, age and emotional reaction to IVF and Embryo Transfer.<sup>58</sup>

Note that in neither of these two discussions does the Commission state that the woman must be a member of a married or de facto, heterosexual couple. It does, however, state that the woman must be a member of a couple, which would preclude single women from gaining access to ART. Despite this, many would assume that 'couple' referred to a heterosexual couple living in a stable domestic relationship, whether legally married or not.

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<sup>56</sup> *QFG v GK and JM*, Supreme Court of Queensland, unreported judgement No OA No 1877 of 1997.

<sup>57</sup> *JM v QFG & Another*, Supreme Court of Queensland, Court of Appeal, unreported judgement, Appeal No 10523 of 1997, p. 6; p. 8. The author contacted the Queensland Anti-Discrimination Tribunal on 1 October 1998, to be told that the matter was not yet before the Tribunal, and that it was possible that the woman was considering an appeal to the High Court.

<sup>58</sup> NSWLRC, n 51, p. 65.

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Such was the position of the Warnock Committee in the United Kingdom, who reported on the issue in 1984.<sup>59</sup> That committee raised these additional questions:

- Should a woman who previously has been voluntarily sterilised at her own request be allowed access to ART?
- Should a woman who already has a child be allowed to utilise ART in order to have additional children?

These are questions to which there are no easy answers. The question turns on whether or not it is believed a person has a *right* to reproduce, or whether the ultimate test is based on the best interests of the child. If there is a fundamental right to reproduce, then a person cannot be denied access to ART if it is necessary in order to exercise that right.<sup>60</sup> If the test is the best interests of the child, then no single characteristic of the parent *per se* should be sufficient to preclude them from receiving ART treatment. If this approach is followed, access to ART must be examined on a case by case basis, taking into account *all* relevant factors (this approach could even incorporate factors such as the relationships and financial stability of the person). Guidelines in this area can only be that - a guide, rather than a strict and inflexible set of rules.<sup>61</sup> There are those who would argue that certain characteristics of a person, such as age, marital status or homosexuality, are, in themselves, enough to preclude the person from gaining access to ART, and legislation should give effect to this.

Note also that practising homosexual males who have had male to male sexual intercourse any time since 1977 are prohibited from donating semen under the Human Tissue Regulation 1995. The prohibition originally came into force to protect recipients from the

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<sup>59</sup> Kennedy & Grubb, n 53, p. 779.

<sup>60</sup> This is an argument which has been forwarded in support of allowing cloning for reproductive purposes. See Pence, n 185, pp 100-101.

<sup>61</sup> This was the view adopted by Karen Dawson and John Leeton in their 1995 article, 'The regulation of assisted reproductive technology in Australia: some issues and solutions', *The Medical Journal of Australia*, vol 163, 21 August 1995, p. 204. In this article, the authors considered the following aspects of any regulatory (licensing) system to be essential:

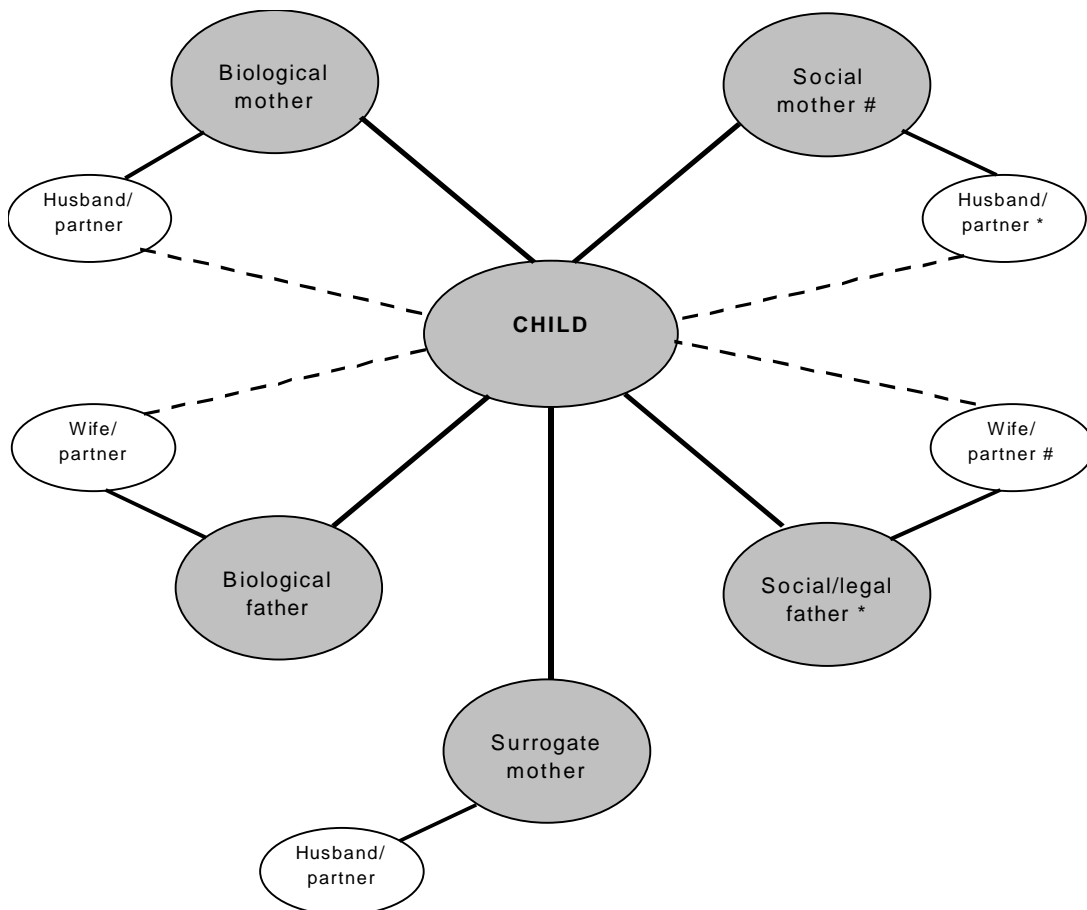
- latitude and flexibility to explore all aspects of the issues involved;
- capacity to interpret the intention of the legislation (not simply apply the words);
- facility for research proposals to be modified and adjusted efficiently;
- a reporting system that is interactive between the researchers and the committee (in the context of this article, the authors were referring to the Victorian Standing Review and Advisory Committee on Infertility, which was established under the Victorian Act to approve all research involving human embryos), and
- an audit capacity to fully ascertain the extent of the issues involved.

The article was mainly concerned with the licensing of research facilities, but the ideas can be applied equally to the licensing of treatment facilities.

threat of HIV when screening for that disease was inefficient and “too often wrong to be relied upon”.<sup>62</sup> The accuracy of HIV screening is no longer an issue which causes concern, and in any event, sperm donations are always frozen and quarantined until the donor has been retested and cleared, unless the semen is to be used to inseminate the donor’s partner or wife.<sup>63</sup> This may take up to six months to complete. If the semen is found to be positive for any pathogenic micro-organism, it may not be used.<sup>64</sup>

#### 4.2 Parental responsibilities/rights

The legal question may seem a simple one - who, in law, is the mother and father of the child? When ART is involved in the conception of a child, however, the answer may in fact be anything but simple. As an example, the diagram below illustrates the potential difficulty in determining the family relationships of children of ART.



<sup>62</sup> Jansen, n 52, p. 327.

<sup>63</sup> Ibid.

<sup>64</sup> Human Tissue Regulation, Schedule 4, clause 2.

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\* The social mother's husband/partner could in fact be the social/legal father. The legal father (that upon whom parental responsibility has been bestowed) may be different from the social father if the social mother is in another relationship or has remarried.

# The social/legal father's wife/partner could in fact be the social mother.

The NSW *Artificial Conception Act 1984* deals with the parentage of children conceived either through donor insemination or IVF using donor sperm. The following presumptions of parentage are made in section 14. Any presumption regarding parentage arising under section 14 is irrefutable. The term "married" used in this context includes a man and wife who are living on a bona fide domestic basis as husband and wife, although not legally married. The presumptions are as follows:

1. when a married woman has undergone a fertilisation procedure as a result of which she becomes pregnant, the **woman** is presumed to be the mother, even if she did not provide the ovum used in the procedure. Her **husband** is presumed to be the father of any child born even if he did not provide the sperm used in the procedure. This only applies if the husband assented to the procedure. The consent is presumed under the Act. However, it can be challenged in court.
2. when a woman (married or unmarried) becomes pregnant by means of a fertilisation procedure using sperm obtained from a man who is not her husband, that man is not presumed to be the father of any child born as a result of the pregnancy.
3. when a woman (married or unmarried) becomes pregnant by means of a fertilisation procedure using an ovum obtained from another woman, that other woman is not presumed to be the mother of any child born as a result of the pregnancy.

Point 3 has the effect that a woman who acts as a surrogate for another woman is legally the mother of the child, regardless of whether or not there was a surrogacy agreement in place, or if the sperm and ovum used came from the couple who engaged her as a surrogate.

The NSW legislation was the first to deal with the legal status of children born as a result of assisted reproduction in Australia. While it clarifies the status of children conceived using donated sperm and ova, it does not define the status of a child born from donated embryos. Nor does it deal with other complex issues such as the ownership of gametes and embryos and whether or not donors and children should have access to identifying or even non-identifying information about each other (discussed in more detail in Part 4.3, page 19, below). There are similar Acts operating in other States - see the table in Part 5.5, from page 49, below.

The Federal *Family Law Act 1975* contains similar provisions in section 60H. The *Family Law Act 1975* relies on State legislation to a large degree to determine the parentage of a child - for example where a woman is married to a man and has a child born as a result of an artificial conception procedure, then if the procedure was carried out with their consent, *or* if the child is their child under State law, then the child their child for the purposes of the *Family Law Act*. When the woman is not married to the man, only when the child is the

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child of the woman or the man under State law does the *Family Law Act* recognise the child as theirs.<sup>65</sup>

The issue of legal parentage is important because it is from this that parental responsibility is drawn. “Parental responsibility” is defined in section 61B of the *Family Law Act 1975* to be “in relation to a child, all the duties, powers, responsibilities and authority which, but law, parents have in relation to children”. It is understood to mean all the common law rights and responsibilities of a parent in respect of a child, and is taken to include the obligation to have regular contact with the child, and to provide appropriate direction and guidance to the child in the course of the child’s upbringing.<sup>66</sup> The former notions of custody and guardianship are drawn upon for an understanding of what constitutes parental responsibility, although the *Family Law Reform Act 1995* replaced the concepts of guardianship, custody and access with that of parental responsibility, covering such issues as residence and contact, reflecting a shift in focus from parents’ rights to custody, access etc, to children’s rights to care and protection.

In a practical sense, there are financial implications of parentage which include the provision of child support under the *Child Support (Assessment) Act 1989*. That Act provides that an eligible carer (the person who is the sole or principle provider of on-going daily care for the child) is able to apply for child support from a parent of the child with whom the eligible carer is not living. Ordinarily under the Act, the biological parents of the child are the legal parents of the child and thus liable for child support. However, in cases where the child is born as a result of artificial conception procedures, a person is only a parent of the child where they are so defined under section 60H of the *Family Law Act*. It is therefore essential that the relationships which are created by ART are clearly defined, and that the State and Federal legislation is comprehensive enough to cover all scenarios.

An example of the relationship between Commonwealth and State legislation in this area is *B v J*<sup>67</sup> In this case, a man donated sperm on two occasions to a lesbian friend so that she could have a child with her partner. All three parties agreed that the man would have no future parenting obligations with respect to the children, and would under no circumstances be liable for financial support. However, with the man’s consent, he was registered as the father on the children’s birth certificates. The women’s relationship eventually broke down and the Department of Social Security informed the woman that payment of her pension would be stopped unless she claimed child support from the father. The man applied to the Family Court for a declaration that he was not a person from whom child support could be claimed, under section 26 of the *Child Support (Assessment) Act 1989*. For the man to be liable for child support, he had to be the father according to the provisions of section 60H(3). This involves a two-fold test: the child must be born as the result of an artificial conception procedure, and the child must be the child of the man under “a prescribed law

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<sup>65</sup> Section 60H (3)(b)

<sup>66</sup> H Finlay, et al, *Family Law in Australia* (5th ed), Butterworths, 1997, paras 7.43-7.48.

<sup>67</sup> (1996) ¶92-716.

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of the Commonwealth, State or Territory”. As there was no relevant prescribed law in Victoria, the second limb of the test was held not to be satisfied and the man was not the parent of the children, and consequently not liable for child support. In this situation, the result did in fact reflect the wishes of the parties, and also reflects the position of the States whereby the provider of semen is not to incur any liabilities in respect of any child born.

### 4.3 Record keeping & disclosure of information about donors

There are two questions which need to be addressed in relation to record keeping: which records should be kept, and by whom; and in what situations should access to information (identifying and non-identifying) contained in such records be granted, and to whom?

The NSW Human Tissue Regulation 1995 regulates the type of records and the length of time for which these records must be kept in relation to semen donation. See Part 5.1.2 below (page 37). There is no other legislative requirement in NSW that records must be kept, however the Fertility Society of Australia *Code of Practice* states that a permanent record must be kept of all procedures, identifying the patients, doctors and recipients involved in fertilisation and embryo formation, and the final outcome of any attempted fertilisation and of any conception formed by IVF. Similarly, the NHMRC Guidelines state that records should be kept so to “enable staff in a Reproductive Medicine Unit to trace what happens to an individual embryo, egg or sperm sample from the date of collection so as to facilitate appropriate access, where permitted, to relevant medical, social and demographic information”.<sup>68</sup> The Medical Practice Regulation 1998, which commenced operation on 1 September 1998 deals for the first time with the issue of medical records. A record must be made and kept in respect of each patient of the practitioner, and must be kept for at least seven years from the date of the last entry in the record, or where the patient is less than 18 years old, must be kept until the patient would have attained the age of 25 years (clauses 13-15). The information which must be contained within the record is stipulated in Schedule 2, and includes:

- sufficient information to identify the patient to whom it relates;
- any information known to the medical practitioner relevant to his or her diagnosis or treatment, details of any clinical opinion reached by the practitioner, any plan of treatment for the patient and particulars of any medication prescribed for the patient;
- the date of treatment, nature of treatment, the name of any person who performed the treatment, the type of anaesthetic given to the patient (if any), the tissues (if any) sent to pathology, the results or findings made in relation to the treatment, and any written consent given by a patient to any medical treatment.

The NSWLRC in its Artificial Insemination report raised the question who is a “patient”

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<sup>68</sup> NHMRC, n 45, p. 12. For a full examination of the NHMRC guidelines as they relate to record keeping, see Part 5.1.2 below, at p. 42.



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for the purposes of record keeping, and concluded that if a heterosexual couple was seeking treatment for infertility, both members of the couple would be patients. Strictly speaking, sperm donors are not “patients”, however, it could be argued that donors who have to undergo a medical procedure (for example removal of an ovum) would be “patients” and therefore come under the gambit of the regulations. The Commission also stated that the patient status of an ART child could be created contractually by the parents.<sup>69</sup> This is particularly important in relation to access to the records, since if the child is a patient, the records must be kept until the child is 25 years old. If not, the records could be destroyed seven years after the parents’ last consultation, when the child may be less than seven years old.

Details of all conceptions and births must be passed on to the Australian Institute of Health and Welfare’s National Peri-Natal Statistics Unit by clinics who practice ART. The clinics must pass on information relating to assisted conception using IVF, GIFT and ICSI. The information is then summarised in a yearly report. The clinics are not, however, required to pass on any information regarding artificial insemination either by the woman’s partner’s sperm or donor sperm, although the Human Tissue Regulation 1995 requires clinics for maintain records in respect of each donation for a period of 10 years where the donor is aged 20 years or over, or until the donor reaches the age of 30 where the donor is younger than 20 at the time of the donation.<sup>70</sup> It has been asserted that in many cases clinics do not know whether or not a pregnancy has occurred as a result of donor insemination, and it is “virtually unknown for clinics to do any form of follow-up of recipients of donor insemination procedures.”<sup>71</sup> There is the added complication of “do-it-yourself” artificial insemination like that which was carried out by the parties in the case *J v B*, discussed above, where no records of any type are kept. The result is incomplete records which may not paint an accurate picture of the number of people receiving ART treatment of all kinds, particularly in relation to AI.

The National Health and Medical Research Council *Guidelines* (see Part 5.1.2 below, page 42), state in paragraph 3.1.5 that:

Children born from the used of ART procedures are entitled to knowledge of their biological parents. Any person, his spouse or partner, donating gametes and consenting to their use in an ART procedure where the intention is that a child may be born must ... be informed that the children may receive identifying information about them.

The NSWLRC in its reports on Artificial Insemination and In Vitro Fertilisation came to the following conclusions:

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<sup>69</sup> NSWLRC, *Human Artificial Conception*, Report No. 49, 1986, p. 95.

<sup>70</sup> Schedule 4, clause 8.

<sup>71</sup> C Lorbach, *The Hidden Paternity*, paper presented at the Proof of Paternity Seminar, Sydney, 19 February, 1998, p. 5..

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- A statutory right be created where AID recipients, children, donors and any other person showing “good cause” may have access to recorded **non-identifying** information either by agreement with the record keeper, or failing agreement, upon the decision of a person or body nominated by the Minister for Health. The majority of the Commission defined good cause to involve the health and welfare of a party to ART. However, others favoured a more restricted definition, relating only to the physical well being of the ART child.<sup>72</sup>
  - No person should have a legal right of access to information that may **identify** a party to AID, and no record keeper should divulge such information, unless the person who is the subject of the information formally consents.<sup>73</sup> There appeared to be two main basis upon which this conclusion relied: the principle of “the claim of competent adults to personal autonomy and liberty to make their own decisions in relation to reproduction and family matters, including the welfare of their children”<sup>74</sup>, and status of children legislation, which deliberately rejects the supremacy of biological parenthood and replaces it with social parenthood in cases of donor conception. This illustrates a policy decision whereby social parentage is paramount, and to insist upon biological parentage is inconsistent with this decision.<sup>75</sup>

Where there is a conflict of interest between a donor’s expressed wish for anonymity and a resulting child’s wish to learn of his or her genetic origins, the Commission accepted that the paramount consideration should be the welfare of the ART child. However, the Commission also stated that determining the best interests of the child is difficult and sensitive, and might not necessarily result in the child being given access to the information contained within records.<sup>76</sup>

Research has been conducted which attempts to determine the attitudes of parents of children conceived by donor insemination to telling their children about their origins. The research took the form of a questionnaire survey, during 1992-93, of parents who had had a child by donor insemination at four NSW clinics between 1979 and 1990. A total of 646 couples had been seen by the clinics during this period. Of those, 393 could be contacted and 353 agreed to take part in the research. Of those, 276 (70%) responded to the questionnaire. The 276 couples taking part had had a total of 420 children through donor insemination. The main findings of the research include:

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<sup>72</sup> NSWLRC, n 69, pp. 93-94. Although the comments were made specifically in relation to Artificial Insemination, they apply equally to any procedure which uses donated gametes.

<sup>73</sup> Ibid, p. 93.

<sup>74</sup> Ibid, p. 92.

<sup>75</sup> Ibid, pp. 92-93.

<sup>76</sup> NSWLRC, n 51, p. 93.

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- Before conception, 18% of families planned to tell the child of its origins, 52% said they would not tell their child, and 30% were undecided.
  - Of the group who planned to tell their child, 45% had done so and 14% had changed their minds. The remainder still intended to tell the child, but had not done so at the time of the research. None of the parents who had indicated they would not tell their child had changed their minds.
  - 71% of couples had told others of the origins of their child.
  - 94% of families had not told their child of their origins. Of the 29% who had not told others, none had told the child.
  - 5.2% (22 children) had been told of their origins. The mean age at which the child was told was 6.3 years (the range was 2 to 13 years). For those parents who did intend to tell their children, the mean age at which they intended to disclose the child's origin was 8.4 years.<sup>77</sup>

The results of this study were supported by a 1996 study in Western Australia in which only 3% of children had been told of their donor origins, and a 1997 Canadian study in which only one from 300 children had been informed of his or her origins.<sup>78</sup> The study pointed out a risk of accidental disclosure in the situation where others knew of the child's origins but the child had not yet been informed, stating that this could be a potential cause for parental anxiety. The study concluded that, given it is a parent's right to decide whether to tell their child, appropriate non-identifying information should be available for children who are aware of their donor origins. A high level of record keeping by clinics would make this possible, and is already demanded by the Fertility Society of Australia. Consequently, the authors of this study concluded that extensive registers of semen donors would be unnecessary, given the small number of children who could potentially seek information on the donor.<sup>79</sup> Bearing in mind these conclusions, the validity of responses such as that in Victoria, according to which parents must compulsorily inform their children of their origins (see below), must be questioned.

Whether or not children born from ART procedures should have a right to identifying information about the donors of the gametes from which they were conceived stems from a similar debate in regard to adoption practices. The debate focuses around the notion of "genealogical bewilderment", which has been defined to mean "a state of confusion and uncertainty in children who have no, or only uncertain, knowledge of their natural parents". It is argued that this state may undermine a child's security and affect his or her health.<sup>80</sup>

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<sup>77</sup> Durna, n 23, pp. 257-258.

<sup>78</sup> Ibid, p. 258.

<sup>79</sup> Ibid, p. 259.

<sup>80</sup> Ibid, p. 256.

Identity formation, it is argued, is critical for personality development in adolescence and movement towards adulthood. It is important for the adolescent to know about the past in order to move towards the future. It has been argued in the adoption context that the more information children have about their biological parents and the circumstances of their relinquishment, the more easily they can establish a basis from which identity formation and integration can take place.<sup>81</sup>

There has been considerable debate on the similarities between the adoption and donor insemination experiences. Parallels are often drawn, particularly in relation to the information which is made available. Despite the desire by many to couple the two experiences together, differences do exist between the adoption experience and the donor insemination experience. The NSWLRC stated that there were “factual differences in the circumstances of children in a typical adoption and those in typical cases of AID and IVF”.<sup>82</sup> The fundamental difference relates to the biological relationship between the child and the parents. Unlike an adopted child, a child born as a result of donor insemination usually carries the chromosomal complement of the mother - the mother’s genes. The mother experiences a normal pregnancy, and is seen to be pregnant by friends, relatives and neighbours.<sup>83</sup> It has been asserted that this “bond formed *in utero* between the mother and child plays a large part in the formation of the child’s personality”.<sup>84</sup> There can be no doubt about a donor’s consent, which may further differentiate between children born as a result of sperm donation and those children who were adopted. In relation to adopted children, there are increasing claims that the birth mother was forced to release her child for adoption in some cases.<sup>85</sup> These differences need to be kept in mind when looking to the

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<sup>81</sup> P Westwood, ‘Who am I? Issues relating to identity formation and adoptee adolescents’, *Youth Studies Australia*, Vol 14, No 1, Autumn 1995, p. 52.

<sup>82</sup> NSWLRC, n 69, p. 86.

<sup>83</sup> Durna, n 23, p. 256. This is not necessarily the case in IVF situations where donated embryos may be used, although the mother at least experiences the phenomenon of pregnancy.

<sup>84</sup> Westwood, n 81, p. 53.

<sup>85</sup> A Bernoth, ‘Mothers win inquiry into forced adoption’, *Sydney Morning Herald*, 5 March 1998. It is claimed that 80,000 unmarried mothers were confronted with coercion in the form of bullying, psychotropic drugs and emotional blackmail, to force them to give their child for adoption. The Minister for Community Services, the Hon F Lo Po’, MP, announced a Parliamentary Inquiry into past adoption practices on April 2 1998. The terms of reference of the inquiry included inquiring into and reporting on:

- the professional practices in the administration and delivery of adoption and related services, particularly relating to the taking of consents, offered to birth parents and children in NSW from 1950 to 1998;
- whether adoption practices during this time involved unethical and unlawful practices and/or practices that denied birth parents access to non adoption alternatives for their child; and
- if so, what measures would assist persons experiencing distress due to such

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adoption experience for answers to questions raised by donor insemination.

In light of the Standing Committee on Social Issues' current reference on past adoption practices in NSW (see n 85), and the NSWLRC's recent report on adoption in NSW, this Paper will not include an extensive discussion of adoption practices in NSW. It does, however, look at the NSW response to the question of access to information as it applies to adopted people. The debate regarding access to information about adopted parents, culminated in NSW in the *Adoption Information Act 1990*. The objects of this Act are:

- (a) to give adult adopted persons greater access to information concerning their origins, and
- (b) to give the birth parents and adoptive parents of adult adopted persons greater access to information concerning their children, and
- (c) to preserve controls adoptive parents have over the access of adopted children to information concerning their origins while recognising the paramount interests of adopted children, and
- (d) to give the relatives of adopted persons, birth parents and other persons access to information concerning adopted persons' origins in special circumstances, and
- (e) to protect the privacy of adopted persons and birth parents by establishing a system of vetoes against contact with persons identified through access to information concerning persons adopted before the date of assent to this Act, and
- (f) to limit the disclosure of information concerning the personal affairs of persons that might unduly intrude on their privacy, and
- (g) to make provision for a Reunion and Information Register to facilitate reunions between adopted persons, birth parents and other persons (if desired by the persons concerned) and to facilitate exchange of messages between persons concerned in or affected by an adoption.

Under the *Adoption Information Act 1990*, an adopted person who has reached the age of 18 years is entitled to receive his or her original birth certificate (that which is registered under the *Births, Deaths and Marriages Registration Act 1995*) and any "prescribed information" relating to the person's birth parents or to any adopted brother or sister of the person (section 6). In relation to information about the birth parents, the Regulation prescribes the following information for the purposes of section 6 of the Act:

- any relevant information that is held by an information source about the physical

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adoption practices.

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and intellectual attributes, educational and vocational qualifications, social and cultural background, health and welfare, family and other relationships, religious beliefs, hobbies and interests of a birth parent, sibling, grandparent, aunt or uncle of the adopted person and that will give the adopted person knowledge of his or her origins, and

- any of the following information held by an information source:
  - the date on which the person was placed with adoptive parents
  - the date of an adoption order;
  - a copy of the instrument of consent to the adoption;
  - a copy of the request to make arrangements for the adoption;
  - a copy of adoption order or memorandum of adoption (or both);
  - the reason the person was adopted (as stated by the birth parent or recorded by the information source before placement for adoption);
  - copies of medical reports of examinations of the adopted person made before the date of the adoption order;
  - a document certifying particulars of the birth of a birth parent;
  - a document certifying particulars of the marriage of a birth parent;
  - a document certifying particulars of the death of a birth parent, and
  - messages given to the information source by a birth parent for the adopted person if clause 17 is complied with (by which a signed release of the information must be given).<sup>86</sup>

It is argued by organisations such as the Donor Conception Support Group of Australia that similar provisions must be put in place in relation to ART records. Of course, since adoption has been traditionally organised by government departments, there is a greater retention of records relating to adopted children than there are in a lot of cases of children born from donor insemination, which makes legislation such as the *Adoption Information Act* more feasible. In Victoria and Western Australia centralised donor registries have been established to enable some sort of similar right to information for donor children. Under the Victorian *Infertility Treatment Act 1995*, all people conceived after January 1, 1995 who have knowledge of their donor insemination status have the right to know the identity of their donors once they reach the age of 18 years. Victoria is also establishing a voluntary

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<sup>86</sup> Clause 6(1).

register for past donors and recipients who do not come under the 1995 rules, where they may lodge information about themselves in order to be matched up.<sup>87</sup> In Western Australia, a central register stores information on donors. The records are required to be kept for 25 years, and donor offspring may access non-identifying records about their donors. Similarly in South Australia, although there is no central record, children may access non-identifying records. Clinics are required to keep their own records for 50 years under the *Reproductive Technology Act 1988*.

#### 4.4 Storage of embryo/egg/sperm

It is not uncommon for individuals who undergo ART procedures to have as many as 20 excess embryos at the completion of treatment. Many couples decide to store these excess embryos, and most ART clinics have the capacity to do this.<sup>88</sup> Sperm has been frozen and stored since 1953, and it is now possible to store eggs also. For a discussion of the procedures involved, see Part 3.9 - Cryopreservation, above at page 9.

The issues which surround storage of ART material include the status of the frozen material, and whether that material can possess “rights”, the uses to which the material is put and who decides this, and destruction of the material. The United Nations *Declaration on the Rights of the Child*, states in its preamble that “the child by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, *before* as well as after birth”.<sup>89</sup> This is the only international instrument which gives any indication of whether or not a child is recognised as existing before birth. It has been suggested that this was deliberate, allowing individual states to give these terms meaning. It also avoids potential conflict between those rights and other rights, particularly those of women.<sup>90</sup>

There has been a considerable amount of debate about whether or not a *foetus* has a legal persona, and is consequently afforded rights. This debate is useful insofar as it sheds some light on a likely position in relation to embryos. It has been suggested that the most appropriate approach is to give an embryo a separate status, deserving moral recognition and special respect, due to its potential to become a person, although to a lesser extent than enjoyed by an actual person.<sup>91</sup> An embryo is therefore given greater recognition than other

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<sup>87</sup> Lorbach, n 71, pp. 6-7.

<sup>88</sup> The cost of a three year plan, including freezing and storage at North Shore ART is \$470. Alternatively, it costs \$120 to freeze and \$170 per year to store biological material. There is also a \$60 release from storage fee payable.

<sup>89</sup> United Nations Commissioner for Human Rights, *Declaration of the Rights of the Child*, proclaimed by General Assembly resolution 1386(XIV) of 20 November 1959, preamble (emphasis added).

<sup>90</sup> Bunney, n 22, p. 126.

<sup>91</sup> *Ibid*, p. 131, Quoting from the Tennessee Supreme Court decision in *Davis and Davis*, 843 SW 2d 588, 1 June 1992.

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human tissue, but not at the expense of a couple's own legal rights. The consequences of vesting legal rights in a foetus or embryo is that, according to the principles of the *Family Law Act*, the rights of that child embryo would have to become paramount. This in turn would favour the implantation of the embryo in the donor mother, or in another recipient if the donor mother was unwilling to undergo implantation. It would also make the removal of embryos from storage, the continuation of cryopreservation or using embryos for research less acceptable, as these would all involve the destruction or possible damage to the embryo "child".<sup>92</sup> Complications could also arise if the father wanted to retain the embryos for use with a new spouse, or even a surrogate. If the woman wished the embryos to be destroyed, the courts could be compelled to approve a surrogacy agreement in light of the best interests principles.<sup>93</sup> There have already been cases before the courts which deal with this type of problem: a case in Brisbane concerning the future of a separated couple's frozen embryo's has apparently been settled out of court, and in Victoria proceedings were initiated by a woman seeking orders which required her husband to pay all the costs associated with an IVF program. She wished to have a fertilised egg implanted whereas the husband opposed this course in view of the breakdown of their marriage. There is no indication of the eventual outcome of this case, as the case itself dealt with the issue of whether or not it was appropriate that the husband's solicitor continue to represent him in light of a conflict of interest with the wife.<sup>94</sup>

In what may be seen as contrary to the principles of the *Declaration on the Rights of the Child*, it has been held on numerous occasions in Australian courts that the meaning of "child" does not include an unborn child. For example, In *In the Marriage of F*, a case in which a husband applied for an injunction to restrain his wife from having an abortion, Lundenmeyer J held that "a foetus has no legal personality and cannot have a right of its own until it is born and has a separate existence from its mother".<sup>95</sup> It is the act of "live birth" which bestows upon a foetus the legal rights and responsibilities of being a person. This is not to say that the courts have not been prepared to vest any rights in a foetus (which could be extended to an embryo also). A foetus may have rights, but they are contingent rights and only vest and become enforceable upon its live birth. Tort law recognises that there may be a duty of care owed to unborn foetuses, and there may be an argument whereby a technician, nurse or doctor who might drop a petrie dish containing an embryo could be charged with murder, or against a manufacturer of a faulty cryogenic tank if it malfunctions.<sup>96</sup>

There are also rights in succession, which were at issue in a recent Tasmanian case. In this case, a child which was conceived *in vitro* and implanted in its mother's womb after its

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<sup>92</sup> Bunney, n 22, p. 127.

<sup>93</sup> Ibid.

<sup>94</sup> *In the Marriage of A and B* [1990] FLC ¶92-126, extracted in Bunney, n 22, p. 122.

<sup>95</sup> *In the Marriage of F* (1989) 13 FamLR 189.

<sup>96</sup> Bunney, n 22, p. 128.



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biological father's death was held to have the same rights to its father's estate as a child who was in the mother's womb at the time of the father's death.<sup>97</sup> This is the first reported decision in any common law jurisdiction which deals with the succession rights of an embryo. However Justice Spicer expressly ruled out any wider discussion of the ethical or moral status of embryos, stating that he was not concerned with "any philosophical or biological question of what is life since the question [in the present case] relates solely to the status recognised by law and not to any moral, scientific or theoretical issue".<sup>98</sup> The common law rule with regard to foetuses is that a child in its mother's womb at the time of death is, if born alive, deemed to have been born at the time of the deceased's death and can therefore claim on the deceased's estate. The judge in this case concluded that if an IVF child was born posthumously, he or she is in exactly the same position as the child in the mother's womb at the time of death, and the same legal principles ought to apply: "a child, being the product of his father's semen and his mother's ovum, implanted in the mother's womb subsequent to the death of the father is, upon birth, entitled to a right of inheritance afforded by law".<sup>99</sup>

The length of time which an embryo may be stored is also an issue. If embryos are not to be destroyed, they can either be kept in cryopreservation indefinitely, or used for research. Experimentation on embryos is discussed in Part 4.5 below. The NSWLRC recommended that an overall time limit of 10 years be placed on the storage of embryos. The Commission based this recommendation on concern for the possible adverse side effects of long-term storage, and the legal and ethical implications of disposing of embryos whose parents had died, divorced or separated.<sup>100</sup> An overall time limit, it was believed, could circumvent some of these potential problems. The NHMRC *Guidelines* adopt a similar approach, stating that embryos may be kept for a period not exceeding 10 years, after which time, if not used by the couple, they may be donated or "allowed to succumb". The arrangements can be varied on compassionate grounds by an Institutional Ethics Committee. Similar provisions are contained in the various state legislation - see Part 5.5, page 49 for details.

#### 4.5 Embryo experimentation

In its introduction to Part 6 - Research on Embryos, the NHMRC stated:

Research involving early human embryos raises profound moral and ethical concerns. There are differences of opinion amongst Australians regarding the moral status of the human embryo, particularly in its early stages of development.

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<sup>97</sup> *In the Matter of the Estate of the Late K and in the Matter of the Administration and Probate Act 1935; Ex parte the Public Trustee*, Supreme Court of Tasmania, Slicer J, 22 April 1996.

<sup>98</sup> *Ibid*, p. 5, quoted in D Chalmers, 'Frozen assets: the inheritance rights of embryos', *Australian Lawyer*, Vol 131, No 6, p. 21.

<sup>99</sup> *In the Matter of the Estate of the Late K*, n 97, p. 7.

<sup>100</sup> NSWLRC, n 51, p. 86.

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It summed up the position in Australia by continuing

Some believe that there is the same obligation to refrain from harming an embryo as that which is recognised in relation to human beings in general. If so, then any destructive or other harmful experimentation would be morally unacceptable to researchers or gamete donors with this belief. Others believe that research which may potentially harm the embryo may be justified where it is undertaken for the direct benefit of other embryos. Still others believe that research which is harmful to embryos may be justified on the basis of advancing knowledge or improving technologies for treatment.

And concluded by stating that “at the present time these differences cannot be resolved”.<sup>101</sup> The NHMRC guidelines were written to reflect these differences in opinion. The *Guidelines* state:

- 6.2 Embryo experimentation should normally be limited to therapeutic procedures which leave the embryo, or embryos, with an expectation of implantation and development.
- 6.3 Non-therapeutic research which does not harm the embryo may be approved by an Institutional Ethics Committee (IEC).
- 6.4 Non-therapeutic research which involves the destruction of the embryo, or which may otherwise not leave it in an implantable condition, should only be approved by an IEC in exceptional circumstances: a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research; a restricted number of embryos will be involved, and the gamete providers, their spouses and partners, have consented to the specific research.

...

A Senate Select Committee on the Human Embryo Experimentation Bill 1985 reported in September 1986. The Committee recognised a distinction between experimentation of diagnostic and/or curative value (therapeutic experimentation), and experimentation with no such value, but undertaken to advance medical/scientific knowledge (non-therapeutic experimentation). The Committee made a further distinction between non-destructive and destructive experimentation, in which the experiments are, in the present state of scientific knowledge, so invasive as to inevitably cause the destruction of the subject of the

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<sup>101</sup>

NHMRC, n 45, p. 10.

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experimentation.<sup>102</sup> This distinction is commonly made in reference to biomedical research on embryos, and more generally. The Catholic church, for example, makes the distinction (see below), as does the legislation which deals with the issue of embryo experimentation. While recognising a certain respect which may be accorded to the embryo in deference to the ‘human and social origins of the sperm and eggs which formed them’, it was the Committee’s view that a further degree of respect was due to the embryo “in deference to the embryo’s human and social future”.<sup>103</sup> The Committee based its recommendations to prohibit destructive non-therapeutic experimentation on the respect it felt to be due to an embryo’s “orientation to the future”.

The Catholic Church’s view has been stated in the Papal Encyclical titled *Instruction on respect for human life in its origin and the dignity of procreation: replies to certain questions of the day*. Its view is that “the human being must be respected - as a person - from the very first instant of his existence”. Consequently, the Encyclical stated

Medical research must refrain from operations on live embryos, unless there is a moral certainty of not causing harm to the life or integrity of the unborn child and the mother, and on the condition that the parents have given their free and informed consent to the procedure. It follows that all research, even when limited to the simple observation of the embryo, would become illicit were it to involve risk to the embryo’s physical integrity or life by reason of the methods used or the effects induced.

As regards experimentation, and presupposing the general distinction between experimentation for purposes which are not directly therapeutic and experimentation which is clearly therapeutic for the subject himself, in the case in point one must also distinguish between experimentation carried out on embryos which are still alive and experimentation on embryos which are dead. If the embryos are living, whether viable or not, they must be respected just like any other human person; experimentation on embryos which is not directly therapeutic is illicit.<sup>104</sup>

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<sup>102</sup> Senate Select Committee on the Human Embryo Experimentation Bill 1985, *Human Experimentation in Australia*, Parliamentary Paper No 437/1986, p. xiii. This Bill was introduced as a Private Member’s Bill by Tasmanian Senator Brian Harradine in April 1985, and aimed “to prohibit experiments involving the use of human embryos created by in vitro fertilisation.” It was referred to the Select Committee prior to a second reading vote was taken. The Committee finally determined that an accreditation and licensing scheme was the most appropriate legal method for regulating the biomedical (continued over page) technology experimentation. Consequently, the Committee did not believe that the prohibitory regime, with its reliance on criminal law and injunctions as proposed by Senator Harradine’s Bill, would be effective.

<sup>103</sup> Ibid, p. 25.

<sup>104</sup> Congregation for the Doctrine of the Faith, *Instruction on respect for human life in its origin and the dignity of procreation: replies to certain questions of the day*, authorised Vatican translation, <http://listserv.american.edu/catholic/church/vatican/giftlife.doc>, parts 1.3-1.4.

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Both South Australian and Victorian legislation ban experimentation on human embryos which will be harmful. For example, South Australian legislation bans research “that may be destructive to an embryo”.<sup>105</sup> Similarly, section 24 of the Victorian *Infertility Treatment Act 1995* states

A person must not carry out research, outside the body of a woman, involving the use of an embryo -

- (a) if the embryo is unfit for transfer to the woman; or
- (b) in the case of an embryo which is fit for transfer to a woman, if the research would -
  - (i) harm the embryo; or
  - (ii) make the embryo unfit for transfer to a woman; or
  - (iii) reduce the likelihood of a pregnancy resulting from the transfer of the embryo.

The Western Australian legislation does not deal specifically with what types of experimentation will be allowed. It states, however, that only that research which is approved by the WA Reproductive Technology Council may be undertaken. In the Directions which accompany the Act, it states “... the person responsible must ensure that the application for approval gives evidence ... that this is intended to be therapeutic for that embryo, and unlikely to have any detrimental effect on it”.<sup>106</sup>

#### 4.6 Financial costs

The cost of ART is relatively high. In Australia Medicare covers part of the cost, but even so couples embarking on ART procedures can expect to have to contribute to the costs. Medicare covers 75% of the scheduled fee for inpatients, and 85% of the scheduled fee for outpatients having IVF treatments for up to six cycles. After six cycles, the patient must cover the full cost. The cost varies from clinic to clinic, and depends upon whether the patient needs day surgery, and anaesthetist, pathology testing etc. As an indication of the cost of ART procedures in NSW, the costs associated with ART treatment at North Shore ART, a private ART centre affiliated with the University of Sydney Department of

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<sup>105</sup> *Reproductive Technology Act 1988*, section 14(2)(b).

<sup>106</sup> *Human Reproductive Technology Act Directions*, Given by the Commissioner of Health to set the standards of practice under the *Human Reproductive Technology Act 1991* on the advice of the WA Reproductive Technology Council, Article 9.4. See Part 5.3, p. 45, below for an explanation of how these Directions fit into the Western Australian regulatory system.

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Obstetrics and Gynaecology are attached in Appendix 2.<sup>107</sup>

Should the cost of ART services be regulated, to a greater extent than results from Medicare determining a scheduled fee? As can be seen from the table of costs in Appendix 2, the actual cost to the patient can greatly exceed the scheduled fee. Does the relatively high cost of ART reflect the technology and expertise that is involved in the procedures, or is it taking advantage of couples' desperate desire for a family? Should a person expect to receive ART treatment for free, or should they be expected to contribute to the costs? In the present climate of limited health funding, the question which must be answered is whether or not these large amounts of money would be better directed elsewhere. Would the answer to the above questions be different if the couple were attempting to have a second, or subsequent child using ART technology? The answers to all these questions go right to the heart of our understanding of the importance of families and children in society, our right to reproductive freedom, and the whether or not ART constitutes "interfering" with "nature".

Another question regards the provision of ART services for a profit, and the impact that profit-driven organisations will have on the ethical provision of services. Particularly in relation to private funding of research, there is a concern that large multinational drug corporations and surgical instrument manufacturers will influence the direction of research and the availability of new fertilisation technologies.<sup>108</sup>

#### 4.7 Posthumous use

In March 1997 Englishwoman Diane Blood won the right to take her deceased husband's frozen sperm to Belgium to attempt pregnancy. A similar case was heard in Australia in mid 1998, in which a Victorian Supreme Court judge permitted a doctor to collect sperm from a woman's deceased husband so that the woman might bear a child. Although the woman could not legally use her dead husband's sperm in Victoria (see below), the Victorian Infertility Treatment Authority allowed her to take the sperm to another state where she might be inseminated with it.<sup>109</sup> It has in fact been claimed that the practice of extracting sperm from dead men is becoming commonplace.<sup>110</sup> An American woman, the first in the world to do it, was reported in July 1998 to be one month pregnant with a child conceived using sperm taken from her deceased husband soon after death.<sup>111</sup> The legal question involved in posthumous use of sperm is centred on the issue of consent. If the

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<sup>107</sup> North Shore ART, information supplied to the author by facsimile, 14 October 1998. The information is dated March 1998. Note that these costs are *indicative* only, and do not represent the costs at *all* ART clinics. The scheduled fee which is included in the tables is, however, standard across all clinics.

<sup>108</sup> Libesman, n 29, p. 67.

<sup>109</sup> H Kuhse, 'The moral right to reproductive freedom', *The Australian*, 23 July 1998, p. 13.

<sup>110</sup> L Carty, 'A question of ethics in a brave new world', *Illawarra Mercury*, 5 March 1997.

<sup>111</sup> D Smith, 'Sperm counts', *The Sydney Morning Herald*, 23 July 1998, p. 11.

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decision is made after the man has died, he is unable to give consent for the harvesting of his sperm, or determine who is allowed access to his sperm. In the case of the Bloods, the court allowed her to use sperm which had been extracted while the man lay dying in hospital from bacterial meningitis. The decision was based on a belief that, had he been conscious, Mr Blood would have given his consent to the procedure.

Victoria is the only state where legislation specifically regulates posthumous use, and makes posthumous use an offence:

a person must not inseminate a woman with sperm from a man known to be dead, transfer a gamete or a zygote or embryo formed from a gamete from a person known to be dead, form a zygote with sperm from a man known to be dead or form a zygote from an oocyte from a woman known to be dead.<sup>112</sup>

This would apply to a situation like that described above, as well as to anonymous donors, which would explain the specification “known to be dead” in the legislation. The Directions made under the Western Australian Act also prohibit the use of gametes in a fertilisation process after the known death of the donor.<sup>113</sup>

A different situation could arguably arise where the sperm has been extracted and frozen prior to a man’s death, with the intention of using it at a later date to have a child with his partner who outlived him (although the Victorian legislation does not appear to make this distinction). In this case, there is a clear intention that the frozen sperm will be used at a later stage to create a child. The NSWLRC in its report *In Vitro Fertilisation* recommended that:

no action be taken to enact legislation to regulate or prohibit directly AIH (artificial insemination by husband) where a widow wishes to use that procedure to become pregnant by her late husband’s stored sperm.<sup>114</sup>

Furthermore, the Commission recommended that

the law recognise the deceased husband as the father of a child born as a result of such a procedure, provided that the woman is his widow and unmarried at the time of insemination and birth, and further that the law allow the register of births to record the deceased husband’s paternity in such a case.<sup>115</sup>

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<sup>112</sup> *Infertility Treatment Act 1995*, section 43.

<sup>113</sup> *Human Reproductive Technology Act Directions*, n 106, Article 8.5.

<sup>114</sup> NSWLRC, n 51, p. 80.

<sup>115</sup> *Ibid.*

The effect of this would be that the child would be regarded as the child of the deceased man for the purposes of inheritance. The Commission recognised a practical difficulty in implementing this recommendation where the deceased's estate had been fully distributed before the birth of the child. Authorities differ on what is the appropriate response. The Ontario Law Reform Commission recommended that legislative provision be made creating an entitlement for a posthumously conceived child as if the child had been conceived prior to the death of the father. A 1984 United Kingdom report,<sup>116</sup> however, unequivocally rejected this proposition, recommending that the child be disregarded for the purposes of inheritance. See further the discussion in Part 4.4, page 26, above. The NSWLRC concluded that the law should not preclude a man from making a specific gift to the posthumously conceived child, but because of the practical difficulties, such a child should not participate in the distribution of the man's estate should he die intestate.<sup>117</sup>

## 5.0 REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGY

The Ontario Law Reform Commission examined the arguments for and against the regulation of ART and the options for regulation if appropriate in its report *Human Artificial Reproduction and Related Matters* (1985). In that report, the Commission stated that the fundamental question in this regard is whether or not “the law should treat artificial reproduction differently than in the manner in which it treats natural reproduction, at least insofar as the decision to conceive a child is concerned.”<sup>118</sup> The Commission continued by differentiating between two significant approaches to reform, which it stated “represented the two extreme points on what is clearly a continuum”.<sup>119</sup> These two approaches are:

- ***private ordering approach***, where the legal regime is designed to give effect to the intentions of the parties, and the
- ***state regulation approach***, where the free choice of the parties does not determine what that they do or the consequences of their actions, but where the State actively intervenes to set mandatory standards of conduct.<sup>120</sup>

The private ordering approach is not necessarily adverse to legislation, and may in fact require legislative intervention in order to give effect to the wishes of individuals, or to preclude interference with those wishes. However, this type of legislation merely serves to facilitate a person's activities where necessary, and does not purport to tell people what to

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<sup>116</sup> *Report of the Committee of Inquiry into Human Fertilisation and Embryology*, July 1984.

<sup>117</sup> *Ibid.*, pp. 80-81. For a detailed discussion of this issue, see pages 80-83.

<sup>118</sup> Ontario Law Reform Commission, *Human Artificial Reproduction and Related Matters*, Queens Printers for Ontario, 1984, extracted in Kennedy & Grubb, n 53, pp. 762-768, at p. 764.

<sup>119</sup> Kennedy & Grubb, n 53, p. 763.

<sup>120</sup> *Ibid.*

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do or not to do, as would legislation in the state regulation approach. An example of this type of legislation can be found in the area of de facto relationships, in which the law serves to formalise a choice already made by people to live in a de facto situation, imposing on such people the same rights as are enjoyed by legally married couples.<sup>121</sup> The NSW Department of Health's *Discussion Paper* articulated this question slightly differently by asking the question whether or not legislation is necessary to prevent harm, or the risk of harm to the public, notably the consumers of ART and persons born as a result of ART, or whether some other means of regulation (or no regulation) is sufficient.<sup>122</sup>

Upon considering the question of which approach should be taken, the Ontario report concluded that

the law must impose a degree of intervention in the case of artificial conception that is neither desirable nor possible in the case of natural reproduction. The wishes of the parties - particularly, the desire of the prospective social parents to have a child - are, in fact, only one of the many considerations that should affect the determination of the new legal regime. Given the implications of artificial conception for persons other than the prospective parents, we strongly believe that 'private ordering' cannot be the sole governing factor. In our view, there are strong philosophical and practical reasons for embracing, at least in some areas, an approach that does not give free rein to the wishes of the parties...<sup>123</sup>

In Australia, three states have legislated in the area of ART: South Australia, Victoria and Western Australia. Each of these legislative regimes will be discussed in more detail below. Those states where legislation exists clearly ascribe to the perspective of the Ontario Law Reform Commission advocating an interventionist approach. Although the New South Wales Government has not legislated directly in the area of assisted reproductive technology, there is some indirect regulation in the *Human Tissue Act 1983*, which effects the supply of semen. Furthermore, the National Health and Medical Research Council *Guidelines on Assisted Reproductive Technologies* operate in New South Wales. The means of regulation in NSW are examined below. The question which needs to be answered is whether or not such regulation is sufficient. If it is not considered sufficient, and legislation is determined to be the most appropriate alternative, the question then becomes which legislative model should be adopted.

The *Discussion Paper* issued by the NSW Health Department refers to two additional principles which it states the NSW Government will apply to any proposed legislation. These principles are a result of the National Competition Principles Agreement, which commits Commonwealth, State and Territory Governments to consider the potential anti-

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<sup>121</sup> In NSW this law is contained within the *de Facto Relationships Act 1984*.

<sup>122</sup> NSW Health, n 4, p. 5.

<sup>123</sup> Kennedy & Grubb, n 53, p. 764.



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competitive effect of all legislation. Fundamentally, the Agreement has the effect that legislation should not restrict competition unless it can be demonstrated that:

- the benefits of the restriction to the community as a whole outweigh the cost, and
- the objectives of the legislation can only be achieved by restricting competition.<sup>124</sup>

The regulatory scheme in NSW will be examined in detail below, and the schemes operating in each of the States in which legislation has been passed will be discussed. A detailed examination of the interstate legislation does not form part of this paper, however a comparative table with section references, compiled by the Chief Executive Officer of the Victorian Infertility Treatment Authority, Ms Helen Stokes, is included to enable comparison elements common to all States. The table provided by Ms Stokes also includes the regulation in those states where there is no relevant legislation.

## 5.1 New South Wales

In NSW the carrying out of artificial insemination and other forms of ART *per se* is not regulated. Rather, the supply of semen is regulated by the *Human Tissue Act 1983*. Regulation is from the point of view of minimising infection through contaminated donor semen,<sup>125</sup> rather than from the point of view of controlling the provision of reproductive technology services *per se*.

### 5.1.1 Human Tissue Act 1983

There are two means by which the *HTA* regulates the supply of semen: by requiring a certificate from a potential donor pertaining to potential contamination of the semen, and by requiring authorisation of businesses engaged in the supply of semen.

Semen, like blood or blood products, is not to be removed from a person unless that person has signed a certificate relating to his medical suitability as a donor (section 21C). A sample of such a certificate can be found in Appendix 3. The maximum penalty for infringing this requirement is 2 penalty units, which at the time of writing equalled \$220. If a false or misleading statement is made by a potential donor when filling out a certificate, the maximum penalty is 50 penalty units (\$5,500) or imprisonment for one year, or both. A certificate made under section 21C must be retained by the organisation collecting the semen, for a period of 10 years from the date on which it was signed (Human Tissue Regulation 1995, clause 5). The issues of record keeping in relation to semen donors is discussed below, and in relation to record keeping generally see Part 4.6, page 31, above.

The Act also serves to regulate the businesses supplying semen. The act is limited to those

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<sup>124</sup> NSW Government Policy Statement on Legislation Review, June 1996, p. 24, extracted in NSW Health, n 4, p. 5.

<sup>125</sup> NSW Health, n 4, p. 11.

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businesses supplying semen to medical institutions and other persons for the purposes of using all or some of that semen for the artificial insemination of women. Any business carrying on such activities must be authorised under the Act (section 21G). The information which must be supplied by an applicant for authorisation is contained in Schedule 2 and includes:

- his or her full name and address;
- the proposed name of the business;
- the proposed location of the business and plans of the premises in which the business will be carried on;
- details of the management structure of the business;
- details relating to the registration of a corporation if relevant, and
- the name and qualifications of the person who will be supervising the collection, testing, storage and supply of semen, and the relevant records relating to those activities.

When granting authorisation, the Secretary of the Department of Health (or his or her representatives) may impose any conditions he or she may consider necessary to maintain the health of the community. A list of prescribed conditions are contained in Schedule 4 of the Human Tissue Regulation, and include:

- semen may be stored only at the premises specified in the authorisation, an accredited pathology laboratory or the premises of an exempt supplier;
- all donated semen other than that donated solely for the purpose of artificially inseminating the donor's spouse must be tested for any pathological micro-organism;
- blood samples must be taken from the donor at the time of donation and, at the expiry of the quarantine period, be tested for Hepatitis B, Hepatitis C, Human T-lymphotrophic virus, HIV and *Preponema pallidum*. If any blood is found to contain any of these contaminants, the donor and the referring medical practitioner must be notified, any semen stored or subsequently obtained from the donor must not be used for any therapeutic purpose without the approval of the Director-General, and any cryo-storage vessel containing the semen must be labelled to indicate the presence of the contaminant. No semen may be released for use until after the expiry of the quarantine period mentioned above;
- each straw containing donated semen must be labelled with a code identified in the records as being from the donor as well as the date of donation;

- all semen must be stored and transported in cryo-storage vessels containing liquid nitrogen;
- the following records must be maintained by the authorised supplier in respect of each donation:
  - full name and date of birth of the donor;
  - the donor’s written consent;
  - the results of all tests performed on the donated semen and donor’s blood sample;
  - the identification details in relation to the straw containing the donor’s semen, and
  - the name of the medical practitioner to whom the semen is supplied.

The records must be retained for the following amount of time:

- where they relate to a donor aged 20 years and over - for a period not less than 10 years from the date of donation;
- where they relate to a donor aged under 20 years at the time of donation - until the donor attains, or would have attained, the age of 30 years.

An authorisation will remain in force until revoked by the Secretary. Any premises being used for the business of supplying semen may be entered and inspected at all reasonable times by an inspector appointed by the Secretary for the purpose of ascertaining whether or not the provisions of the Act are being adhered to (section 21Q). Samples and records may be inspected or removed for the above purpose, and where a person or organisation is found to be engaging in practices which are in contravention of the Act, an injunction may be sought preventing the person from engaging in those practices (section 21U).

### ***5.1.2 NHMRC Ethical Guidelines on Assisted Reproductive Technologies***

The National Health and Medical Research Council (NHMRC) *Ethical Guidelines on Assisted Reproductive Technologies* (“the *Guidelines*”) apply across Australia, but are most relevant to those States where there is no operating legislation. In fact, Part 1 of the *Guidelines* states that “in those States where there is specific legislation regulating assisted reproductive technology (ART), compliance with provisions of the statutes must be observed. Where both the State law and the guidelines apply, the State law prevails”.<sup>126</sup> The *Guidelines* are, consequently, particularly relevant in NSW where there is no overriding

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<sup>126</sup>

NHMRC, n 45, p. 2.

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legislation. It must be remembered that these guidelines do not have the force of legislation, although some guidelines and codes of practice can be legislatively backed. Where this is the case, contravention constitutes an offence for which the contravener can be punished. If NSW decides to regulate ART and takes the code of practice approach, it seems preferable that such guidelines should have legislative backing, or some other means of enforcement. This is the case in Canada, for example, where funding is not provided to those individuals and organisations who do not comply with the Canadian code of practice (see Part 5.6.2, page 54, below). The *Guidelines* cover the following areas:

***Accreditation*** <sup>127</sup>

- All organisations offering ART must obtain accreditation from the Reproductive Technology Accreditation Committee. A number of factors must be taken into account when determining whether to grant accreditation:
  - compliance with NHMRC Guidelines;
  - compliance with the Code of Practice of the accreditation or licencing body (the Reproductive Technology Accreditation Committee);
  - certification and maintenance of appropriate professional standards for all personnel involved in relevant clinical and laboratory work, and
  - maintenance of quality assurance programs for both laboratory and clinical work.
- Any specific research projects which require the use of gametes and/or embryos must comply with the specific legislation on the particular state and must be approved by an Institutional Ethics Committee (IEC) constituted in accordance with the *NHMRC Statement on Human Experimentation*.
- Improvements in existing treatment methods should not be introduced into routine clinical practice without prior evaluation of safety and efficacy, and consideration of legal and ethical issues (by an IEC).

***Informed decision-making and consent*** <sup>128</sup>

- Informed decision making is applicable to all participants, including donors of gametes and embryos. All participants who are to give their consent should be given an oral explanation, supported by written information in plain language which can be taken away and read prior to giving consent. All information which may be significant to ensure an informed decision is made must be given to the participant.

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<sup>127</sup> Ibid, pp. 3-4.

<sup>128</sup> Ibid, pp. 5-7, p. 13.

Included should be information regarding:

- the ART procedures;
  - relevant success and failure rates;
  - potential benefits;
  - treatment options;
  - details of costs involved (including a breakdown of component costs of each treatment cycle);
  - short and long term physical and psychological risks, including any risk of adverse outcome for any children born and any risks associated with multiple births, ectopic pregnancies and spontaneous abortion;
  - information on counselling services available;
  - details of what records will be kept, and
  - whether procedures for which consent is being sought are experimental or established.
- Children born of ART are entitled to knowledge of their biological parents. Any person (and his spouse) donating gametes must be informed that identifying information may be provided to any child that is born as a result of that donation.
  - An ART procedure, including one where gametes and embryos are used, may only be carried out after obtaining the consent of the person to be treated and any spouse or partner of that person. Where applicable, consent must be given in accordance with existing State legislation, and with the Code of Practice of the accreditation body. Consent should be given in writing, following the provision of relevant information as detailed above. It is the responsibility of the medical practitioner to ensure that participants are aware of the implications of proposed treatments and that they have consented in a free and informed way.
  - The gamete provider and any spouse or partner of that person must give consent to the keeping or use of any gametes, and if the intention is to create an embryo or embryos outside the body, the consent must specify the purpose or purposes for which that embryo is to be used. The couple who are consenting to the storage and use of their embryos should specify the maximum period of storage, and give an advanced directive as to what should be done with the embryos if one or both members of the couple should die, become incapable of or fail to give further instructions. Where disputes arise between couples about the storage of embryos, those embryos shall be kept until the dispute is resolved and a decision made regarding those embryos.

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- All participants should be given information about the relevant routes for complaint. Institutions should ensure that procedures are in place for investigating and resolving complaints, consistent with relevant State legislation where appropriate.

### ***Counselling***<sup>129</sup>

Counselling is to be an integral part of any ART program. Counselling is to be of a supportive and therapeutic nature. It may be provided within, or independently of the clinic and should be incorporated into the routines of the clinic and be available as part of long-term follow-up.

### ***Research***<sup>130</sup>

The NHMRC recognises the differences of opinion held by Australians in relation to the status of human embryos. It further recognises that these differences can not be solved at the present time. This recognition is implicit in the guidelines it developed on research on embryos.

- Research on human embryos must take place within the limits prescribed by the law. Where there is no law operating, research may only take place in accordance with the NHMRC *Guidelines*.
- Embryo experimentation should normally be limited to therapeutic procedures which leave the embryo, or embryos, with an expectation of implantation and development.
- Non-therapeutic research which does not harm the embryo may be approved by an Institutional Ethics Committee. Non-therapeutic experimentation which involves the destruction of the embryo or otherwise leaves it in an unimplantable position should only be approved by an IEC in exceptional circumstances. Approval in these circumstances requires:
  - a likelihood of significant advance in knowledge or improvement in technologies as a result of the proposed research;
  - that the research involves a restricted number of embryos, and
  - that the gamete providers, and their spouses or partners, have consented to the specific form of research.

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<sup>129</sup> Ibid, p. 8.

<sup>130</sup> Ibid, pp. 9-10.

***Storage of gametes and embryos***<sup>131</sup>

- Clinics should seek to avoid the likelihood of the production of embryos in excess of the needs of the couple, consequently techniques and procedures which create an embryo surplus should be discouraged in ART clinics.
- Embryos may be kept for a period not exceeding 10 years. Following this period, if not used by the couple, they may be donated or allowed to succumb. Embryos may be allowed to succumb by a withdrawal of support by the couple who generated the embryo. If indicated in their consent, the couple's wishes are to be respected in this matter. Where no consent exists for the storage of the embryo, the embryo should remain in storage until the expiry of the maximum period of storage and may then be allowed to succumb.
- The identity and location of any gametes, and the identity, number and location of any embryos in storage is to be recorded in detail. In the case of donated gametes and embryos, the identity of the donor(s) should be accurately recorded, using labelling methods which are not susceptible to unauthorised, undetectable or accidental alteration.

***Record keeping***<sup>132</sup>

- Records should enable staff of a clinic to trace what happens to an individual embryo, egg or sperm from the date of collection of the sample. Detailed clinical and laboratory records should be kept which will be adequate to facilitate both short and long-term follow-up of the effects of treatments, enable linkage studies with other health data and facilitate the study of the long and short-term outcomes of any ART procedure that is commenced.
- Arrangements should be made by clinics for ART and donor records to be maintained indefinitely. Any practitioner who ceases practice should make arrangements to transfer these records to another suitable person or location, and should leave instructions on how this is to be carried out should he or she die or become unable to make such arrangements.

***Conscientious objection***<sup>133</sup>

Those staff who conscientiously object to research projects or therapeutic programs conducted by institutions that employ them should not be obliged to participate in those programs, and they should not be put at a disadvantage because of their objection.

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<sup>131</sup> Ibid, p. 11.

<sup>132</sup> Ibid, p. 12.

<sup>133</sup> Ibid, p. 14.

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***Prohibited and unacceptable practices***<sup>134</sup>

The following practices are considered to be ethically unacceptable by the NHMRC and should, therefore, in their opinion, be prohibited:

- developing embryos for purposes other than for their use in an approved ART treatment program;
- culturing of an embryo in vitro for more than 14 years;
- experimentation with the intent to produce two or more genetically identical individuals, including development of human embryonal stem cells with the aim of producing a clone of individuals;
- using fetal gametes for fertilisation;
- mixing of human and animal gametes to produce hybrid embryos;
- mixing of gametes or embryos of different parental origin so as to confuse the biological parentage of the conceptus;
- placing an embryo in a body cavity other than in the human reproductive tract;
- embryo flushing;
- commercial trading in gametes or embryos;
- paying donors of gametes or embryos beyond reasonable expenses;
- the use in ART treatment programs of gametes or embryos harvested from cadavers;

**5.2 South Australian *Reproductive Technology Act 1988***

South Australia was the first Australian state to legislate specifically in the area of ART. The 1988 Act is not as comprehensive as some of the later Acts, and relates predominantly to the establishment and functions of the SA Council on Reproductive Technology and the requirement for licences. The Council's functions are set out in section 10, and include:

- formulation of a code of ethical practice to govern the use of ART and research involving experimentation with human reproductive material. The Act states the welfare of any child to be born as a consequence of an artificial fertilisation procedure must be treated with paramount importance, and accepted as a

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<sup>134</sup>

Ibid, p. 15.



fundamental principle in the formulation of the Code. The Code must contain provisions to the following effect:

- a ban on embryo flushing;
- any persons on whose behalf an embryo is stored outside the human body must have the right to decide how the embryo is dealt with or disposed of;
- a human embryo must not be maintained outside the human body for a period of more than 10 years, and
- the culture of the human embryo outside the human body must not progress beyond a stage at which it can be implanted.

These provisions are important because they illustrate the South Australian Parliament's direction and what they consider to be morally important. The Code of Practice is contained in Schedule 1 of the Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995.

- formulation of appropriate conditions for licenses authorising research involving experimentation with human reproductive material;
- to carry out research into the social consequences of reproductive technology, and promote research into the cause of human infertility , and
- to promote informed public debate on the ethical and social issues which arise from reproductive technology.

The *Family Relations Act 1975* also applies in regard to surrogacy and other factors.

### **5.3 Western Australian *Human Reproductive Technology Act 1991***

The Western Australian *Human Reproductive Technology Act 1991* ('the *HRTA*') was assented to on 8 October 1991, after having been first introduced into the Legislative Assembly on 21 November 1990, almost one year prior. The main purposes of the Act, outlined in the long title of the Act, are:

... to establish the Western Australian Reproductive Technology Council; to require the compilation of a Code relating to the practice of, the procedures used in, and the ethics governing, human reproductive technology; to make provision with respect to the use of that technology in relation to artificially assisted human conception and for the regulation of certain research; and for related purposes.

In his second reading speech, the Minister for Health highlighted the balance the Bill was trying to achieve:

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Balancing competing interests, such as the pursuit of knowledge, the refinement of technology, compassion for the infertile, and respect for social attitudes is a complex and difficult task.<sup>135</sup>

A preamble to the Act further illustrates this difficulty, and sets out very clearly the principles under which the Western Australian Parliament enacted the legislation:

- A. In enacting this legislation Parliament is seeking to give help and encouragement to those eligible couples which are unable to conceive children naturally or whose children may be affected by a genetic disease.
- B. Parliament considers that the primary purpose and only justification for the creation of a human egg in the process of fertilisation or embryo in vitro is to assist these couples to have children, and this legislation should respect the life created by this process by giving an egg in the process of fertilisation or an embryo all reasonable opportunities for implanting.
- C. Although Parliament recognises that research has enabled the development of current procedures and that certain non harmful research and diagnostic procedures upon an egg in the process of fertilisation or an embryo which may be licit, it does not approve the creation of a human egg in the process of fertilisation or an embryo for a purpose other than the implantation in the body of a woman.
- D. Parliament considers the freezing and storage of a human egg in the process of fertilisation to be acceptable only:
  - (i) as a step in the process of implanting; and
  - (ii) only in extraordinary circumstances once the freezing and storage of eggs can be carried out successfully.

The *HRTA* establishes a system of licensing for persons or organisations who either carry out ART procedures or maintain storage facilities for human sperm, eggs or embryos. Licenses are granted by the Commissioner of Health on the recommendation of the Western Australian Reproductive Technology Council, established under the Act (section 8). Licenses will be granted where the applicants comply with a Code of Practice developed by the Council. In introducing the Bill into the Western Australian Legislative Assembly, the Minister stated that “a system of licensing is the most appropriate way to approach regulation in such a complex, fast moving area of medical science”.<sup>136</sup>

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<sup>135</sup> Hon K Wilson, MP, 22 November 1990, WAPD, p. 7638.

<sup>136</sup> Hon K Wilson, MP, WAPD, 22 November 1990, p. 7641.

In reality, the Code of Practice was never formulated and passed by Parliament. Instead, the Commissioner of Health issued a number of **Directions**, which are standards of practice which must be complied with in order to be granted a license. The Directions cover all areas of the practice of ART, including:

- personnel, premises and minimum standards of practice;
- records/reporting;
- consent;
- information;
- assistance with decision making and counselling;
- use and storage of gametes and embryos;
- eligibility and assessment;
- specific clinical practice issues, and
- approval of laboratory and clinical procedures.

The Western Australian Minister for Health moved on 15 May 1997 that a Select Committee on the *Human Reproductive Technology Act 1991* be appointed. The purpose of the committee, as contained within its Terms of Reference, is to

... inquire into and report on the adequacy of the Human Reproductive Technology Act (the Act) in fulfilling its stated objectives, in controlling the practice of, the procedures used in, and the ethics governing, human reproductive technology, and in regulating the use of reproductive technology in artificially assisted human conception and in research....<sup>137</sup>

The Committee is to report to Parliament on 17 December 1998.

#### **5.4 Victorian Infertility Treatment Act 1995**

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<sup>137</sup> Select Committee on the Human Reproductive Technology Act 1991, *Terms of Reference*. Specific areas for consideration include the right of access to procedures, research and experimentation on gametes, eggs and embryos, pre-implantation diagnoses and genetic testing of embryos, rights to stored gametes and embryos, the storage of gametes, eggs and embryos, the appropriateness and effectiveness of the WA Reproductive Technology Council's obligation to compile a Code of Practice, and the effectiveness of powers of enforcement and disciplinary provisions under the Act, and the adequacy of offences and penalties. The terms of reference were amended in September 1997 to include an inquiry into the current status and incidence of surrogacy arrangements in WA and to determine what, if any, legislation in that area is required.

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The Victorian *Infertility Treatment Act 1995* ('the *ITA*') was assented to on 27 June 1995. It was first introduced into the Victorian Legislative Assembly on 3 May 1995, and was the subject of intensive debate in both houses. The main purposes of the Act, as contained in section 1 are:

- (a) to regulate the use of in-vitro and other fertilisation procedures and donor insemination procedures;
- (b) to regulate access to information about treatment procedures carried out under this Act and the *Infertility (Medical Procedures) Act 1984*;
- (c) to regulate research using human gametes, zygotes and embryos;
- (d) to promote research into the incidence and causes of infertility;
- (e) to make provisions with respect to surrogacy agreements;
- (f) to establish to Infertility Treatment Authority and the Standing Review and Advisory Committee on Infertility;
- (g) to repeal the *Infertility (Medical Procedures) Act 1984* and amend various other Acts.

The Act contains a number of 'guiding principles' which must be given effect when administering or carrying out the functions under the *ITA*. These principles, listed in descending order of importance, are contained in section 5:

- (a) the welfare and interests of any person born or to be born as a result of a treatment procedure are paramount;
- (b) human life should be preserved and protected;
- (c) the interests of the family should be considered, and
- (d) infertile couples should be assisted in fulfilling their desire to have children.

The *ITA* established the Infertility Treatment Authority, whose functions were spelt out by the Minister for Health in her second reading speech:

Its [the Infertility Treatment Authority] functions will include assessing and granting licenses for centres at which approved research and treatment procedures may be performed, and to approve doctors, scientists and counsellors. The authority will also have the function of approving specific research projects involving zygotes, embryos and *parthenogenesis* in conjunction with the Standing Review Advisory Committee on infertility. The authority will also approve the storage of gametes, zygotes and embryos for periods longer than is generally permitted, and may approve the bringing

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into Victoria or the taking out of Victoria of human gametes, zygotes and embryos. The other major function of the authority is to keep the central register, which is the register which will contain information about children born from donor treatment procedures, their parents and donors.<sup>138</sup>

The Standing Review and Advisory Committee on Infertility, also established by the *ITA*, has two main functions: firstly to provide advice to the Minister for Health, and secondly to consider whether specific research applications should be permitted. The Infertility Treatment Authority will only be able to approve research applications that also have been approved by the Committee. The Minister anticipated in her second reading speech ‘that the Authority will approve research which the Committee has endorsed.’<sup>139</sup> The Committee has a broad membership, with up to 14 members derived from the following categories: children born as a result of reproductive technologies; couples who have undergone reproductive technology treatment procedures; professionals who have carried out treatment procedures or reproductive technology research; members of religious bodies, and people with qualifications and experience in the disciplines of philosophy, medicine, social work or psychology, law, child welfare, health education, infertility and embryology. It was envisaged that the broad membership base of the Committee would ‘ensure that all relevant policy matters and community concerns are taken into account in determining whether research should occur’.<sup>140</sup> The Authority must not approve what the Act describes as “destructive research” on embryos, which is research where the embryo is unfit for transfer to the woman’s body, or where transfer to the woman’s body is likely to cause harm to the embryo or reduce the likelihood of pregnancy resulting from the transfer of that embryo (see Part 4.5, page 28 above, for a discussion of the ethical issues surrounding embryo experimentation).

A number of offences in relation to treatment procedures and research are prescribed by the Act. These offences are interesting because they indicate the ethical approach taken by the Victorian Government when drafting the legislation. It must be noted that since the *ITA* was passed in 1995 there have been significant advances in the science of reproductive technology, making procedures such as cloning and some genetic engineering practices more easily performed. The offences include the following:

- A person must not alter the genetic constitution of a gamete which is intended to be used in a treatment procedure;
- A person must not use for a treatment procedure or research a gamete produced by a person less than 18 years of age, or a zygote or embryo formed from such a gamete, unless that person is married;

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<sup>138</sup> Hon Mrs M Tehan, MP, VPD, 4 May 1995, p. 1246.

<sup>139</sup> Ibid.

<sup>140</sup> Ibid.

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- A person must not use oocytes derived from a foetus in a treatment procedure or research;
  - A person must not inseminate a woman with sperm from a man known to be dead, transfer a gamete or a zygote or embryo formed from a gamete from a person known to be dead, form a zygote with sperm from a man known to be dead or form a zygote from an oocyte from a woman known to be dead;
  - A person must not carry out a treatment procedure or research involving a zygote or embryo removed from a woman's body;
  - A person must not mix the sperm or ova produced by an animal with a gamete, zygote or embryo produced by a man or a woman, unless for diagnostic purposes only. A person also must not insert the gene of an animal into a gamete, zygote or embryo produced by a man or woman;
  - A person must not carry out a treatment procedure using sperm, oocytes, zygotes or embryos produced by more than one person. A person also must not attempt to form a zygote or embryo outside the body of a woman from sperm produced by more than one man;
  - A person must not carry out or attempt to carry out cloning, and
  - A person must not use a gamete, zygote or embryo with the purpose of producing or attempting to produce a child of a particular sex. This prohibition does not apply where it is necessary for the child to be of a particular sex to avoid the transmission of a genetic abnormality or disease to the child.

### **5.5 Comparison of interstate legislative regimes**

The table on the following pages is based partly on a similar table provided to the author by Helen Stokes, Chief Executive Officer of the Victorian Infertility Treatment Authority. It was originally dated November 1997, and was in draft form. The author has attempted to identify any changes which have occurred since that date. A number of areas of concern have been identified, including access to services, storage of embryos etc. For each of these areas of concern, the regulation in each of the States is noted, as well as the provisions contained within the NHMRC *Guidelines*.

<b>SPECIFIC LEGISLATION</b>	
<b>NHMRC</b> <sup>141</sup>	National Guidelines produced for Institutional Ethics Committees.
<b>NSW</b>	No general legislation. <i>Status of Children Act 1996</i> (parentage).
<b>Victoria</b>	<i>Infertility Treatment Act 1995</i> .
<b>Queensland</b>	No general legislation. <i>Surrogate Parenthood Act 1988</i> (surrogacy)
<b>South Australia</b>	<i>Reproductive Technology Act 1988</i> . Exempt from <i>State Equal Opportunity Act 1984</i> .
<b>Western Australia</b>	<i>Human Reproductive Technology Act 1991</i> .
<b>ACT</b>	No general legislation. <i>Substitute Parent Agreement Act 1994</i> (surrogacy).
<b>Northern Territory</b>	Guided by South Australian legislation.
<b>Tasmania</b>	No general legislation. <i>Surrogacy Contracts Act 1993</i> (surrogacy).

<b>ACCESS TO SERVICES</b> <sup>142</sup>	
<b>NHMRC</b>	No specific guidelines.
<b>NSW</b>	IEC <sup>143</sup> decision. No specific guidelines. Access by legally married couples and de facto couples. Some examples of services to single women and same sex couples.
<b>Victoria</b>	Heterosexual de facto and legally married couples only (section 8(1)). Evidence that woman is unlikely to become pregnant without treatment, or to avoid passing on a genetic abnormality of disease (section 8(3)(b)).
<b>Queensland</b>	De facto and legally married couples only. No specific guidelines. Currently appealing a Human Rights and Equal Opportunity Commission decision allowing access to services by single women (see part 4.1, page 13).
<b>South Australia</b>	De facto and legally married couples; single women and same sex couples (sections 13(3); 13(4)). Husband or wife to appear infertile, or to prevent transfer of a genetic defect to the child (section 13(3)(b)).
<b>Western Australia</b>	Heterosexual de facto (of an aggregate of five years duration) and legally married couples only. Infertility, or to prevent the risk of transfer of genetic abnormality to the child. Age must not be the reason for infertility (section 23).
<b>ACT</b>	IEC decision. No specific guidelines.
<b>Northern Territory</b>	Guided by SA legislation.
<b>Tasmania</b>	IEC decision. No specific guidelines.

<sup>141</sup> National Health and Medical Research Council. See Part 5.1.2, page 38, for a detailed examination of the NHMRC Guidelines.

<sup>142</sup> See discussion in Part 4.1, above at page 11.

<sup>143</sup> Institutional Ethics Committee. These committees are usually guided by the NHMRC Guidelines.

<b>STORAGE OF EMBRYOS<sup>144</sup></b>	
<b>NHMRC</b>	10 year limit recommended.
<b>NSW</b>	NHMRC Guidelines.
<b>Victoria</b>	Gametes: 10 year limit. Can apply for extension of period (section 51) Embryos and zygotes: 5 year limit. Can apply for extension of period (section 52).
<b>Queensland</b>	NHMRC Guidelines.
<b>South Australia</b>	Embryos: 10 year limit. No provision for extension. Required to contact couple every 12 months (section 10(3)(b); 10(3)(c)).
<b>Western Australia</b>	Maximum 15 year storage overall. Embryos: consents to be renewed every 3 years. Gametes: consents to be renewed every 5 years. Where the gametes are to be used in treatment of the gamete provider, or for research, the person responsible may apply for an extension (section 24).
<b>ACT</b>	NHMRC Guidelines.
<b>Northern Territory</b>	See SA legislation.
<b>Tasmania</b>	NHMRC Guidelines.

<b>RECORD KEEPING OF DONOR OFFSPRING<sup>145</sup></b>	
<b>NHMRC</b>	Donor offspring have a right to access records about their biological past.
<b>NSW</b>	Status of paternity specified presuming the donor not to be the father for all purposes (section 14 <i>Status of Children Act 1996</i> ).
<b>Victoria</b>	Central register established to record all information about donors and offspring (section 68; 82). Offspring have right to access information. Other parties may access information with consent (section 70). Voluntary register established to address the needs of offspring and donors not covered by Acts of Parliament.
<b>Queensland</b>	IEC decision. No specific provisions, and no records required to be made accessible.
<b>South Australia</b>	Licensee to maintain records of donors (section 13(3)(d)). Access to non identifying information is available for offspring (Reproductive Technology (Code of Ethical Practice) Regulations 1995, Schedule, clause 23(2)).
<b>Western Australia</b>	Register to be kept by the Commissioner of Health (section 45). Records relating to fertilisation procedures to be kept by licensees. Record the identity of offspring and donor, and identity of parents of the child. Confidentiality assured (section 44).
<b>ACT</b>	IEC decision.
<b>Northern Territory</b>	See SA legislation.
<b>Tasmania</b>	IEC decision.

<sup>144</sup> For discussion, see Part 4.4, above at page 26.

<sup>145</sup> For discussion, see Part 4.3 above at page 19.



<b>LEGISLATIVE DEFINITION OF PARENTAGE IN DONOR PROCEDURES<sup>146</sup></b>	
<b>NHMRC</b>	No specific provisions in Guidelines.
<b>NSW</b>	<i>Status of Children Act 1996</i> (section 16).
<b>Victoria</b>	<i>Status of Children Act 1974</i> (Part II).
<b>Queensland</b>	<i>Status of Children Act 1978</i> ( sections 15-18).
<b>South Australia</b>	<i>Family Relationship Act 1975</i> (Part IIA).
<b>Western Australia</b>	<i>Artificial Conception Act 1985</i> (particularly sections 5 and 6).
<b>ACT</b>	<i>Artificial Conception Act 1985</i> (particularly sections 5 and 6).
<b>Northern Territory</b>	<i>Status of Children Act 1978</i> (Part IIA).
<b>Tasmania</b>	<i>Status of Children Act</i> (Part III).

<b>INFORMED DECISION MAKING</b>	
<b>NHMRC</b>	Specific provisions outlined in Guidelines. See Part 5.1.2 (page 38).
<b>NSW</b>	NHMRC Guidelines.
<b>Victoria</b>	Specific requirements for consent outlined in Conditions for Licensing and in the Act. Prescribed matters to be covered in counselling specified in regulations (regs 6, 7 and 9 ). Counselling mandatory (section 11 (recipients); 16 (donor).
<b>Queensland</b>	NHMRC Guidelines.
<b>South Australia</b>	Specific provisions relating to consent in regulations (Part 4). Information Statement Standards specified - written information which must be distributed.
<b>Western Australia</b>	Specific requirements outlined in the Act (Part 3, Div 2). Directions in relation to information, consent and counselling. Counselling requirement contained in Directions.
<b>ACT</b>	NHMRC Guidelines.
<b>Northern Territory</b>	Guided by SA legislation.
<b>Tasmania</b>	NHMRC Guidelines.

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For discussion, see Part 4.2 above, at page 16.

<b>RESEARCH<sup>147</sup></b>	
<b>NHMRC</b>	Therapeutic research allowed subject to IEC approval. Destructive research only approved in exceptional circumstances.
<b>NSW</b>	NHMRC Guidelines.
<b>Victoria</b>	Ban on destructive research on embryos (section 24). Consent must be given for use of gametes (Part 3, Division 2).
<b>Queensland</b>	NHMRC Guidelines.
<b>South Australia</b>	Ban on destructive research on embryos. Non-destructive research requires approval of Reproductive Technology Council (section 14).
<b>Western Australia</b>	Therapeutic of specifically approved research allowed. Ban on destructive research (section 20). Prohibition on keeping embryo longer than 14 days (section 7(c)(iii)).
<b>ACT</b>	NHMRC Guidelines.
<b>Northern Territory</b>	Guided by SA legislation.
<b>Tasmania</b>	NHMRC Guidelines.

<b>SURROGACY<sup>148</sup></b>	
<b>NHMRC</b>	Not included in Guidelines
<b>NSW</b>	No specific laws. Birth parents registered as parent (section 14 <i>Status of Children Act 1996</i> ). Adoption not facilitated in surrogacy - matter referred to Family Court.
<b>Victoria</b>	Illegal to advertise of receive payment for surrogacy arrangement (Part 6). Birth parents registered as parents.
<b>Queensland</b>	Offence to make or see surrogacy arrangement. Surrogacy agreements unenforceable (sections 3 and 4 <i>Surrogate Parenthood Act 1988</i> ).
<b>South Australia</b>	Surrogacy contracts illegal and void, but no penalties imposed. <i>Family Relationships Act 1975</i> relied on to define parentage of children born of surrogacy.
<b>Western Australia</b>	No specific legislation. Rely on common law provisions. Surrogacy against public policy and therefore surrogacy contracts are void.

<sup>147</sup> For discussion, see Part 4.5 (page 28) Above.

<sup>148</sup> See Part 6.0 below (page 58) for a detailed discussion of surrogacy.

<b>ACT</b>	Altruistic surrogacy allowed (where no payment received). Commercial agreements disallowed. Commercial arrangements illegal, as is facilitating a commercial arrangement ( <i>Substitute Parents Act 1994</i> sections 5-10).
<b>Northern Territory</b>	Guided by SA legislation.
<b>Tasmania</b>	Offence to make or arrange surrogacy arrangement ( <i>Surrogacy Contracts Act 1993</i> section 4). Agreements illegal and unenforceable (section 7). Offence to offer support or assistance for such an arrangement (section 5).

## 5.6 Overseas regulation of assisted reproductive technology

Many countries have some form of regulation of ART, whether it be legislative or some other means.<sup>149</sup> The situation in the United States is very similar to that in Australia. There is no Federal legislative scheme, and only some of the States have implemented legislation. There is also no comprehensive national scheme regarding the status of children born as a result of artificial reproductive technology. The United States, therefore, provides a somewhat unsatisfactory example when looking for guidance on regulation of ART. This section will examine briefly the regulation in the United Kingdom, Canada, New Zealand and Spain.

### 5.6.1 United Kingdom

Reproductive technology in the United Kingdom is regulated by the *Human Fertilisation and Embryology Act 1990* (“the HFEA”). The regulatory framework contained therein took effect from 1 August 1991. The HFEA divide ART procedures into three categories: the first category includes those activities such as cloning which are illegal (criminal), and can not be licensed. The second category contains those activities which are illegal unless carried out pursuant to a licence granted by the Human Fertilisation and Embryology Authority, which was established under the HFEA and whose function it is to implement the statute. Activities falling within this second category include the storage of gametes and embryos and the creation of an embryo *ex utero*. The final category of activities contains those activities which are not covered by the HFEA and therefore do not require a licence. Such activities include artificial insemination by the husband of a woman using sperm provided by him.<sup>150</sup> For a comprehensive examination of the operation of the HFEA, see Kennedy & Grubb, *Medical Law: Text with Materials* (2nd ed.), pp. 768-819.

### 5.6.2 Canada

The Royal Commission on New Reproductive Technologies was completed at the beginning of 1994. At this stage there is still no specific legislation concerning the regulation of ART federally in Canada. Nor does it appear that there is comprehensive

<sup>149</sup> For a survey of relevant regulation in countries including Austria, Germany, Switzerland, France, Israel and Sweden, see K Dawson, n 1, pp. 1211-27.

<sup>150</sup> Kennedy & Grubb, n 53, p. 769.

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legislation in any of the Canadian Provinces.

The Medical Research Council of Canada (NMRC) is the major federal agency responsible for funding biomedical research in that country. There are two other relevant Councils in Canada - the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). The NMRC's *Guidelines on Research Involving Human Subjects* were first issued in 1987 and since that time have become the nation's accepted standard on human biomedical research. The other two Councils have adopted the *Code* as the standard of research ethics for the conduct of research involving human participants. The Councils require that funded researchers and their institutions comply with the spirit of the ethical principles contained within the *Code* and comply strictly with the Articles of the *Code*. The Councils have the right to withdraw funding in situations where the *Code* is not complied with.<sup>151</sup> The Articles of the *Code* which are relevant to ART are contained in Section VIII - 'Human Genetic Research' and Section IX - 'Reproduction, Infertility, Embryos and Foetuses'.<sup>152</sup>

- Article 8.1** The genetics researcher must seek informed choice from the individual and report results to that individual. As genetic research involves the family and/or the community in terms of family history, linkage, and other studies, a potential tension exists between the individual, their families, and the group. Therefore, informed choice must also involve those social structures as far as is practical and possible.
- Article 8.2** The researcher and the REB (Research Ethics Board) must ensure that the results of genetic testing and genetic counselling records are protected from access by third parties unless consent is given by the participant. Family information in databanks must be coded by number without the possibility of identification of participants within the bank itself.
- Article 8.3** Researchers and genetic counsellors involving families and groups in genetic research studies must reveal potential harms to the REB and outline how such harms will be dealt with as part of the research project.
- Article 8.4** Genetics researchers and the REB must ensure that the research protocol makes provision for access to genetic counselling for the participants, where appropriate.
- Article 8.5** Research on gene alteration must be limited to somatic cells and tissues. Neither research on germline gene alteration nor non-therapeutic use of gene alteration in humans is permitted.

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<sup>151</sup> 'The Medical Research Council of Canada', <http://www.mrc.gc.ca/whatis/foldeng.html>, p. 3 of 4.

<sup>152</sup> *Code of Ethical Conduct for Research Involving Humans*, Section VII, <http://www.mrc.gc.ca/ethics/code/english>.

**Article 8.6** [There is no Article 8.6 however, there is a subsection between Articles 8.5 and 8.6 titled “Eugenic Concerns”.]

**Article 8.7** Because the banking of genetic material poses potential harms to individuals, their families, and the collectivities to which they may belong, researchers must satisfy the REB and prospective research participants that they have addressed the issues involved in banking of genetic data including confidentiality, privacy, storage, use of the data, and results to come, withdrawal by the participant, and future contact of participants, families, and collectivities.

**Article 8.8** At the outset of a research project, the researcher must discuss with the REB and the research participant the possibility that the genetic material and the information derived from its use could have potential commercial uses.

Of particular relevance are the Articles in Section IX which deal specifically with research into artificial reproductive technology:

**Article 9.1** The researcher must obtain informed consent from the individual from whom human reproductive cells were obtained for the research use of those cells and tissues.

**Article 9.2** No research will be carried out on ova or sperm that have been obtained through commercial transactions.

**Article 9.3** Research must not be carried out with the intent of creating hybrid species which could survive by such means as mixing human gametes with cells or tissues of other species, or vice versa.

**Article 9.4** Human zygotes and embryos must not be specifically created for research purposes; however, research that involves human zygotes and embryos will be ethically acceptable if:

- (a) the ova and sperm from which they were formed are obtained in accordance with articles 9.1, 9.2 and 9.3;
- (b) the research does not involve the genetic alteration of human zygotes/embryos, and
- (c) zygotes or embryos exposed to any manipulations not directed specifically to the ongoing normal development will not be transferred for continuing pregnancy.

**Article 9.5** In keeping with international consensus, the researcher must restrict research on human zygotes and embryos to the first 14 days of development.

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**Article 9.6** Ectogenesis, cloning of human beings, formation of animal/human hybrids, or the transfer of zygotes/embryos between humans and other species are all unacceptable.

Of course, such guidelines are not binding and are only enforceable in situations where an individual or institution receives funding from one of the three Councils. In a situation where a clinic operates commercially and utilises profits from that commercial operation to fund research, the impact of the *Code* would be dependent upon the ethics of the individual researchers and of the clinic itself.

### 5.6.3 *New Zealand*

The Assisted Human Reproduction Bill was introduced into the New Zealand Parliament on 29 September 1998.<sup>153</sup> The Bill has three aims:

- to prohibit certain activities including cloning of human beings, fusing of animal and human gametes, the implantation of human or animal embryos in the opposite species and the supply of gametes and embryos for valuable consideration;
- to establish the National Ethics Committee on Assisted Human Reproduction, and
- to provide for an information scheme with respect to children born as a result of procedures involving donated gametes.

The proposed National Ethics Committee on Assisted Human Reproduction will comprise 10 members appointed by the Minister of health. The main functions of the Committee will be to:

- review assisted human reproductive proposals, to determine whether they are ethical, and in particular whether the rights of the people involved would be protected and proper account would be taken of the ethical perspectives of Maori, and other cultural, religious, ethnic and social groups in New Zealand;
- to develop for provider protocols and guidelines relating to assisted human reproductive procedures and techniques, and
- to advise the minister on issues relation to human assisted reproduction.

The third proposal concerns the retention and dissemination of information. A provider of ART services would be required to keep all information about a donor specified by the Registrar-General of Births, Deaths and Marriages. Providers would also be required to maintain sufficiently efficient systems for keeping track of the births of donor children. A provider would be required to give to donor child, access to information held by the

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<sup>153</sup> The information in this Part is taken from the New Zealand Parliamentary Library's *Bills Digest*, No 470, prepared by J McSoriley.

provider about the child. If asked by the child, the provider would also be required to state whether any donor of a gamete from which the child was conceived had asked for access to information about the child. Once the donor child is over 25 years of age, it is proposed that the donor have access to information about that child. Prior to that age, the Registrar-General would be required to inform the donor, if requested, whether or not any child had been born from his or her donated gametes and the sex of the child.

#### 5.6.4 Spain

K Dawson calls Spain's ART legislation "the most detailed law undertaken so far on this subject".<sup>154</sup> Law No 35/1988 covers such diverse areas as artificial insemination, IVF and GIFT. The law establishes the National Commission on Assisted Reproduction to oversee the provision of ART procedures and, in some cases, to authorise research projects. The law specifies conditions applicable to gamete donors, persons undergoing the procedures as well as the status of resultant children. It permits sperm and embryo freezing, but prohibits egg freezing until the technique is proven to be safe. In relation to experimentation, the law generally permits experimentation as long as the gametes are not used subsequently for fertilisation. Intervention on the embryos *in vitro* and *in utero* is allowed with the informed consent of the woman. *In vitro* but not *in utero* experimentation on embryos are generally permitted in appropriate situations. A number of offences are provided for including fertilisation of ova other than for procreation, and maintaining embryos for longer than 14 days.<sup>155</sup>

## 6.0 SURROGACY

As the New South Wales Law Reform Commission noted in its Discussion Paper *Surrogate Motherhood* (1988), surrogacy is not necessarily a procedure of artificial or technologically assisted conception.<sup>156</sup> However, such techniques can be used, and it is for this reason that a discussion of surrogacy is included in this paper. Where ART is used, it is most common that the surrogate mother becomes pregnant following artificial insemination using the semen of the commissioning husband, and either her own or a donated ovum.<sup>157</sup>

The Law Reform Commission defined surrogacy as:

... an arrangement whereby a woman agrees to become pregnant and to bear a child for another person or persons, to whom she will transfer custody at

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<sup>154</sup> Dawson, n 1, p. 124.

<sup>155</sup> Ibid.

<sup>156</sup> NSWLRC, *Surrogate Motherhood*, Artificial Conception Discussion Paper 3, 1988, p. 9.

<sup>157</sup> Ibid, p. 17.

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or shortly after birth.<sup>158</sup>

A slightly more formal definition can be found in the *Butterworths Concise Australian Legal Dictionary*. A surrogate mother is defined as:

A woman who agrees to carry a child throughout his or her gestation for another woman and after the birth of the child intends to relinquish it and all the indicia of parenthood to her.<sup>159</sup>

The Queensland Parliamentary Library's Research Bulletin on Surrogacy further differentiated between **formal** surrogacy and **informal** surrogacy, with the former relating to arrangements in which the nature and terms of the agreement between the surrogate and commissioning couple are clearly specified, usually in writing. The report also differentiated between **commercial** surrogacy and **altruistic** surrogacy. A commercial surrogacy arrangement exists where payment of some benefit to the surrogate mother, usually money, is arranged. In altruistic surrogacy there is no financial reward for the surrogate mother, although the commissioning couple may involve the surrogate's medical and other related expenses. Altruistic surrogacy usually occurs between close friends or relative.<sup>160</sup>

A 'surrogacy contract' is therefore potentially enforceable in a court of law, and is in fact enforceable in some states of the United States. Legislation in most Australian states has, however, declared surrogacy agreements to be unenforceable. The following provisions are relevant:

- *Infertility Treatment Act 1995* (Vic), section 61
- *Surrogate Parenthood Act 1988* (Qld), section 4
- *Surrogacy Contracts Act 1993* (Tas), section 7
- *Family Relationships Act 1975* (SA), section 10g

In NSW, where there is no specific legislation, surrogacy agreements *per se* are not illegal. However in a surrogacy situation the birth parents are registered as the child's parents.<sup>161</sup> According to the Federal *Family Law Act 1975* the birth mother is considered to be the

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<sup>158</sup> NSWLRC, *Report of the Law Reform Commission on Artificial Conception: Surrogate Motherhood*, December 1988, p. 6.

<sup>159</sup> P Nygh & P Butt (eds), *Butterworths Concise Australian Legal Dictionary*, Sydney 1997, p. 385.

<sup>160</sup> G Emmerson, 'Surrogacy - born for another', *Queensland Parliamentary Library Research Publication No 8/96*, p. 5.

<sup>161</sup> *Status of Children Act 1996* (NSW).



legal mother in all situations.<sup>162</sup> It is also an offence in NSW to supply false or misleading information to register a birth. Therefore a commissioning couple can not register themselves as the parents of the child if they are not the legal parents.<sup>163</sup> There is no specific legislation in Western Australia either, where the common law is relied on.<sup>164</sup> Surrogacy is interpreted as against public policy, therefore surrogacy agreements are declared void.<sup>165</sup> In the ACT the *Substitute Parents Act 1994* allows for altruistic surrogacy where no commercial arrangement is in place. See the table in Part 5.5 for an interstate comparison of legislation applicable to surrogacy (at page 53).

The Warnock Committee (1984) looked at the arguments for and against surrogacy. Briefly, those arguments are:

***Arguments against surrogacy***<sup>166</sup>

- the bond between mother and child *in utero* should be encouraged and not broken by surrogacy;
- it was undesirable to force a woman to surrender a child against her will;
- surrogacy arrangements threaten the sanctity of marriage, and
- it is against human dignity for one woman to use her womb for profit.

***Arguments for surrogacy***<sup>167</sup>

- having a child by surrogacy may be the only course open to a woman who can not have a child of her own either because she does not produce eggs or because she has

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<sup>162</sup> *Family Law Act 1975* (Cth). Sections 69P-69U deal with presumptions of parentage.

<sup>163</sup> *Births, Deaths and Marriages Registration Act 1995*, section 57. See also Libesman, n 29, pp. 68-70.

<sup>164</sup> This is despite the fact that the Western Australian Department of Health's Reproductive Technology Working Party and the Select Committee appointed to inquire into the Working Party's Report both recommended in 1988 that there should be two Acts - the Reproductive Technology Act and the Surrogacy Act, reflecting the fact that "the issue of surrogacy transcends reproductive technology". See Legislative Assembly of Western Australia, *Report of the Select Committee Appointed to Inquire into the Reproductive Technology Working Party's Report*, December 1988, pp. 17-20.

<sup>165</sup> Information supplied to the author by Helen Szoke, Chief Executive Officer of the Victorian Infertility Treatment Authority, May 1998.

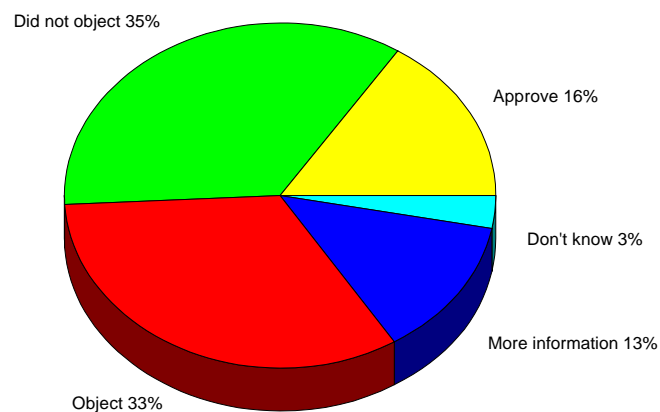
<sup>166</sup> Cusine, n 13, pp. 178-179.

<sup>167</sup> *Ibid*, pp. 177-178.

some condition which prevents her conceiving.<sup>168</sup>

- surrogacy may be the only option for a woman who is advised against pregnancy for health reasons, and
- surrogacy could be seen as an act of generosity on the part of the surrogate, and there is no reason to suspect that surrogates would enter into such agreements lightly. The fact that a surrogate is paid does not, in itself, entail that there is exploitation either of her or the commissioning party.

Arguments in favour of surrogacy are usually from the viewpoint of the infertile commissioning couple. The NSW Law Reform Commission conducted a national survey of public opinion regarding surrogacy in 1987.<sup>169</sup> The respondents were initially asked their opinion of surrogate motherhood as a means of providing children for married couples who can not have children because of medical problems. The respondents were asked to reply in one of four ways: (1) approve of surrogate motherhood; (2) do not object to surrogate motherhood; (3) object to surrogate motherhood, and (4) need to know more. The following responses were recorded:<sup>170</sup>



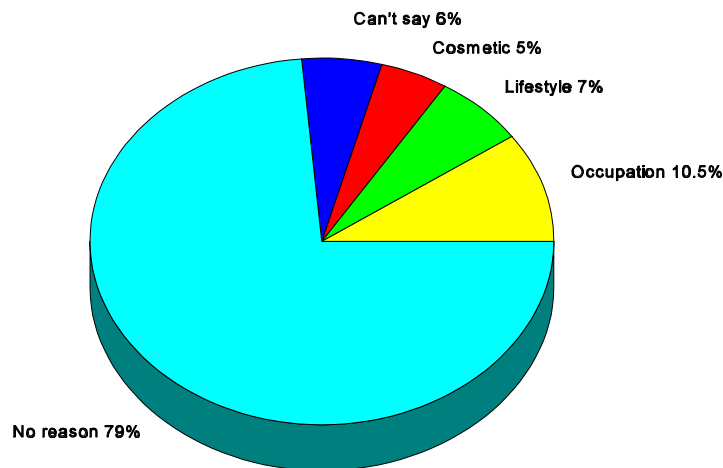
The survey also asked respondents their view on surrogacy for non-medical reasons. The reasons given were: (1) occupation (eg where a woman does not want to take time out of

<sup>168</sup> This argument does not carry so much weight since the development of techniques which enable fertilised embryos to be placed in the woman's uterus, the increasing availability of donor eggs and embryos and techniques such as ICSI which enable fertilisation from a single sperm.

<sup>169</sup> The survey was conducted as part of the Commission's reference into human reproductive technology. The results are published in the NSWLRC, *Artificial Conception Surrogate Motherhood: Australian Public Opinion*, Research Report, May 1987.

<sup>170</sup> *Ibid*, p. 9.

work for pregnancy); (2) lifestyle (eg so as not to interfere with a couple's social life) and (3) cosmetic (eg for women who are concerned about their appearance either during or after pregnancy). No other reasons were nominated by respondents. The results follow. They are divided into those who approved of each of the above reasons, those who did not approve at all, for any reason, and those who could not say.<sup>171</sup>



**No reason** refers to those people who do not approve of surrogacy for any reasons.

Interestingly, there was clear support for providing some form of payment to the surrogate mother. Forty per cent believed the surrogate should be paid her medical expenses *plus* a fee agreed by with the commissioning couple. A further 34% thought that she should receive payment for medical expenses only, and receive no additional payment. Only 17% thought there should be no payment at all, and 9% had no opinion.<sup>172</sup>

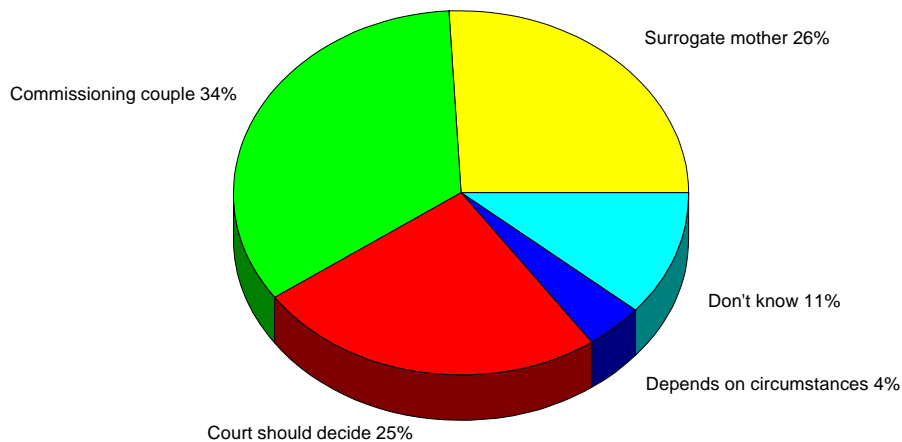
In response to the question about the enforcement of surrogacy contracts, the views were indeed representative of the wide divergence of opinions on the subject. The enforceability of surrogacy agreements was in the Commission's view "arguably the most controversial aspect of surrogate motherhood arrangements".<sup>173</sup> Respondents were asked who they believed should have the first claim to the child if the surrogate mother, after agreeing to give the child to the couple after birth, changes her mind and wants to keep the child. The options were: (1) the surrogate mother; (2) the commissioning couple, or (3) that a court should decide. Some respondents replied that the answer should depend on the circumstances and that other respondents did not have an opinion one way or another. The break-up of responses was as follows:<sup>174</sup>

<sup>171</sup> Ibid, p. 61.

<sup>172</sup> Ibid, pp. 19-20.

<sup>173</sup> Ibid, p. 31.

<sup>174</sup> Ibid, pp. 31-32.



The Commission's view was that "the practice of surrogate motherhood should be discouraged by all practicable and legal means".<sup>175</sup> Consequently, all surrogacy agreements should be void and legally unenforceable. Furthermore, the payment, receipt, ordering or soliciting of any reward in connection with a surrogacy agreement should be an offence.<sup>176</sup> The Commission based this recommendation on notions of the welfare of the child, and recommended to that effect that "the welfare of the child should be the paramount consideration and should prevail over the interests of the adults involved in a surrogate motherhood arrangement".<sup>177</sup> This view is in line with that encapsulated in the relevant legislation in other states in Australia, discussed above.

## 7.0 HUMAN CLONING

... events that alter our very notion of what it means to be human are scattered over the centuries. The birth of Dolly is one of them...<sup>178</sup>

The significance of the birth of Dolly, the cloned sheep, to the development of ART cannot be underestimated. It meant that, if an adult sheep could be cloned, the possibility that an adult human could also be cloned was another giant step closer. Until that time, accepted

<sup>175</sup> NSWLRC, *Report of the Law Reform Commission on Artificial Conception: Surrogate Motherhood*, March 1989, Recommendation 2, p. 38.

<sup>176</sup> K Mason, 'Surrogacy: setting the Australian scene', in M Meggitt (ed) *Proceedings of the National Conference Surrogacy: in whose interests?* February 1991, p. 11.

<sup>177</sup> NSWLRC, n 175, Recommendation 1, p. 37.

<sup>178</sup> Kolata, n 15, p. 2.

wisdom was that it was impossible to create whole new organisms from single adult cells.<sup>179</sup> Human cloning, according to the United States' recently appointed National Bioethics Advisory Commission (NBAC), would involve three novel developments with which people would have to come to terms: the replacement of sexual procreation with a sexual replication of an existing set of genes; the ability to predetermine the genes of a child, and the ability to create many genetically identical offspring.<sup>180</sup> The question facing ethicists and policy makers is whether or not such developments are so radical and abhorrent that they outweigh the possible future gains in terms of biological sciences generally and ART in particular.

In a reaction to the birth of Dolly, the President of the United States requested that that country's National Bioethics Advisory Commission "undertake a thorough review of the legal and ethical issues associated with this technology...". The Commission undertook that review, and in its report and recommendations concluded that "at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning" ('fusion', above). That conclusion was based on current scientific information that indicates that the technique is not safe to use in humans at this point in time.<sup>181</sup> Some of the issues addressed by the Commission include safety issues, individuality, family integrity and treating children as objects. Others, however, have responded to cloning differently. Michael Lupton, Professor of Law at the University of Natal stated in an article in the *Bond Law Journal* that "it would be a great tragedy if we allow the cornucopia of benefits that can be derived from cloning to be lost just because of philosophical misgivings about its use as a tool of reproduction".<sup>182</sup> Despite sentiments such as these, there was an immediate and almost worldwide call for a ban on human cloning. The United States' response is one example. The Vatican, also, has called for an outright ban on human cloning, stating that human beings have a right to be "born in a human way, not in a laboratory"<sup>183</sup>. Another example is the protocol which was added to the European Convention on Human Rights and Biomedicine in January 1998. The protocol, the first legally binding international instrument to do so, bans the use of human cloning for reproductive purposes and was signed by 17 European countries.<sup>184</sup>

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<sup>179</sup> M Lupton, 'Human cloning - the law's response', *Bond Law Review*, Vol 9, No 2, December 1997, p. 123, p. 124. The reason for this is that embryonic cells are *totipotent*, capable of becoming any and every cell in the body, whereas adult cells are differentiated.

<sup>180</sup> National Bioethics Advisory Commission (NBAC), *Cloning Human Beings*, June 1997, p. 2.

<sup>181</sup> *Ibid*, p. iii.

<sup>182</sup> Lupton, n 179, p. 126.

<sup>183</sup> D Butler & M Wadman, 'Calls for cloning sell science short', *Nature*, 6 March 1997.

<sup>184</sup> D Butler, 'Europe brings in first international ban', *Nature*, 15 January 1998.

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## 7.1 The technology of cloning

‘Cloning’ is an ambiguous term, even in science, and can in fact have a number of meanings. Molecular cloning refers to the duplication of strings of DNA containing genes in a host bacterium. In cellular cloning copies of a cell are made, resulting in a ‘cell line’. This is a very repeatable procedure where identical copies of the original cell can be made indefinitely. Embryo twinning is another form of cloning in which an embryo which has already been formed sexually is split into two identical halves. Theoretically, this process could continue indefinitely, but in practice there is a limited number of times an embryo can be twinned and re-twinned. Finally there is the process of fusion. In this process the nucleus of an adult cell is taken and implanted into an egg cell from which the nucleus has been removed. A variation is to place the donor cells next to an *enucleated cell* (without a nucleus) and ‘fuse’ the two with a tiny electric current. The pulse that produces fusion also activates the egg’s development and a blastocyst or pre-embryo begins to form.<sup>185</sup> This is the process which was used to create Dolly, and which had been successfully carried out as early as the mid 1980s when experiments showed that nuclei could be successfully exchanged between fertilised eggs, with 90% reaching blastocyst stage of embryonic development and beyond.<sup>186</sup> It is not a straightforward procedure, however: Dr Wilmut’s team performed two hundred and seventy nuclear transfers on egg cells before they achieved success with Dolly.<sup>187</sup>

A human *clone* has been termed “a new individual genetically identical to an existing (or previously existing) person - a ‘delayed’ genetic twin”.<sup>188</sup> However, it has been argued that a person originated by cloning will not in fact be an exact copy of an adult human being in many senses. At the molecular level there will be differences, even though the gene structure would be very similar. Atoms combine to form molecules that in turn compose enzymes and proteins. At this point, two embryos which may have started out the same atomically will reveal minor variations. The brain, the most complicated of human organs can not be cloned or duplicated from a DNA blueprint. Additionally, the development of a brain can not be replicated in any sense by cloning. This alone would ensure that cloned individuals were still unique.<sup>189</sup>

## 7.2 Arguments for and against cloning

As noted above, the United States National Bioethics Advisory Commission concluded that at the present time, with the present level of scientific knowledge, cloning a human is morally unacceptable. The arguments against cloning can be broadly broken into ethical and

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<sup>185</sup> G Pence, *Who’s afraid of human cloning?*, 1988, p. 11.

<sup>186</sup> NBAC, n 180, p. 19.

<sup>187</sup> Lupton, n 179, p. 123.

<sup>188</sup> NBAC, n 180, p. 3.

<sup>189</sup> Pence, n 65, pp. 13-15.

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religious reasons.<sup>190</sup> Each of these is discussed below:

***Ethical reasons***<sup>191</sup>

- Possible harm to children who may be created by cloning as a result of the manipulation of ova, nuclei and embryos which form part of the process of cloning. Given the present level of understanding of the techniques involved, the use of cloning to create a child “would be a premature experiment that exposes the developing child to unacceptable risks.”<sup>192</sup>
- Acceptance of cloning may in turn lead to an acceptance of other, undesirable practices such as eugenics, where certain genetically inherited characteristics are “bred out” of the human race.
- Possible psychological harm to the children, such as a diminished sense of individuality and personal autonomy, and a degradation of the quality of parenting and family life if parents seek excessive control over children’s characteristics. There is concern that children will become valued according to how well they meet detailed parental expectations, rather than because of natural achievements or personal characteristics. This may in turn undermine the acceptance and openness that typifies a loving family.

The National Bioethics Advisory Commission stated that since human cloning may represent the only means by which some people may achieve reproduction, and in the light of the important social values of personal choice, maintaining privacy and the freedom of scientific inquiry, “limitations on that choice must only be made when the societal benefits of prohibition clearly outweigh the value of maintaining the private nature of such highly personal decisions”.<sup>193</sup> It is, however, the conclusion of the Commission that the inherent dangers to the developing child “are sufficient to justify a prohibition on attempts to clone human beings at this time, even if such efforts were to be characterised as the exercise of a fundamental right to attempt to procreate”.<sup>194</sup>

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<sup>190</sup> These broad groupings were adopted by the US National Bioethics Advisory Commission, which looked at all the issues surrounding human cloning and summarised them in its report (see n 180).

<sup>191</sup> *Ibid*, pp. 62 -81.

<sup>192</sup> *Ibid*, p. 87.

<sup>193</sup> *Ibid*, p. 62.

<sup>194</sup> *Ibid*, p. 87.

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**Religious reasons**<sup>195</sup>

- The National Bioethics Advisory Commission stated that “several major themes are prominent in Jewish, Roman Catholic, Protestant, and Islamic positions, including responsible human domination over nature, human dignity and destiny, procreation, and family life”. Human beings are created in God’s image and receive the gift of freedom and moral agency, which must not be abused (ie humans must not “play God”, which is what many believe cloning is). Many religious thinkers argue that cloning a human to create a child is so intrinsically immoral that it could never be morally justified and should therefore be the subject of a blanket ban. However, others can appreciate that in certain limited circumstances it may be morally justified and cloning must therefore be strictly regulated in order to prevent abuses.
- The Vatican argues that human beings have a right to be “born in a human way, not in a laboratory”. This argument is based on the notion of human dignity: humans have dignity because we are created in God’s image. To clone human beings would be a violation of that human dignity because it would “jeopardize the personal and unique identity of the clone (or clones) as well as the person whose genome was thus duplicated”.<sup>196</sup> Further, human beings have no right to change the way that we are created, because sexual reproduction is ordained by God.<sup>197</sup>

Scientists are, however, starting to fight back against what they believe to be “an increasingly unjustified stigmatisation of the potential dangers of genetic research”.<sup>198</sup> There are now calls for a more informed debate on the issues surrounding cloning, with wider public consultation and a focus on the immediate and realistic possibilities of cloning, rather than “futuristic - often hypothetical - applications”.<sup>199</sup> It must be noted that even amongst the scientific community there is a general consensus that cloning a human being is unadvisable at present (Ian Wilmut endorsed the calls for an international ban on human cloning). However this is not the only use to which the cloning techniques can be put, and the term ‘human cloning’ could be interpreted so as to result in a ban on all research involving the study of the development of human cells in culture after nuclear transplantation from a differentiated adult cell.<sup>200</sup> An example of a scientist who holds these views is the director-general of the World Health Organisation, who condemned the use of cloning to replicate humans as “ethically unacceptable” as it would “violate some of the basic principles governing medically assisted procreation”. He warned, however, that

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<sup>195</sup> Ibid, pp. 39-57

<sup>196</sup> Ibid, pp. 48-49.

<sup>197</sup> Pence, n 185, p. 119.

<sup>198</sup> Lupton, n 179, p. 129.

<sup>199</sup> Butler & Wadman, n 183.

<sup>200</sup> M Wadman, ‘Politicians accused of ‘shooting from the hip’ on human cloning’, *Nature*, Vol 386, 13 March 1997, p. 97.



opposition to human cloning should not lead to an indiscriminate ban on all cloning procedures and research, praising the potential benefits of animal cloning to human health. He also pointed out that the cloning of human cell lines was already a common procedure in the production of monoclonal antibodies for diagnosis and research on diseases such as cancer, which a blanket ban could also end.<sup>201</sup>

The following potential benefits of cloning techniques have been identified:

- the marriage of cloning and genetic engineering facilitates the production of human proteins such as blood clotting factors and Fibrinogen, which aids in healing wounds on a cost effective basis;<sup>202</sup>
- cloning techniques would allow for rapid progress to be made in basic research in areas such as what switches genes on and off during development, as well as in the production of animal nodes for studying human diseases;<sup>203</sup>
- cloning techniques could be used to generate skin grafts for burn victims and bone marrow for patients undergoing cancer therapy. It is also predicted that in five to ten years' time cloning techniques should be sufficiently sophisticated so as to be used to generate tissue for organ replacement.<sup>204</sup>
- cloning may be the only source of assistance to infertile couples in which both partners lack gametes. Cloning would provide an alternative to the current practice of embryo donation, and would provide the only means by which such couples would have a genetically "linked" child. It would also be an alternative to those couples where the male partner lacks gametes, but where sperm donation is not preferred. Some couples who undergo *in vitro* fertilisation therapy may also wish to employ cloning techniques to generate extra embryos which would increase the chance of fertilisation where the female partner has only a few oocytes. It would also avoid repeated cycles of *in vitro* fertilisation therapy which can be expensive both emotionally and financially.<sup>205</sup>
- A number of other 'advantages' of utilising cloning technologies to produce a human, in addition to the benefits to infertile couples, were outlined by Gregory Pence in his book *Who's afraid of human cloning?*, and include:

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<sup>201</sup> M Wadman, 'WHO chief defends use of animal models', *Nature*, vol 386, 29 March 1997, p. 204.

<sup>202</sup> Lupton, n 179, p. 130.

<sup>203</sup> Butler & Wadman, n 183.

<sup>204</sup> Lupton, n 179, p. 130.

<sup>205</sup> Lupton, n 179, p. 130; D Butler, 'Calls for human cloning 'stem from ignorance'', *Nature*, vol 387, 22 May 1997, p. 324.

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- personal liberty and the right to self-reproduce mean that denying a person an essential means by which he or she may reproduce may be illegal;
  - benefiting children by their improved genetic inheritance, manipulating genes in order to ensure the child has certain attributes which could be considered beneficial, such as intelligence, certain physical attributes or strong muscles, or to ensure that a genetic disease is not transferred to the child (examples include cystic fibrosis, spina bifida and Down syndrome, which can cause symptoms including blindness, deafness or dwarfism);<sup>206</sup>
  - creating a genetic connection between the parents and the child, and<sup>207</sup>
  - Pence also identifies as a possible advantage that cloning technologies can be utilised to provide children to gay men and lesbians (others would not agree that this is an advantage at all). Cloning could, for example, make it possible for a lesbian couple to have a baby using the egg from one woman and the genes from the other, doing away with the need for artificial insemination.<sup>208</sup>

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<sup>206</sup> Pence believes this to be the strongest argument for asexual human reproduction (cloning), see n 185, pp. 101-110.

<sup>207</sup> There is increasing reliance on genetic determination as an explanation for a person's personality, and an increasing demand for biological inheritance. In response to arguments of this kind, Axel Kahn, director of the INSERM Laboratory of Research on Genetics and Molecular Pathology at the Cochin Institute of Molecular Genetics, Paris, argues that "human descendance is not only biological, as it is in all other species, but is also emotional and cultural. The latter is of such importance that methods of inheritance where both the parents' genes are not transmitted - such as adoption and insemination with donor sperm - are widely accepted without any major ethical questions being raised": A Kahn, 'Clone mammals ... clone man?', *Nature*, volume 386, 13 March 1997, p. 119.

<sup>208</sup> Pence, n 185, pp. 114-115.

# **APPENDICES**

## APPENDIX 1

## GLOSSARY OF TERMS

<b>Artificial Insemination</b>	Injection of semen into a woman's uterus for the purpose of achieving pregnancy (for more detail see Part 3.2).
<b>Blastocyst</b>	A pre-embryo of about 100 cells or less, before a cell layer has formed.
<b>Clone</b>	To form, outside the human body, a human embryo that is genetically identical to another human embryo or person. <sup>1</sup> A 'clone' is a group of cells genetically identical to each other that have arisen from one cell by asexual reproduction. <sup>2</sup>
<b>Cryopreservation</b>	The freezing of reproductive tissue for storage purposes.
<b>Donor insemination</b>	Artificial insemination using donor sperm.
<b>Ectopic pregnancy</b>	Pregnancy in which the ova lodges outside the womb, usually in the woman's fallopian tube.
<b>Embryo</b>	The foetus in the womb, from about two weeks after conception to about the end of the seventh or eighth week.
<b>Embryo transfer</b>	The transfer of an early embryo that has been undergoing treatment in the laboratory, to the uterus. <sup>3</sup>
<b>Enucleated cell</b>	Cell from which the nucleus has been removed
<b>Fallopian tube</b>	Tubes, one on each side, which are attached at one end to the uterus (womb) and are unattached but lie close to the ovary at the other end. These tubes conduct ova from the ovaries to the interior of the womb. <sup>4</sup>
<b>Fertilisation</b>	The process by which male and female <i>gametes</i> fuse to form a <b>zygote</b> which develops into a human life. In humans, fertilisation occurs in the <b>fallopian tube</b> . <sup>5</sup> The process is not instantaneous and may take 22 to 20 hours to complete. <sup>6</sup>

<sup>1</sup> *Infertility Treatment Act 1995* (Vic), section 3, definition of 'clone'.

<sup>2</sup> G Macpherson (ed), *Blacks Medical Dictionary*, 38th ed (London, 1995), p. 103.

<sup>3</sup> C Wood & A Westmore, *Test Tube Conception: a guide for couples, doctors and the community to the revolutionary breakthrough in treating infertility including the ethical, legal and social issues*, Melbourne, 1983, p. 128.

<sup>4</sup> Macpherson, n 2, p. 185.

<sup>5</sup> *Ibid*, p. 187.

<sup>6</sup> NSWLRC, *Artificial Conception: In Vitro Fertilisation Report*, Report No. 58, July 1988, p. xx.

<b>Foetus</b>	<p>The developing human life from the end of the eighth week after fertilisation until birth. The following table gives approximate average size and weight of as foetus at different stages of development:<sup>7</sup></p> <table border="1"> <thead> <tr> <th>Age</th> <th>Length</th> <th>Weight</th> </tr> </thead> <tbody> <tr> <td>4 weeks</td> <td>5 mm</td> <td>1-3 g</td> </tr> <tr> <td>3 months</td> <td>8-9 cm</td> <td>30-60 g</td> </tr> <tr> <td>5 months</td> <td>15-25cm</td> <td>170-340 g</td> </tr> <tr> <td>7 months</td> <td>32-35cm</td> <td>1360-1820 g</td> </tr> <tr> <td>birth</td> <td>45-60cm</td> <td>3200 g</td> </tr> </tbody> </table>	Age	Length	Weight	4 weeks	5 mm	1-3 g	3 months	8-9 cm	30-60 g	5 months	15-25cm	170-340 g	7 months	32-35cm	1360-1820 g	birth	45-60cm	3200 g
Age	Length	Weight																	
4 weeks	5 mm	1-3 g																	
3 months	8-9 cm	30-60 g																	
5 months	15-25cm	170-340 g																	
7 months	32-35cm	1360-1820 g																	
birth	45-60cm	3200 g																	
<b>Gamete</b>	A reproductive cell, sperm and ova, which fuses at fertilisation to form the zygote.																		
<b>GIFT</b>	Gamete IntraFallopian Transfer (for more detail see Part 3.3).																		
<b>ICSI</b>	IntraCytoplasmic Sperm Injection (for more detail see Part 3.7).																		
<b>In vitro</b>	Literally, “in a glass”, it refers to observations and procedures made <i>outside</i> the body. <sup>8</sup>																		
<b>Infertility</b>	Inability to achieve pregnancy after one year of regular sexual intercourse without contraception.																		
<b>IUI</b>	IntraUterine Insemination (for more detail see Part 3.5).																		
<b>IVF</b>	In Vitro Fertilisation. Fertilisation of the egg outside the body (for more detail, see Part 3.3)																		
<b>Ovum</b>	The female sex cell (gamete) produced in the ovaries (plural, ova). May also be called an <b><i>oocyte</i></b> .																		
<b>Parthenogenesis</b>	Cell division in an oocyte which only involves the chromosomes of an oocyte. <sup>9</sup>																		
<b>Surrogate mother</b>	A woman who carries a child with the intention that when the child is born he or she will be given to a couple who will care for the child as if they are the parents of the child. <sup>10</sup>																		
<b>ZIFT</b>	Zygote IntraFallopian Transfer (for more detail see Part 3.6).																		
<b>Zygote</b>	The single cell formed when an ovum is fertilised by a sperm. The zygote contains all the hereditary material for a new individual. After passing down the fallopian tube, when the zygote starts dividing, it becomes planted in the uterus and develops into an embryo. <sup>11</sup>																		

<sup>7</sup> Macpherson, n 2, p. 188.

<sup>8</sup> Ibid, p. 262.

<sup>9</sup> *Infertility Treatment Act 1995* (Vic), section 3, definition of ‘parthenogenesis’.

<sup>10</sup> Second reading speech VPD, 4 may 1995, p. 1247.

<sup>11</sup> Macpherson, n 2, p. 563.

## APPENDIX 2 ART PROCEDURES - INDICATIVE COSTS

It must be remembered that the costs in the table below are an indication of costs, and do not represent the cost structure of all clinics in NSW. Clinics attached to public hospitals are usually less expensive, with the clinic charging only marginally above the scheduled fee.<sup>12</sup> Only the total costs of a procedure, drugs and hospital stay is included in the table. However it is important to be aware that, for Medicare purposes, the procedure is broken up into its components, including planning and management, treatment cycle and cryopreservation plan. Some of the components, such as cryopreservation, which are included in the total costs below are in fact optional. Note that the costs below are **per treatment cycle** and in most cases more than one cycle is necessary. Note also that some procedures must be taken in conjunction with other treatments, such as ICSI which must be taken in conjunction with a superovulated treatment, such as IVF.

IVF				
	Medicare	Health Fund	Patient cost	Total
Procedure total	1798.25	89.25	1691.55	3579.05
Hospital total	96.85	957.25	100.90	1155.00
Drugs	2190.00	-	-	2190.00
<b>TOTAL</b>	<b>4085.10</b>	<b>1046.50</b>	<b>1792.45</b>	<b>6924.05</b>

FROZEN EMBRYO TRANSFER				
	Medicare	Health Fund	Patient cost	Total
Procedure total	644.05	0.00	445.75	1089.80
Hospital total	-	195.00	-	195.00
<b>TOTAL</b>	<b>644.05</b>	<b>195.00</b>	<b>455.75</b>	<b>1284.80</b>

ICSI				
	Medicare	Health Fund	Patient cost	Total
Procedure total	1798.25	89.25	2021.55	3909.05
Hospital total	96.85	957.25	100.90	1155.00
Drugs	2190.00	-	-	2190.00
<b>TOTAL</b>	<b>4085.10</b>	<b>1046.50</b>	<b>2122.45</b>	<b>7245.05</b>

<sup>12</sup> T Libesman & V Sripathy, *Your Body Your Baby, Women's Legal Rights from Conception to Birth*, Redfern Legal Centre Publishing, 1996, p. 67. The author gives the example of Sydney IVF's Royal Prince Alfred Hospital at which public patients incurred \$144 per treatment cycle above the scheduled fee. This publication was published in 1996, so although the costs may have changed, the proportion payable by the patient is likely to have remained fairly similar.

<b>ARTIFICIAL INSEMINATION</b>				
	Medicare	Health Fund	Patient cost	Total
Procedure total (AI)	410.55	0.00	326.55	737.10
Procedure total (DI)	410.55	0.00	46.55	837.10

<b>FALLOPIAN INTRA CYTOPLASMIC SPERM INJECTION</b>				
	Medicare	Health Fund	Patient cost	Total
Procedure total	1798.25	89.25	2021.55	3909.05
Hospital total	96.85	837.25	170.90	1105.00
Drugs	2190.00	-	-	2190.00
TOTAL	4085.10	926.50	2192.45	7204.05

<b>CONTROLLED OVARIAN STIMULATION WITH INSEMINATION</b>				
	Medicare	Health Fund	Patient cost	Total
Procedure total	410.55	0.00	341.55	752.10
Drugs (FSH estimate)	-	-	315.00	315.00
TOTAL	410.55	0.00	656.55	1067.10

<b>NATURAL IVF (WITHOUT SUPEROVULATION)</b>				
	Medicare	Health Fund	Patient cost	Total
Procedure total	945.15	89.25	1051.55	2085.95
Hospital total	96.85	957.25	100.90	1155.00
TOTAL	1042.00	1046.50	1152.45	3240.95

<b>NATURAL ICSI (WITHOUT SUPEROVULATION)</b>				
	Medicare	Health Fund	Patient cost	Total
Procedure total	154.90	51.60	165.005	371.50
Hospital total	96.85	759.30	100.80	1155.00
TOTAL	1042.00	1046.50	1482.45	3570.95

<b>TESTICULAR BIOPSY</b>				
	Medicare	Health Fund	Patient cost	Total
Procedure total	387.25	129.10	215.25	731.50
Hospital total	87.90	759.30	37.80	885.00
<b>TOTAL</b>	<b>475.15</b>	<b>888.40</b>	<b>253.05</b>	<b>1616.50</b>

<b>OVULATION INDUCTION</b>				
	Medicare	Health Fund	Patient cost	Total
Procedure total	110.85	-	346.45	457.30

<b>POST COITAL TEST</b>				
	Medicare	Health Fund	Patient cost	Total
Procedure total	32.75	-	306.15	338.90

<b>TESTICULAR BIOPSY LAB</b>				
	Medicare	Health Fund	Patient cost	Total
Procedure total	82.60	14.55	193.35	290.50

In addition, there are consultation costs, interviews, counselling, pathology tests and other miscellaneous costs which the patients must pay. There is also a cost to the recipient when using donor sperm, oocytes and embryos, which are as follows. These costs are *indicative costs* only, and depend on a number of factors including the patient's needs, which drugs are prescribed, and doctors' hospital fees.

<b>ANONYMOUS DONOR</b>			
	Sperm	Oocytes	Embryo
Medical review, counselling, registration fee etc	726.85	1245.85	1245.85
Recovery of biological material expenses	100.00	6230.00	5500.00
Artificial insemination & program management costs	380.90	500.10	500.10
Hospital accommodation		195.00	195.00
<b>Total indicative cost</b>	<b>1207.75</b>	<b>7751.00</b>	<b>7021.95</b>



<b>KNOWN DONOR</b>			
	Sperm	Oocytes	Embryo
Medical review, counselling, registration fee etc	326.85	326.85	326.85
Recovery of biological material expenses	900.00	3700.00	-
Artificial insemination & program management costs	380.90	500.10	500.10
Hospital accommodation		195.00	195.00
<b>Total indicative cost</b>	<b>1607.75</b>	<b>4721.95</b>	<b>1871.95</b>

	<b>Dedicated Anon donor oocytes</b>	<b>Shared donor oocytes</b>
Medical review, counselling, registration fee etc	326.85	326.85
Recovery of biological material expenses	6010.00	2495.00
Artificial insemination & program management costs	500.10	500.10
Hospital accommodation	195.00	195.00
<b>Total indicative cost</b>	<b>7031.95</b>	<b>3516.95</b>

The available Medicare rebates for recipients is \$103.70 on the medical review of the couple, \$54.35 on the artificial insemination and \$54.35 on the frozen embryo transplant planning and management, a total of \$212.40.

### APPENDIX 3                      CERTIFICATE BY PERSON DONATING SEMEN

This certificate is copied from Part B of Form 1 which is contained within Schedule 1 of the Human Tissue Regulation 1995, made under the authority of section 21C of the *Human Tissue Act 1983*.

#### BEFORE YOU DONATE SEMEN

There are some people in the community who **MUST NOT** donate semen because it may transmit infections to patients who receive it.

You must complete this form if you want to donate semen. If you do not know how to answer any of the questions, please check with a nurse or medical practitioner. It is against the law to knowingly make a false or misleading statement. If you do, you may receive a \$5,500 fine or 1 year in prison, or both.

#### TO THE BEST OF MY KNOWLEDGE MY ANSWERS TO THE FOLLOWING QUESTIONS ARE TRUE

1.	Have you any reason to believe that: - you have AIDS (Acquired Immune Deficiency Syndrome)? - you have been infected with the virus that causes AIDS (HIV)?	Yes Yes
2.	In the last 6 months have you had: - night sweats? - unexplained weight loss? - persistent fever? - diarrhoea? - swollen glands?	Yes Yes Yes Yes Yes
3.	Have you had male to male sexual activity since 1977?	Yes
4.	Have you had sexual activity with a bisexual male since 1977?	Yes
5.	Have you had sexual activity with any person who might have been exposed to the virus that causes AIDS (HIV)?	Yes
6.	Have you EVER injected yourself, or been injected with, any drug not prescribed by a doctor?	Yes
7.	Have you EVER shared drug needles?	Yes
8.	Have you accidentally been struck with a used needle in the last 12 months?	Yes
9.	Have you EVER been a male or female prostitute?	Yes
10.	Have you had sexual activity with a male or female prostitute in the last 12 months?	Yes
11.	Have you been tattooed within the last 12 months?	Yes
12.	Have you received a blood transfusion or treatment with human blood products in the last 12 months?	Yes
13.	In the last 2 years have you had jaundice or hepatitis, or been in close contact with any person with either of these illnesses?	Yes
14.	Are the answers to questions 1-13 also correct for you present and past spouse(s) and past sexual partner(s)?	Yes

**Please do not sign the form yet.**

**Take it with you to the interviewer**

Signature of Donor  
Name (PRINT)

Signature of Witness  
Name (PRINT)  
DATE