

Tabled by:

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K.M.

Canberra Fertility Centre

Surrogacy Information Pack

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Disclaimer

The information and fees listed in this booklet are correct at 1 September 2004 and are subject to change without notice. We will discuss future amendments to this booklet with prospective patients before commencing any procedures.

Amendment to Surrogacy Booklet September 2004 Edition

With Compliments

The Substitute Parent Agreement Act 1994 referred to on Page 2 has been replaced by the **Parentage Act 2004**.

This is the Act that governs the surrogacy process in the ACT.
There is a link to view this Act in the surrogacy section of the
Canberra Fertility Centre website
(www.canberrafertilitycentre.com.au).

Canberra Fertility Centre
November 2004



**Canberra
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Introduction

Surrogacy involves an IVF procedure. The eggs and sperm come from the female and male called the “commissioning couple”, (that is the couple who want the baby). The surrogate female is also called a “gestational carrier” and is the female that will have a fertilised egg put into her body with the aim of becoming pregnant and carrying the commissioning couple’s baby. The commissioning couple must find their own surrogate.

The surrogacy process in the ACT is governed by the Substitute Parent Agreement Act 1994. There is a website link to view this Act on the Canberra Fertility Centre website (www.canberrafertilitycentre.com.au). All surrogacy applications are submitted to the John James Memorial Hospital Ethics Committee for approval and a copy of their Surrogacy Guidelines is included in Appendix A. Further information on the IVF process is included in the Canberra Fertility Centre Patient Information Booklet (which can be downloaded from our website noted above).

Surrogacy Enquiries

Thank you for your enquiry regarding surrogacy. Dr Martyn Stafford-Bell manages all surrogacy applications with the Canberra Fertility Centre. All questions and initial enquiries regarding surrogacy should be directed in writing to Dr Stafford-Bell.

Dr M.A. Stafford-Bell
The Australian Surgeons Building
Suite 8 / 13 Napier Close
DEAKIN ACT 2600
AUSTRALIA
Telephone: (02) 62852966
Facsimile: (02) 62852746
e-mail: staffordbell@bigpond.com.au

Application for Surrogacy

An application for surrogacy has two parts:

PART ONE:

Initial application letter

1. Application must be in writing to Dr Stafford-Bell.
2. Application must include a copy of the independent gynaecological report for commissioning (genetic) mother giving the reasons why surrogacy is required. See guidelines in Appendix C.
3. Applications must be sent to: Dr. M.A. Stafford-Bell
Suite 8/ 13 Napier Close
DEAKIN ACT 2600
Ph: (02) 62852966
Fax: (02) 62852746

AWAIT reply to above from Dr Stafford-Bell before proceeding with Part two

PART TWO:

Formal application for Surrogacy

Listed below are the steps to follow once your initial enquiry for surrogacy has been addressed and you have been advised by Dr Stafford-Bell to proceed with the formal application for surrogacy.

1. Medical records are not required at this stage. They will be requested as required.
2. Applications must be sent to: Dr. M.A. Stafford-Bell
(Address as above)
3. Applications should include a copy for Dr Stafford-Bell of the following reports: (Guidelines to be addressed for each of these reports are included in the appendix)
 - a) The commissioning mother and the surrogate are both required to obtain an **independent gynaecological report** on their health, past

history, suitability for a surrogacy arrangement and a discussion of the various risks involved (The independent gynaecological report already submitted in Part One is sufficient for the commissioning mother). This can be carried out in their home state. (Appendix C)

- b) The commissioning parents, the surrogate, her partner and any dependent children (aged 4-18 years) will be required to attend an **interview with an independent counsellor** of their choice. This can be in their home state. (Appendix D)
- c) The commissioning parents, the surrogate and her partner will be required to seek **independent legal advice** on the subject of a surrogacy arrangement and the adoption laws as they apply in their home state. (Appendix E)
- d) A statutory declaration is required to be signed by the commissioning couple, the surrogate and her partner, if any, to the effect that the arrangement in which they are entering confers no financial benefit on any of the parties.

The above formal application letters and reports need to be received and reviewed by Dr Stafford-Bell at least two weeks prior to any interview date booked with Dr Stafford-Bell/Canberra Fertility Centre Counsellor.

4. The commissioning parents, the surrogate and her partner will be required to **attend interviews** with Dr. Stafford-Bell and **counselling** with the Canberra Fertility Centre counsellor. Also you will liaise with the nurse coordinator.
5. An application will be made on your behalf by Dr Stafford-Bell to the John James Memorial Hospital Ethics Committee. This committee meets three to four times each year. It will consider the application and **has the responsibility for approving the application**. Its decision is final. (Appendix A)
6. The cost of preparation of the application is approx \$3,500.00, irrespective of the outcome. There will also be the cost of travelling to Canberra and elsewhere for interviews. The commissioning parents are expected to pay for the out of pocket expenses incurred by the surrogate and her partner. In addition to these preparation costs there are the relevant costs for the IVF egg collection, embryo freezing, and embryo transfer procedure/s as outlined in the Explanation of Fees for Surrogacy section.

Surrogacy

Surrogacy in the ACT has been legal since November 1994. The Canberra Fertility Centre terms a "surrogate" as a woman who carries a pregnancy for another woman. The embryo contains none of the surrogate's genetic material. The surrogate is a "gestational carrier" only. The genetic "make-up" of the embryo comes from the "Commissioning Couple". The "Commissioning Couple" is the couple who want the child.

The surrogacy process may be considered by a "Commissioning" woman:

- who has functioning ovaries but no uterus
- who has reproductive tract malformations
- who is incapable of carrying a pregnancy for medical reasons
- who has had many unsuccessful attempts at IVF and embryo transfers
- who has history of repeated miscarriage

Evaluation

The evaluation of the infertile couple for gestational surrogacy includes:-

1. A complete medical history from both partners by their own gynaecologist.
2. An assessment of the commissioning couple and surrogate and the surrogate's partner by two counsellors; one counsellor from the Canberra Fertility Centre and an independent counsellor. Any dependent children over the age of four of either couple will also require an assessment by an independent counsellor only.
3. Assessment of the commissioning mother and the surrogate mother by Dr. Stafford-Bell.
4. A legal report by a lawyer in the state where the baby will be delivered.
5. Blood screens - Hepatitis B Surface Antigen, Hepatitis C, HIV, Antibodies, Rubella, Syphilis, Blood Group and antibodies, and any blood tests showing reproductive hormone levels.

These reports are then brought to the John James Hospital Ethics Committee which assesses each case individually. There is a **period of three months termed a "cooling off period"** which begins after the interview with the clinic's counsellor, before any treatment can begin.

The Surrogate

As the ACT law stands, neither the Canberra Fertility Centre nor Dr. Stafford-Bell can procure a surrogate for any couple. Surrogates usually include relatives or close friends. The ACT law states that the Commissioning couples **CANNOT** advertise for a surrogate. All surrogacy is to be altruistic:- this means that the surrogate may not be paid for her services.

The ideal surrogate:

- is between 25-37 years of age
- has previously carried a pregnancy to term without complications
- does not abuse any drugs such as alcohol, cigarettes or marijuana
- if she is sexually active, has a monogamous relationship
- is healthy, having no known illnesses such as diabetes etc
- is not Rh sensitive (i.e. sensitivity to antibodies that could jeopardize the health of the foetus and the surrogate).

Procedure

The commissioning mother will have an in vitro fertilization (IVF) cycle using drugs to produce multiple follicles. At the optimum time the oocytes (eggs) are collected in the operating theatre and fertilised with the commissioning father's sperm. The embryos that form after this procedure are frozen using cryopreservation and stored in tanks at the Canberra Fertility Centre.

It is recommended that the commissioning couple have a second blood test for Hepatitis B Surface Antigen, Hepatitis C and HIV six months after the embryos are frozen and that the surrogate wait for the result of that test before having the embryos transferred to her uterus.

In Vitro Fertilization (IVF) Information for Surrogacy

In Vitro Fertilisation (IVF) is the process where eggs are taken from the woman's body and fertilised in the laboratory with the partner's sperm.

Resulting embryos are then replaced into the woman's body (embryo transfer procedure) with remaining embryos frozen and stored for future use. In a Surrogacy Arrangement, the embryos formed from the Commissioning couple's IVF procedure are frozen and stored. The embryos are later thawed and replaced into the uterus of the Gestational surrogate (termed a frozen embryo transfer procedure).

The basic stages involved in the IVF procedure are detailed below, but do not be surprised if the stages are slightly different from the procedure you follow. Everyone is an individual and the tests may differ or even some stages may be added or not included in your treatment. You should discuss your treatment with your specialist or the Nurse Coordinator.

The IVF treatment involves the following main stages:

- Growth and maturation of several eggs.
- Exact timing of collection of these eggs.
- The collection of the eggs.
- Fertilisation of the eggs that may become embryos.
- Transfer of the embryo/s back into the uterus.
- Freezing of remaining suitable embryos.

Medications used in Ovarian Stimulation

The normal cycle usually produces one egg but fertility drugs are used to hyperstimulate the ovaries to develop a number of eggs in the IVF cycle. Follicle Stimulating Hormone is the most common method of stimulating follicular development. Puregon and Gonal-F are synthetic forms of Follicle Stimulating Hormone (FSH) and your specialist will prescribe one of these medications to stimulate the ovaries to produce many eggs. Some patients may be treated with FSH only, but most patients will also use Lucrin, Synarel, Cetrotide or Orgalutran in conjunction with the FSH injections. Lucrin and Synarel are both GnRH agonists and Cetrotide and Orgalutran are GnRH antagonists. These medications act on the pituitary gland to stop ovulation occurring before the egg collection in an IVF cycle. Individual instructions will be given to you. Please discuss the cost of your medications before commencing.

Injections (Lucrin, Cetrotide, Orgalutran, Puregon and Gonadotropin) can be conveniently self-administered at home by yourself or your partner. The nurse coordinator will give you and your partner instructions and a teaching session/s. You will be supervised at the clinic until you feel confident to self-administer at home. Synarel nasal spray is conveniently given at home and an instruction sheet and video are available.

Ovarian Stimulation Protocols

There are almost as many stimulation protocols in use in the world as there are IVF clinics. The most common protocol used by our clinic is the Down Regulation Protocol and it is very similar to that used by most IVF units around Australia. Others used include Flare Protocol using GnRH (Synarel/Lucrin), Short Protocol using Cetrotide or Orgalutran, and combination protocols. Your specialist will advise you which protocol they believe will provide the optimum result.

Overview of the Down Regulation Protocol

In this protocol the GnRH analogue (Lucrin or Synarel) is started in the mid-luteal phase, 7 days after ovulation. Lucrin or Synarel is continued daily for 10 days then a blood test is performed to check that hormone levels are at a baseline. If a baseline has not been reached then Lucrin or Synarel is continued for a further three to five days. A blood test is performed again to test for baseline levels. This is performed every 5 days until baseline levels have been achieved and at this stage the stimulation drugs (Puregon or Gonadotropin) are commenced, concurrently with the GnRH.

Monitoring Egg Development

The eggs (ova) develop inside the ovaries in follicles, which are like little cysts or fluid filled sacs. These follicles produce increasing amounts of oestradiol (an oestrogen hormone) as they grow. The size can be measured by ultrasound, although the eggs themselves are much too small to see. A blood test and ultrasound scan will be done on about the seventh morning after commencing FSH. Thereafter blood tests and ultrasound scans will be carried out as required.

a) Blood Tests

Blood is taken at intervals from about Day 7 of the simulated cycle to measure oestradiol levels. Blood tests are done at the Canberra Fertility Centre between 7.30am and 9.00am so that the results are available for your specialist on the same day. Clients living out of Canberra or interstate will need to discuss with the Nurse Coordinator whether tests can be arranged closer to home.

b) Ultrasound Examinations

Patients will have ultrasound examinations to measure the size, number and development of follicles growing. Ultrasounds are performed trans-vaginally and an empty bladder is required. Sound waves are used to produce pictures of the growing follicles, so that they may be counted and measured. The number of eggs collected may differ from the number of follicles seen on ultrasound. These scans are done at the Canberra Fertility Centre between 7.30am and 9.00am weekdays by appointment. Clients living out of Canberra or interstate will need to discuss with the Nurse Coordinator whether tests can be arranged closer to home.

Admission to Hospital

Admission will be arranged at the John James Memorial Hospital prior to egg pick-up. You are to remain in hospital for about 2-4 hours after egg pick-up for recovery from the anaesthetic/sedation used during surgery.

Timing of Egg pick-up

This will be undertaken using laparoscopy or an ultrasound guided pick-up. Your specialist will advise you as to which method will be best for you. The oestradiol levels (from the blood tests) and the number and the size of the follicles (from the ultrasound) are together used to assess the maturity of the eggs and the right time for egg collection. There is no "correct" oestradiol level to reach and there is enormous variation between patients. It is the whole pattern of blood and ultrasound results which determine whether the response to treatment is optimum. In general, however, it is important that the oestradiol level rises steadily until the eggs are collected. It is very important to realise that a wide range of individual treatments are used in

the program. Please do not be alarmed if your treatment is different from someone else's. The aim is to design the best individual protocol for you. For patients who are not using Lucrin, Synarel, Cetrotide or Orgalutran, the hormone that normally triggers ovulation, LH, may be present and its levels are not under your specialist's control. If it is detected, egg pick-up must be timed according to the results of the blood tests.

hCG Injections

HCG (human chorionic gonadotropin) is a hormone that performs the function of LH, triggering the final maturation of the eggs and ovulation. In an IVF cycle a single injection of hCG medication (Pregnyl or Profasi) is given usually 37 hours before the operation is planned. Your operation time is determined by the oestradiol level and the ultrasound measurement. Most patients give this injection at home at the specified time, and you will receive instructions from one of the Canberra Fertility Centre Nurse Coordinators. After this trigger injection the other medications (Lucrin / Synarel / Cetrotide / Orgalutran and Puregon / Gonad-F) are normally stopped. Some clients may be asked to recommence Synarel/Lucrin after egg pick-up so you are advised to keep any remaining medication until the cycle is completed.

Ovum pick-up (Egg Collection)

The egg collection is done under a "light" anaesthetic. The follicles are visualised using trans-vaginal ultrasound, and the fluid inside them is sucked through a needle and tubing into a test tube. The tube is passed immediately to the embryologist who looks for the egg under the microscope. The eggs are then put in the incubator. Most patients are sleepy, and some are nauseous for a few hours after the operation. You can be discharged 2-4 hours after the operation. You will be visited by the Canberra Fertility Centre nurse coordinator and given further instructions before discharge. If you are having a laparoscopic egg collection it is performed under general anaesthetic and you may have a longer recovery time before being discharged.

Sperm Collection

We will inform you of the approximate sperm collection time once the egg collection time has been arranged. It is usually 1-3 hours after the operation. Two to three days abstinence from intercourse/masturbation is preferred prior to the time of egg collection. The sperm sample is produced by masturbation at the Centre or by other means by arrangement. There is a room for this purpose. You are asked to wash your hands beforehand to minimise the chance of contamination. Lubricants are NOT to be used. It can be very difficult for some men to produce a sperm sample on request under these conditions. If you are worried about this aspect of the program, please discuss it with us at or before the start of the treatment cycle, so that arrangements can be made to freeze some semen if necessary as freezing must be done at least a week before egg collection. Sexual activity may be continued as usual until three days before the time of the woman's egg collection. Sexual activity may resume 72hrs after the egg collection if comfort levels allow.

Events in the Laboratory

The sperm sample is prepared and put with the eggs (fertilisation), 3-6 hours after collection. The eggs and sperm are kept in an incubator until next inspected 15-20 hours later. At this time they are checked under the microscope to determine whether fertilisation has occurred. You will be in contact with the Nurse Coordinator during these interim days and they will inform you of the fertilisation results and availability of embryos for freezing.

Freezing of Embryos

Canberra Fertility Centre has been freezing embryos since 1985, and the subsequent transfer of these has resulted in the birth of many healthy babies. There is no increase in the incidence of abnormalities in children born from frozen embryos, than those from 'fresh' embryos. Embryos can be frozen after 24, 48 or 72 hours in culture and also at blastocyst stage. Consent forms are signed relating to the "ownership" of the embryos in the event of death/divorce etc and any disputes are directed to the Commissioner of Health. In addition consent forms are signed to formalise the Surrogacy Arrangement.

Follow-up tests

After egg collection blood tests will be ordered to monitor the hormone levels. Follow-up blood screens may also be required.

Further Steps – Unsuccessful Cycles

All patients are asked to notify us of their next period whether or not ovum pick-up and/or embryo transfer is performed. This information helps us plan future management.

Cancellation of Cycles

Hormone levels (Oestradiol) from the blood tests and follicle numbers from the ultrasound scan will be used to assess the progress of the cycle. The aim is to collect between 6 and 10 eggs. If your blood hormone levels and follicle numbers are too high, your specialist may decide that your cycle be cancelled to avoid the risk of OHSS (Ovarian Hyperstimulation Syndrome). The Nurse Coordinator will explain this risk to you at the initial meeting. This is only a temporary set back. Similarly if the blood hormone levels and ultrasound measurements show that insufficient follicles are growing then your specialist may also decide that the cycle be cancelled. A cycle may also be cancelled if follicles develop on an inaccessible ovary (eg. follicles developing on the wrong side when scar tissue allows only one ovary to be accessible) or if ovarian cysts impede the cycle.

Cycle cancellation occurs in about one in seven cycles. In the majority of cases, this is just a reflection of the variation in the biological system and a more satisfactory response is obtained in the next cycle attempt, possibly using a different drug dose or protocol. Rarely an industrial dispute or other circumstances beyond our control could result in a cycle being cancelled.

Cancellation of Treatment Components

No Eggs Collected

This occasionally happens and occurs where there is no access to the follicles, or ovulation has unexpectedly occurred prior to egg collection, or there are no eggs obtained from the follicles at egg collection. Possible reasons for the failed egg collection and future plans are discussed at a follow up appointment with your specialist.

No Fertilisation

This happens in about 5% of patients who have eggs collected. Sometimes it is because of known problems such as low sperm count, sometimes because of unpredicted problems with eggs or sperm, and sometimes there is no obvious reason. This will be discussed with you and usually an appointment will be made to further review the situation and make future plans.

Management of the Frozen Embryo Transfer (FET) for Surrogacy Treatment Cycle

A treatment plan needs to be organised by your specialist gynaecologist before your Surrogate can commence an embryo transfer cycle. It is recommended that the results of the six-month post egg collection blood screening tests are known and cleared before proceeding with embryo transfer to the Surrogate. You may also need to make a booking for an FET for Surrogacy cycle, so please check with the Nurse Coordinator in advance. All parties will need to sign consent forms before the procedure commences, and these consent forms must be signed for each transfer cycle. We cannot thaw any of your embryos without your written consent. It is also necessary for the appropriate prepayment to be paid before the cycle begins.

In a "natural" FET cycle (where no medications are used before the embryo transfer), the cycle is tracked for ovulation using blood tests to monitor the hormone levels. As ovulation draws near an ultrasound will be requested to measure the thickness and maturity of the endometrium. If this is suitable, the embryo transfer to your Surrogate will be performed 2-3 days after ovulation, or a few days later if blastocyst culture is used.

In a "controlled" FET cycle, Progynova (oestrogen) tablets are administered in order to prepare the endometrium for implantation. The development of the endometrium is monitored by ultrasound scanning (approximately 1-2'scans). The first ultrasound is usually performed on day 10-12. When the endometrium is of the right maturity, the embryos will be thawed for transfer to your Surrogate. Progesterone pessaries are used in conjunction with Progynova to maintain the endometrium, and these medications may need to be continued for the first trimester of a pregnancy.

Thawing Your Embryos

The embryologist will thaw your embryos so that the age of the embryos corresponds with the maturity of the uterine lining of your Surrogate. The exact timing will depend upon the stage at which the embryos were frozen. You are asked to ring the day before your embryo transfer to confirm the time for which the procedure is booked. Not all embryos survive the freezing, storage and thawing process. You will be notified by the Nurse Coordinator or your Specialist if there is a problem.

Embryo Transfer Procedure

The surrogate has her menstrual cycle tracked using blood tests and ultrasounds to predict ovulation. Two to three days after ovulation the embryos from the commissioning couple are transferred to the uterus of the surrogate. The embryo transfer is carried out at the Canberra Fertility Centre. Under normal circumstances no more than 2 embryos will be replaced because of the risk of multiple pregnancies. No anaesthetic is required and the procedure itself takes approximately 3 minutes. The Specialist will insert a speculum into the vagina, as for a Pap smear. This allows a view of the cervix. A fine tube (catheter) is passed through the cervix and up into the uterus. The embryos are then injected into the uterus using a fine inner catheter. This technique does not normally require sedation, and may be a little uncomfortable but not painful. Your surrogate is then requested to do light duties only, and if possible, avoid strenuous work or activities until a pregnancy has been diagnosed or excluded. Bleeding does not necessarily mean that a pregnancy is not developing. Your surrogate must continue blood tests until a final outcome is known. You and your surrogate will be advised of follow-up tests required and any medication required.

Pregnancy

The blood tests taken two weeks after the Surrogate's ovulation will detect whether the pregnancy hormone (hCG) is present: however it is too early to know whether there is a healthy continuing pregnancy. Further blood tests and an ultrasound examination are needed. Your specialist usually orders an ultrasound at approximately 7 weeks of pregnancy, and antenatal visits with the specialist commence at 10-12 weeks of pregnancy. Please refer to your specialist and the Canberra Fertility Centre for instructions. Unfortunately IVF/Surrogacy procedures, like natural conception, can lead to a biochemical pregnancy (a transient rise in pregnancy hormone followed by a late period), miscarriage (which may need curettage), or an ectopic (tubal) pregnancy (requiring surgery), as well as the happier outcomes. Therefore unfortunately even a positive blood test is not the end of the waiting. Multiple pregnancy (twins or triplets) are more common with IVF/Surrogacy than with natural conception, because of the practice of transferring more than one embryo. If you do not want to risk having twins please discuss with your doctor the replacement of only one embryo in an attempt to reduce this risk.

Psychological Issues

People who are considering surrogacy must have professional counselling prior to proceeding with surrogacy because of the many issues surrounding these processes. It is important that all parties involved are comfortable with the procedure as an alternative means of having a family. Resolution of any potentially ambivalent feelings that either couple may have needs to be addressed. Issues of confidentiality need to be addressed and the extent of the relationship after birth between child and surrogate and her family must be determined prior to starting treatment.

Ethical, moral and legal issues in relation to surrogacy follow a long way behind the technical capabilities in reproductive medicine. There is little known of the long-term psychological effects of surrogacy on either the child born from surrogacy, the surrogate mother or the commissioning parents.

Legal Issues

There are many legal issues concerning surrogacy and they vary from state to state in Australia. It is essential to consult a lawyer knowledgeable in this area. Each state may view the birth mother differently.

Summary

The surrogacy option may offer many people a possibility for parenthood that was previously non-existent. The issues (psychological, ethical, moral and legal) all need careful consideration. Anyone contemplating surrogacy should explore all the options, obtain as much information as possible, and seek guidance from both counsellors and specialists in choosing the best path to parenthood for you.

Resources

1. Canberra Fertility Centre Policy Manual
2. "Patient Guide to Third Party Reproduction" American society for Reproductive Medicine copyright 1995
3. John James Hospital Ethics Committee Guidelines

Contraception for Surrogates

By the time a couple have definitely decided that they will offer to carry a pregnancy for another couple, they will need to consider what form of contraception they will take to ensure no pregnancy of their own takes place.

If a permanent form of contraception exists, for instance a vasectomy or tubal ligation, then of course no further action is needed.

If, however, no permanent form of contraception exists, then it becomes essential that the couple are very careful regarding contraception.

The oral contraceptive pill cannot be used immediately prior to surrogacy and your specialist will advise you when to stop taking it if this is your usual form of contraception. A barrier method of contraception will be advised.

The barrier method (i.e. condoms) or abstinence are the only forms of contraception that can be used before surrogacy and should be used at all times during the cycle.

Any questions about this issue can be directed to either Dr Stafford-Bell or to the Canberra Fertility Centre, at any time.

Contraception for Commissioning Couple

Depending upon the reason for surrogacy, prevention of spontaneous pregnancy may be necessary for the commissioning couple. The barrier method (i.e. condoms) or abstinence are the only forms of contraception that can be used before surrogacy and should be used at all times during the cycle.

Appendix A

John James Memorial Hospital Ethics Committee

Guidelines for Surrogacy (January 2003)

Introduction

These guidelines have been prepared to assist the John James Hospital Ethics Committee (the Ethics Committee) with deliberations concerning surrogacy arrangements in the ACT. They are designed to conform with the *Substitute Parent Agreements Act 1994 (ACT)* (the Act) and other relevant guidelines and legislation. They will be applied on a case-by-case basis with a certain measure of flexibility in accordance with the general purpose of the Act.

1. Non commercial

Surrogacy agreements shall be non-commercial. Section 3 of the Act indicates that a payment or award on account of expenses connected with a surrogate pregnancy or the birth and care of the child so born is not considered to render the agreement commercial. Obviously the greater such payments or awards, the harder it will be to adequately link them to such expenses.

2. Permanent Residency

All parties to the surrogacy arrangements must normally be resident in Australia for the period of the procedure and pregnancy. This includes the genetic parents, the surrogate mother and the surrogate's partner if there is one.

4. The Genetic Parents

- 4.1 The genetic mother must be over 18 years of age and generally under 38 years of age at the time of referral (the IVF pregnancy rate for patients over the age of 40 is negligible).
- 4.2 The genetic parents should not have more than one live child each or more than one from their present relationship.
- 4.3 The genetic mother should be suffering from some medical condition making pregnancy unlikely, but which is unlikely to reduce the ability to care for her child, or reduce her life expectancy until the child has at least reached majority. Without restricting the foregoing, examples of such conditions are absent uterus, diseased or damaged uterus, abnormal uterus, repeated failed IVF attempts and repeated miscarriage.
- 4.4 The genetic parents should not be suffering from a medical or psychological condition likely to be exacerbated by her entering the surrogacy arrangement.
- 4.5 The genetic parents must have a commitment to lifelong care of the child.

5. The Surrogate Mother

- 5.1 The surrogate mother must be over 18 years of age and generally under 40 years of age at the time of referral (the IVF pregnancy rate for patients over the age of 40 is negligible).
- 5.2 The surrogate mother should have at least one child by her partner in her present marriage or stable defacto relationship of over three years, or if separated, widowed or divorced, have at least one child. Neither the surrogate's financial situation or the care of her existing children should suffer unduly as a result of the surrogacy arrangement.
- 5.3 The genetic mother and her partner should nominate the surrogate mother. The relevant gynaecologist or fertility specialist or their employees should not attempt to procure, or provide any professional or technical assistance to facilitate a surrogacy arrangement. The relevant gynaecologist or fertility specialist has discretion, however, to assess other people who volunteer to be surrogates, as to their suitability.

6. Counselling

- 6.1 The genetic parent(s) and surrogate parent(s) must be counselled by the relevant gynaecologist or fertility specialist according to a set protocol. Counselling should address such matters as;
- 6.1.1 the reasons for surrogacy;
 - 6.1.2 the ability of the genetic mother to care for the child;
 - 6.1.3 the surrogate's obstetric, gynaecological and medical history; and
 - 6.1.4 the medical risks the surrogate will face by entering the arrangement.
- 6.2 Where surrogacy is required because of the genetic mother's medical condition a report from her treating physician is also required.
- 6.2.1 The genetic parent(s) and surrogate parent(s) should be counselled by a solicitor with expertise in Family Law according to a set protocol on matters such as the legal implications of surrogacy, the consequences of refusal of the genetic parents to accept a disabled child and the implications of how the child's paternity is assigned on the birth certificate.
- 6.2.2 All parties (including children over the age of 4 and under the age of 18) shall be assessed separately by an independent psychologist. Parties other than children are then assessed by a trained counsellor on the IVF program. Both assessments shall answer a set of questions prepared by the Fertility Centre. The relevant gynaecologist or fertility specialist then counsels the genetic parents and the surrogate parents.

7. Declarations

- 7.1 All involved adults must signify their agreement to the surrogacy by signing a declaration that the above counselling has taken place and that all other preconditions are satisfied.
- 7.2 All involved adults must sign a statutory declaration that the surrogacy arrangement conveys no financial advantage upon any of them.

8. Ethics Committee Approval

- 8.1 The relevant gynaecologist or fertility specialist (Dr M Stafford-Bell) must then submit each surrogacy arrangement to the John James Hospital Ethics Committee for approval.
- 8.2 It must be made clear to the parties involved, in writing, that the Ethics Committee makes no charge for this service. (*NOTE at October 2003 the Ethics Committee introduced a charge for their service and this is included in the Explanation of Fees Stage 1 in Appendix B*)
- 8.3 The Ethics Committee shall approve or reject each case after consideration of the declarations and statutory declarations and any relevant written reports.

9. Cooling-Off Period

A cooling-off period of three months shall apply from the time of counselling as above during which any of the parties may withdraw from the arrangement.

10. Modification of Guidelines

The Ethics Committee may modify these guidelines from time to time.

Note: point three was originally omitted in Ethics Committee Guidelines when originally prepared.

Appendix B

Canberra Fertility Centre

Explanation of Fees (IVF and FET for Surrogacy Procedures)

Introduction

There are three stages to a Surrogacy Arrangement. This handout covers the estimated costs involved in all these stages.

- Stage 1 involves the preparation and submission of an application for surrogacy. Surrogacy can only proceed once this application is accepted.
- Stage 2 involves an IVF Procedure and the freezing of subsequent embryos.
- Stage 3 involves the thawing and transfer of these embryos to the surrogate.

Medicare Benefits Not Applicable for Surrogacy Procedures

Although surrogacy arrangements have legal standing in the ACT, the Commonwealth Government which administers the Medicare scheme specifically prohibits the payment of Medicare Benefits for IVF services which are provided in conjunction with a surrogacy arrangement.

Consequently IVF-Surrogacy involves considerable out-of-pocket expenses.

This handout has been designed to explain the source of these expenses and give patients an estimate of the approximate amounts involved. The amounts have been calculated as the average cost per treatment. An individual

patient's account is dependent upon the actual treatment received and therefore may differ from the average shown in this handout.

Private Fund Benefits

Private fund benefit may apply to the laparoscopy procedure item number 35637 and the day surgery expenses. Please check with your fund for eligibility.

Travel and Accommodation

Some allowance must be made for travel to and accommodation in the ACT for all the adults required for the Stage 1 interviews. An overnight stay is generally all that is required. The interview process is usually from 9.00am and generally takes 4 hours. Both interviews occur concurrently and a booking is required, allowing discount advance purchase airfares to be investigated. Allow for at least 3 nights accommodation for all those who will need to attend the Stage 2 IVF procedure, and at least overnight accommodation for those attending the Stage 3 embryo transfer procedure. It is often not possible to take advantage of pre-purchase discounts for airfares, so allowance for at least full-fare economy fares may have to be made. Also if appropriate blood and ultrasound testing facilities are not available/affordable in your area, you may need to allow for a longer period of stay in Canberra to have all testing performed at the Canberra Fertility Centre.

Stage 1 Expenses

These are the expenses incurred in the preparation and submission of an application for surrogacy to the John James Hospital Ethics Committee. No surrogacy arrangement can proceed without approval from this committee. Reports from the following professionals are needed:

- Independent gynaecologist in your home state
- Independent clinical psychologist in your home state
- Legal opinion from a lawyer specialising in family law in your home state

These professionals will bill you independently for their services. As we are unable to estimate what these reports will cost it is your responsibility to find out what these expenses are before undertaking them. Once these reports are received it is necessary for all parties (including the partner of the intended surrogate) to see Dr Stafford-Bell and the clinic counsellor. These fees are outlined in Table 1.

Table 1 –Preparation/Consultation Fees for Surrogacy

DESCRIPTION	MEDICARE ITEM NO.	FEE (\$)	EXPECTED REBATE (\$)	GAP EXPENSE (\$)	BILLED BY:
Consultation of each adult with Dr M. Stafford-Bell	104	120.00	60.45	59.55	Dr Stafford-Bell ¹
Consultation with Clinic Counsellor	-	500.00	Nil	500.00	Canberra Fertility Centre ¹
Preparation/ Submission of application to Ethics Committee	-	2000.00	Nil	2000.00	Dr Stafford-Bell ²
Ethics Committee Surrogacy application fee for submission and administration	-	550.00 (includes GST)	Nil	550.00	Dr Stafford-Bell on Behalf of Ethics Committee ²

¹ These accounts must be paid at the time of consultation.

² Billed once submitted and must be paid before further treatment commences.

Stage 2 Expenses

These are the expenses incurred in the collection, fertilisation, and storage of your embryos. Many different health professionals are involved in the Stage 2 procedures and each will bill separately for their respective services. You will receive accounts from the following sources:

- Your Gynaecologist/ Canberra Fertility Centre
- Your Anaesthetist
- John James Memorial Hospital

The exact nature of the account will depend on the procedure undertaken, the amount of medications used and the length of stay in hospital.

Stage 2 Surrogacy Fees from Gynaecologist/Canberra Fertility Centre

This section covers the **expected** costs from your gynaecologist/Canberra Fertility Centre for Stage 2 expenses. Tables 2 and 3 detail these fees and the Medicare item numbers used. Please be aware that the gap expense on your account may differ depending on the extent of extra services used as outlined in Table 6.

Table 2 – IVF/Surrogacy Procedures

ITEM NO.	DESCRIPTION	FEE (\$)	EXPECTED REBATE (\$)	GAP EXPENSE (\$)
- ¹	IVF procedure	4,390.60	Nil	4,390.60
-	Planning & Management	180.00	Nil	180.00
35637 ²	Laparoscopy	337.95	337.95	Nil
-	Semen preparation	100.00	Nil	100.00
TOTAL		5,008.55	329.70	4,670.60

¹ Included is the provision of Synarel or Lucrin to oocyte retrieval. For ICSI add \$250.00 to prepayment. Includes the cost of embryo freezing. A rebate of \$500.00 will apply if embryos are not frozen.

² Includes a refund of \$84.45 from private health fund. If you do not have private health cover or are not eligible for this refund then this amount will increase the gap expense. Contact your fund to confirm your eligibility.

Stage 2 Surrogacy Pre-Payment

A pre-payment of **\$5,008.55** (or \$5258.55 if using ICSI) must be paid in *full* before commencing Stage 2 treatment. Please pay this amount to the Canberra Fertility Centre before your cycle starts. An ideal time is at the paper signing appointment. The balance of the account is rendered at the completion of treatment and is due within 30 days of that time.

Stage 2 Surrogacy Anaesthetist Fees

The fees charged range from \$200 - \$450 and the Medicare rebate is \$98.55. Please speak to the coordinating sister to find out who your anaesthetist is likely to be. If you have private health cover you may be eligible for a further rebate. Contact your fund to clarify your position.

Stage 2 Surrogacy John James Memorial Hospital Fees

The expected cost of hospitalisation is \$1045.00 but will depend on the length of stay in hospital and whether you elect for day care, shared or private accommodation. If you have private health insurance the contract rates as agreed between your fund and the hospital will apply. The level of rebate may vary according to your table. In any event you are strongly advised to contact your health fund to see what rebates will apply. Please note, if you contact the hospital they will only be able to give you an estimate of the expected cost.

Stage 2 Cancelled IVF for Surrogacy Cycle Fees

An IVF treatment cycle is considered “cancelled” if an egg collection procedure does not take place. The cost of a cancelled IVF for Surrogacy cycle will vary depending upon how many blood and ultrasound tests have been performed, and if any medications have been used. An account will be issued for the cost of any blood and ultrasound tests performed at the Canberra Fertility Centre and will include the fee for planning and management of a cancelled IVF for Surrogacy cycle (see Table 3 below). This amount will be deducted from any pre-payment that has been made. Please pay any outstanding balance to the Canberra Fertility Centre to finalise the account. A positive account balance may be used for future treatments or a refund requested (proof of identity required). Tests performed elsewhere will need to be settled with the relevant providers.

Table 3 – Cancelled IVF for Surrogacy Procedures

ITEM NO.	DESCRIPTION	FEE (\$)
-	Planning & Management (Cancelled IVF for Surrogacy Cycle)	500.00
TOTAL		500.00

Stage 3 Expenses

This section describes the expected costs associated with the thawing and transfer of stored embryos (FET) which is Stage 3 of a surrogacy arrangement.

Stage 3 Surrogacy Fees from Gynaecologist/Canberra Fertility Centre

Table 4 details the expected costs from your gynaecologist/Canberra Fertility Centre.

Table 4 – Basic Frozen Embryo Transfer for Surrogacy Procedures

ITEM NO.	DESCRIPTION	FEE (\$)	EXPECTED REBATE (\$)	GAP EXPENSE(\$)
-1	FET procedure	1,550.00	Nil	1,550.00
-	Planning & Management	450.00	Nil	450.00
TOTAL		2,000.00	Nil	2,000.00

1 Included in these amounts is provision for progesterone pessaries or Crinone to 12 days post ovulation (Day +12).

Stage 3 Surrogacy Pre-Payment

A pre-payment of \$2,000.00 must be paid in full before commencing Stage 3 treatment. Please pay this amount to the Canberra Fertility Centre before your surrogate is due to commence the embryo transfer cycle. An ideal time is at the paper signing appointment. The balance of the account is rendered at the completion of treatment and is due within 30 days of that time. Please refer to the handout entitled Cancelled IVF/FET Surrogacy Procedures for details when the treatment is cancelled.

Stage 3 Cancelled FET for Surrogacy Cycle Fees

A FET treatment cycle is considered “cancelled” if an embryo transfer does not take place. The cost of a cancelled FET for Surrogacy cycle will vary depending upon how many blood and ultrasound tests have been performed, and if any medications have been used. An account will be issued for the cost

of any blood and ultrasound tests performed at the Canberra Fertility Centre and will include the fee for planning and management of a cancelled FET for Surrogacy cycle (see Table 5 below). This amount will be deducted from any pre-payment that has been made. Please pay any outstanding balance to the Canberra Fertility Centre to finalise the account. A positive account balance may be used for future treatments or a refund requested (proof of identity required). Tests performed elsewhere will need to be settled with the relevant providers.

Table 5 – Cancelled FET for Surrogacy Procedures

ITEM NO.	DESCRIPTION	FEE (\$)
-	Planning & Management (Cancelled FET for Surrogacy Cycle)	200.00
TOTAL		200.00

Payment of Accounts

You will receive an account from the Canberra Fertility Centre that includes the services provided by your gynaecologist during your treatment. The pre-payment amount will have been deducted, and the balance owing will be shown. This account is due within 30 days.

Canberra Fertility Centre (Accounts)

PO Box 228

CURTIN ACT 2605

Telephone: 02 6282 5458

Facsimile: 02 6281 2087

Other expenses

Refer to Table 6 for details of costs.

a) Lucrin/Synarel/Progesterone Pessaries/Crinone

These drugs are often required for IVF treatments. Lucrin, Synarel, Progesterone Pessaries and Crinone are included for the periods indicated in the fee tables. Cetrotide and Orgalutran must be paid for at the time of collection of the medication. See Table 6 for prices.

b) Puregon/Gonal F/hCG/Pregnyl

These drugs will be required for the IVF procedure. You may be eligible to obtain these drugs by prescription. Please discuss this with your gynaecologist. The expected cost if not available by prescription is in the range \$600.00 to \$3000.00. Note the price indicated in Table 6 may vary if the drugs are obtained interstate or from a pharmacy.

c) Embryo Freezing

If The cost of embryo freezing is \$500.00 and has been included in the cycle prepayment. This fee includes the cost of freezing and ongoing storage for the period outlined in the "Cryopreservation and Storage of

Embryos" consent form. This fee is refunded if there are no embryos available for freezing.

d) ICSI (Intracytoplasmic Sperm Injection)

If ICSI technique is to be used the fee associated is \$250.00. This fee forms part of the prepayment for the procedure. This fee is refunded if the technique is not used.

e) Assisted Hatching

If you have elected to use Assisted Hatching the cost is included in the cycle prepayment.

f) Blastocyst Culture

If you have elected to use Blastocyst Culture the cost is included in the cycle prepayment.

g) Semen freezing

If your partner is going to be unavailable during the treatment then the cost of freezing and storage of a sperm sample is \$500.00. This includes all ongoing storage for the period outlined in the "Cryopreservation and Storage of Semen" consent form.

Table 6 – Extra Costs

ITEM DESCRIPTION	COST (\$)	WHEN PAID
Cetrotide 3mg ampoule	545.00	At time of collection of medication
Cetrotide 250µg ampoule	79.00	At time of collection of medication
Orgalutran 250µg dose	77.00	At time of collection of medication
Progesterone Pessary 200mg	4.00	At time of collection of medication
Crinone 8%	12.50	At time of collection of medication
Puregon Cartridge 300IU	198.00	At time of collection of medication
Puregon Cartridge 600IU	396.00	At time of collection of medication
Gonal F Pen 300IU	165.00	At time of collection of medication
Gonal F Pen 450IU	247.50	At time of collection of medication
Gonal F Pen 900IU	495.00	At time of collection of medication
hCG 5000 IU injection	44.00	At time of collection of medication
Embryo Freezing	500.00	Paid at commencement of cycle as part of prepayment
ICSI (Intracytoplasmic Sperm Injection)	250.00	Paid at commencement of cycle as part of prepayment
Semen freezing	500.00	At time of collection of sample

Testing performed outside Canberra Fertility Centre

In some instances blood tests and/or ultrasound scans need to be performed by outside providers. This will most likely be the case if you live outside the ACT/surrounding NSW. Outside service providers often charge higher prices than those charged by the Canberra Fertility Centre. For surrogacy procedures a prepayment is made to the Canberra Fertility Centre. The Canberra Fertility Centre will pay a proportion of the fee incurred for tests performed at another centre and you are responsible for any balance. The proportion paid by the Canberra Fertility Centre is the equivalent cost a patient would have incurred by having such tests performed at the Canberra Fertility Centre. The contribution made by the Canberra Fertility Centre is shown in Table 7.

Table 7 – Contribution by Canberra Fertility Centre to the cost of Outside provider services for Surrogacy Procedures.

Medicare ITEM NO.	DESCRIPTION	CANBERRA FERTILITY CENTRE CONTRIBUTION (\$)
55733	Follicle Watch Ultrasound	29.95
66695	Blood test of one hormone level	26.10
66698	Blood test of two hormone levels	37.25
66701	Blood test of three hormone levels	48.65
66704	Blood test of four hormone levels	60.05
66707	Blood test of five hormone levels	71.45
73529	Blood test for Pregnancy hormone	24.80
73907	PEI – Patient episode initiation	14.80

Appendix C

Guidelines for Independent Gynaecological Assessment

It is a requirement of the John James Memorial Hospital Ethics Committee that an independent gynaecological assessment be performed. This assessment is very specific and must include the following points:-

Commissioning (Genetic) Mother

1. The genetic mother's obstetric, gynaecological and medical history.
2. Confirmation of the reasons as to why surrogacy is required.
3. An opinion of the ability of the genetic mother to care for the child/ren.
4. Counselling of the genetic parents in regard to the associated risks for the surrogate, including the possibility of any as yet unknown short and long term risks, the risks of pregnancy, the risks of multiple pregnancy, complications of pregnancy, the risks of operative delivery of an IVF pregnancy, death, permanent disability and loss of child bearing ability.

Surrogate (Gestational Carrier)

1. The surrogate's obstetric, gynaecological and medical history.
2. Counselling of the surrogate including the possibility of any as yet unknown short and long term risks, the risks of pregnancy, the risks of multiple pregnancy, complications of pregnancy, the risks of operative delivery of an IVF pregnancy, death, permanent disability and loss of child bearing ability.

Medical Issues

There is a need for a clear plan beforehand with doctors interstate as to precisely how much they can do or are prepared to do either with stimulation, tracking or the management of a subsequent pregnancy. This will alleviate the anxiety that surrogates may experience in wondering who does what, when and where.

If surrogates are from interstate and intending to be confined in the ACT, the surrogate should have a couple of antenatal visits with Dr Stafford-Bell prior to coming for induction or labour. This is to establish a working relationship between surrogate and delivering doctor.

The management of IVF pregnancies from Canberra, including regular blood tests, progesterone support, repeat ultrasounds and so forth, must be made known to surrogates from the outset. It is common for the surrogate to experience isolation and “management by remote control”. Outlining the necessity of managing pregnancies and how to combat a feeling of isolation should be attended to by the clinician and by the Canberra Fertility Centre staff at initial interviews.

Appendix D

Guidelines for Independent Clinical Psychologist Initial Assessment

It is a requirement of the John James Memorial Hospital Ethics Committee that both an assessment by our counsellor and an independent psychological assessment be performed. The ethics committee requires assessment and a report addressing these specific items:-

1. Assessment of both couples separately to include psychological and marital stability.
2. Implications for each marital relationship.
3. Implications for relationships between the couples.
4. Implication for the existing children.
5. Possibilities of complications which may effect both couples, specifically medical and obstetric problems which may include death for both women.
6. Change of heart by any of the parties before or during the process.
7. Refusal of the surrogate to relinquish the child.
8. Refusal of the genetic parents to adopt a disabled child.
9. The motivation and attitudes of the surrogate.
10. The attitudes of the genetic parents to a disabled child.
11. The attitudes of both couples towards investigation for foetal abnormality and termination of any abnormal pregnancy.
12. The genetic parents' intentions regarding directing custody of the child should the genetic parents die.
13. Appropriate counselling and psychological assessment of any existing children of the genetic parents and the surrogate over the age of 4 years.

Counselling Requirements for Surrogacy Cases

Initial Assessment

The commissioning (genetic) couple, the gestational carrier (surrogate) and her partner (if applicable), plus any dependent children over the age of four, of either couple, must attend counselling assessment sessions with an independent counsellor, who will write a report to be submitted to the hospital ethics committee. This counsellor must be a registered Psychologist, and psychological testing must be done.

At the time of consultation with the clinician in Canberra, an appointment will also have been made to attend the initial counselling assessment sessions with the Canberra Fertility Centre. The children do not need to attend these sessions if they have been seen by the independent counsellor. A written report will be submitted to the ethics committee.

Ongoing Counselling Requirements

The requirements for ongoing contact with the surrogate and her partner include assessments of the surrogate's preparation for the ongoing pregnancy and birth. Hence, follow up interviews need to occur at 28 and 36 weeks of the pregnancy; a debriefing session with all parties soon after delivery and a follow up of all parties about a month post-partum.

These additional requirements have been introduced to attend to issues having arisen from successful surrogacy cases; for instance, potential grief reactions and ready access to adequate support networks. One surrogate felt the need for a "closing ceremony" post surrogacy. Of course, such a symbol would need to "fit" the client, but these sorts of issues have been identified as useful to discuss during the process of surrogacy.

Interstate surrogates must have a contract with the independent counsellor in their home state. Hence, such a contract should be discussed at the initial interview, outlining the requirements for further sessions throughout and after the surrogacy procedure. A brief report should then be addressed to Dr. Stafford-Bell stating that the interview has taken place, and outlining any concerns.

A contract must be made with one of the two counsellors for the following:

A counselling session at 20 weeks gestation for the gestational carrier (surrogate).

A counselling session at 30 weeks gestation for the gestational carrier (surrogate).

These appointments may be with the independent counsellor in her home state, or with the clinic counsellor if she resides in the A.C.T. The counsellor will write a report outlining issues discussed.

Post Surrogacy Counselling Requirements

There are counselling appointments post surrogacy at about 6-8 weeks post delivery:

1. With the gestational carrier (surrogate), by herself
2. With the gestational carrier's partner, by himself
3. With both the male and female together
4. With the commissioning couple.

Again, a contract to this effect must be made with one of the two counsellors seen.

The counsellor will write a report outlining issues discussed, how the birth went, who attended, outcomes for the commissioning couple, any ongoing problems or issues for the surrogate and her partner, and any other pertinent issues.

Of course, at any time during the process of surrogacy, any or all of the parties are welcome to seek counselling.

Issues for Counsellors

It is necessary to clarify the difference between assessment and counselling. Obviously, when a counsellor is writing a report for the ethics committee for their consideration in approving a surrogacy case, the role of the counsellor is not one of counselling but assessing. This role may well change throughout the relationship with the client(s), and become one of the counsellor, supporter, clarifier, maybe even mediator. It is useful to clarify these roles during the first session with the parties.

Confidentiality thus becomes another issue for counsellors. It is useful to clarify during the initial interview when and with whom confidentiality can or cannot be maintained. For instance, during the assessment phase, because the counsellor is reporting to an ethics committee, the patients need to understand that anything relevant to such an assessment must be recorded. Again this may change as the role of the counsellor shifts from assessor to counsellor, but the patients need to be made aware of this.

Appendix E

Guidelines for Legal Report Requirements

It is a requirement that couples seeking surrogacy obtain legal advice.

A report covering the following issues must be submitted as part of the surrogacy application.

1. The legal implications of the surrogacy arrangement.
2. The consequences of refusal of the surrogate to surrender the child.
3. The refusal of the genetic parents to adopt a disabled child.
4. The adequate provision for the surrogate's dependants in the event of hospitalisation, illness or death related to the pregnancy.
5. The adequate provision of guardianship of embryos or any existing children should either or both of the genetic parents die.
6. Currently there is no law that can force the surrogate to give up the child and it is expected that the surrogate will give up the child for adoption with the commissioning couple applying to adopt the child after a period of 6-12 months. It is important that all the issues regarding the adoption process, its time frame and the costs involved as they pertain to the state in which the birth will occur are thoroughly covered. The report must clearly show that this issue has been discussed and a plan of action needs to be prepared.