

Minutes of the Forty First Meeting of the Ethics Committee on Assisted Reproductive Technology

7 March 2013

Held on 7 March 2013
Medsafe, Deloitte House, 10 Brandon Street, Wellington

In Attendance

Kate Davenport	Chair
Huia Tomlins-Jahnke	
Freddie Graham	
Adriana Gunder	
Brian Fergus	
Deborah Payne	
Deborah Rowe	
Carolyn Mason	
Kirsten Forrest	Secretariat
Rohan Murphy	Secretariat
Sarah Delgado	Secretariat
Nic Aagaard	Secretariat
Mike Legge	ACART member
Stella Li	ACART Secretariat

Apologies

There were no apologies for this meeting.

1. Welcome

Carolyn Mason opened the meeting and talked about the importance of looking after ourselves in order to be able to truly critically reflect on applications. Carolyn highlighted the roles that adequate sleep and nutritious eating play in keeping people well and gave an example from a study that looked at decisions made by parole board members on parole applications before and after they had eaten lunch.

The Chair acknowledged that Huia Tomlins-Jahnke's second term will finish on 1 April 2013 and expressed thanks for her wise counsel and her ability to make clear, considerations about Maori in the context of assisted reproductive procedures. The Chair also acknowledged that Adriana Gunder's first term will finish on 1 April 2013 and expressed thanks to her for her service.

Mr Rohan Murphy expressed thanks to both members for their service on behalf of the ECART secretariat.

2. Declarations of interest

There were no declarations of interest made regarding applications for review at the meeting.

Carolyn Mason declared that she has been elected to the University of Canterbury Ethics Committee.

3. Action points from previous meeting

The minutes from ECART's 29 November 2012 meeting were confirmed as an accurate record of the meeting.

4. Application E13/01 Clinic-Assisted Surrogacy

Freddie opened the discussion for this application. The committee considered this information in relation to the *Guidelines on Surrogacy Arrangements involving Providers of Fertility Services* and the principles of the HART Act 2004.

Issues discussed included:

- The intending mother's medical history and why the need for a surrogacy arrangement arose.
- The prognosis for the intending mother's previous medical condition and the risk of death. While the risk appears low, it is an important consideration for the committee.
- The important medical considerations for the birth mother for pregnancy. She has had uneventful past pregnancies.
- The level of risk that the result of treatment for a previous medical condition may hold for the health and well-being of a foetus if pregnancy is achieved. The risk is considered low and will be further reduced by a single-embryo transfer.
- The risk to the birth mother of the pregnancy exacerbating a previous medical condition.
- The outlook for a successful pregnancy appears good given the intending mother's age at the time the embryos were created.
- There are four embryos and the birth mother is willing to undergo two cycles at this stage.

Decision

- the committee has made its decision taking into account the guideline in 2(a)(ii) that *"the intending mother has a medical condition that prevents pregnancy or makes pregnancy potentially damaging to her and/or any resulting child"*.
- the committee was satisfied that IM has a medical condition affecting her ability to carry a pregnancy.
- each party has received appropriate counselling, medical and legal advice.
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.

The committee agreed to **approve** this application.

Actions

Secretariat to draft a letter from the Chair to the clinic informing the medical director of the committee's decision to approve this application.

5. Application E13/02 for Embryo Donation for Reproductive Purposes

Kate opened the discussion for this application. The committee considered this information in relation to the *Guidelines on Embryo Donation for Reproductive Purposes* and the principles of the HART Act 2004.

Issues discussed included:

- The recipient woman's medical condition and its history. The committee questioned whether the condition would have any impact on a child born of this arrangement and agreed that the genetic risk was low. It may be likely only if the child was conceived naturally.
- There are risks to the birth mother in carrying a pregnancy given her medical condition. However, the committee was satisfied that the medical risks have been explained and understood by the BM and that an appropriate medical plan is in place to mitigate the risks.
- Whether the level of on-going contact expressed by the donor woman was appropriate for both parties. The committee was satisfied that there appears to be consent and shared understanding from both parties to on-going contact.

Decision

- the committee has made their decision taking into account the requirements in guideline 2(a)(i) that *"the recipient or recipient's partner must have a medical condition, affecting his or her reproductive ability, or a medical diagnosis of unexplained fertility, that makes embryo donation appropriate"*
- the committee was satisfied that RW has a medical diagnosis of unexplained infertility that makes embryo donation appropriate
- each party has received appropriate counselling and medical advice
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.
-

The committee agreed to **approve** this application.

Actions

Secretariat to draft a letter from the Chair to the clinic informing the medical director of the committee's decision to approve this application.

6. Application E13/03 for Clinic-Assisted Surrogacy

Adriana opened the discussion for this application. The committee considered this information in relation to the *Guidelines on Surrogacy Arrangements involving Providers of Fertility Services* and the principles of the HART Act 2004.

Issues discussed included:

- Whether the intended arrangement is prohibited by law and permissible under ACART guidelines. The committee sought legal advice, which was that there doesn't appear to be any reason in law to prevent ECART considering this application in the usual way.
- The health and well-being of children is paramount under the HART Act and this application raises the moral issue of knowingly having a child with a genetic condition.

- A discrepancy exists between the medical and counselling accounts about how the process of testing for a genetic condition will take place.
- Whether the parties had enough time to think about the issues involved in this arrangement given the timing of the counselling sessions.

Decision

- the committee has made its decision taking into account the guideline in 2(a)(ii) that *“the intending mother has a medical condition that prevents pregnancy or makes pregnancy potentially damaging to her and/or any resulting child”*.
- the committee was satisfied that IM has a medical condition affecting her ability to carry a pregnancy.
- each party has received appropriate counselling, medical and legal advice.
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.

The committee agreed to **approve** this application on the condition that only unaffected embryos are placed in the birth mother’s uterus. If no unaffected embryos become available, then a further application must be made to ECART.

Actions

Secretariat to draft a letter from the Chair to the clinic informing the medical director of the committee’s decision to approve this application.

7. Application E13/04 for Clinic-Assisted Surrogacy

Deborah Payne opened the discussion for this application. The committee considered this information in relation to the *Guidelines on Surrogacy Arrangements involving Providers of Fertility Services* and the principles of the HART Act 2004.

Issues discussed included:

- The age of the birth mother’s children and that there has been no indication of whether support will be needed for the birth mother.
- The increased risk to the birth mother and her foetus given her previous medical condition. However, planned pre-emptive care is in place to mitigate the risks.
- The likelihood, given the significant number of embryos stored, that pressure may be placed on the birth mother to have a double-embryo transfer. A double-embryo transfer could be detrimental to the birth mother and the babies.
- The committee noted with interest, the long-standing friendship of the birth partner and intending partner and the role that they are considered to play in supporting this arrangement.
- The thorough legal advice and the timeframe for an adoption process to take place.

Decision

- the committee has made its decision taking into account the guideline in 2(a)(ii) that *“the intending mother has a medical condition that prevents pregnancy or makes pregnancy potentially damaging to her and/or any resulting child”*.
- the committee was satisfied that IM has a medical condition affecting her ability to carry a pregnancy.

- each party has received appropriate counselling, medical and legal advice.
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.

The committee agreed to **approve** this application.

Actions

Secretariat to draft a letter from the Chair to the clinic informing the medical director of the committee's decision to approve this application.

8. Application E13/05 for Clinic-Assisted Surrogacy

Brian opened the discussion for this application. The committee considered this information in relation to the *Guidelines on Surrogacy Arrangements involving Providers of Fertility Services* and the principles of the HART Act 2004.

Issues discussed included:

- There are medical risks to the birth mother given her birthing history. However, the committee was satisfied that the medical risks have been well-explained and understood by the BM and that an appropriate medical plan is in place to mitigate the risks.
- Whether there is adequate support in place for the birth mother while she is pregnant. The committee was satisfied that she
- It is not clear how long the intending parents have been together but some sense of time can be gleaned from their treatment history.
- The intending partner's age is not stated in the application and whether it would be useful to know his age as a factor to weigh up in the committee's decision making process.

Decision

- the committee has made its decision taking into account the guideline in 2(a)(ii) that *"the intending mother has a medical condition that prevents pregnancy or makes pregnancy potentially damaging to her and/or any resulting child"*.
- the committee was satisfied that IM has a medical condition affecting her ability to carry a pregnancy.
- each party has received appropriate counselling, medical and legal advice.
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.

The committee agreed to **approve** this application.

Actions

Secretariat to draft a letter from the Chair to the clinic informing the medical director of the committee's decision to approve this application.

9. Application E13/06: Application for Embryo Donation for Reproductive Purposes

Huia opened the discussion for this application. The committee considered this information in relation to the *Guidelines on Embryo Donation for Reproductive Purposes* and the principles of the HART Act 2004.

Issues discussed included:

- A child born of this arrangement will be genetically related to both parties because the recipient woman is a blood relation of one of the donor parents. As such, he or she would be recognised in the wider family context. While the couples live some distance from each other, the recipient woman is strongly anchored in her family history and would make sure any child born has access to this history.
- The relationship is long-standing and the parties appear to agree about the terms of the donation. The nature of their relationship makes this application straightforward.
- The chances of a successful procedure were discussed given the age of the donor woman when the embryos were created.

Decision

- the committee has made their decision taking into account the requirements in guideline 2(a)(i) that *“the recipient or recipient’s partner must have a medical condition, affecting his or her reproductive ability, or a medical diagnosis of unexplained fertility, that makes embryo donation appropriate”*
- the committee was satisfied that RP has a medical diagnosis of unexplained infertility that makes embryo donation appropriate
- each party has received appropriate counselling and medical advice
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.

The committee agreed to **approve** this application with the recommendation that a single embryo transfer is carried out.

Actions

Secretariat to draft a letter from the Chair to the clinic informing the medical director of the committee’s decision.

10. Application E13/07 for Clinic-Assisted Surrogacy

Freddie opened the discussion for this application. The committee considered this information in relation to the *Guidelines on Surrogacy Arrangements involving Providers of Fertility Services* and the principles of the HART Act 2004.

Issues discussed included:

- There are no concerns of any risks to the birth mother. She has had straightforward previous pregnancies and the committee was satisfied that any potential risks to her and a baby at the time of delivery are low.
- This is the second surrogacy arrangement that the intending parents are entering into. A letter from the previous birth mother did not make clear why she will not act as a surrogate in this arrangement, but she did report a positive experience.
- The intending parents have a positive relationship with the previous birth mother.

Decision

- the committee has made its decision taking into account the guideline in 2(a)(ii) that *“the intending mother has a medical condition that prevents pregnancy or makes pregnancy potentially damaging to her and/or any resulting child”*.
- the committee was satisfied that IM has a medical condition affecting her ability to carry a pregnancy.
- each party has received appropriate counselling, medical and legal advice.
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.

The committee agreed to **approve** this application.

Actions

Secretariat to draft a letter from the Chair to the clinic informing the medical director of the committee’s decision to approve this application.

11. Application E13/08: Application for Embryo Donation for Reproductive Purposes

Huia opened the discussion for this application. The committee considered this information in relation to the *Guidelines on Embryo Donation for Reproductive Purposes* and the principles of the HART Act 2004.

Issues discussed included:

- The donor couple have children born through IVF treatment and the embryos being donated are existing embryos created from their gametes as part of their own treatment.
- Potential identity issues may arise for a child born of this arrangement as he or she would be raised by parents who are in a mixed-race relationship. The issues surrounding this appear to have been well thought through, however.
- There is a need for information-sharing and protecting the future/identity of children born into such relationships.
- Both couples understand the importance of a child growing up knowing who he or she is and have plans to put this into practice.
- The chances of success were discussed given the donor woman’s age when the embryos were created.

Decision

- the committee has made their decision taking into account the requirements in guideline 2(a)(i) that *“the recipient or recipient’s partner must have a medical condition, affecting his or her reproductive ability, or a medical diagnosis of unexplained fertility, that makes embryo donation appropriate”*
- each party has received appropriate counselling and medical advice
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.

The committee agreed to **approve** this application.

Actions

Secretariat to draft a letter from the Chair to the clinic informing the medical director of the committee's decision.

12. Application E13/09 for Clinic-Assisted Surrogacy

Carolyn opened the discussion for this application. The committee considered this information in relation to the *Guidelines on Surrogacy Arrangements involving Providers of Fertility Services* and the principles of the HART Act 2004.

Issues discussed included:

- The birth mother has had uncomplicated pregnancies in the past but she may need some care later in any further pregnancy she carries. Any risk to her will be mitigated in the event of a pregnancy and a single embryo transfer is planned.
- Concern that IVF cycles for the intending mother may trigger symptoms of her past experience. Opinion was given that while this may be the case for a pregnancy, it may not be the case for IVF.
- The committee wasn't clear on whether the intending mother's past experience was hormone-related or related to having a child and questioned whether the act of simply having a child would trigger the same feelings in her.

Decision

- the committee has made its decision taking into account the guideline in 2(a)(ii) that "*the intending mother has a medical condition that prevents pregnancy or makes pregnancy potentially damaging to her and/or any resulting child*".
- each party has received appropriate counselling, medical and legal advice.
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.

The committee agreed to **defer** this application and requests receipt of a psychiatric report for IM that:

- looks objectively at the risks to her health and that of a foetus given that she will undertake a cycle of IVF treatment while she is on medication, and
- addresses coping strategies for being able to bond with any baby she will be given if the procedure is successful.

Actions

Secretariat to draft a letter from the Chair to the clinic informing the medical director of the committee's decision to defer this application.

13. Application E13/10 for Clinic-Assisted Surrogacy

Deb Rowe opened the discussion for this application. The committee considered this information in relation to the *Guidelines on Surrogacy Arrangements involving Providers of Fertility Services* and the principles of the HART Act 2004.

Issues discussed included:

- Adoption issues have been well-discussed and understood.

- IM had her eggs frozen on the basis that she would have treatment for a medical condition that would mean she could not produce eggs.
- The committee understands that an approval decision given for this application would be for the use of IM's own eggs in the first instance and if unsuccessful, approval for ED to donate eggs.
- The medication that BM is currently taking and whether this procedure would impact on her health or the health of the child.
- Medical history for both IM and BM and that there is no update on their current health status.

Decision

- the committee has made its decision taking into account the guideline in 2(a)(ii) that *"the intending mother has a medical condition that prevents pregnancy or makes pregnancy potentially damaging to her and/or any resulting child"*.
- each party has received appropriate counselling, medical and legal advice.
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.

The committee agreed to **approve** this application subject to receiving reassurance that both IM's and BM's current health status is good.

Actions

Secretariat to draft a letter from the Chair to the clinic informing the medical director of the committee's decision to approve this application.

14. Request for extension of approval for application E09/27 for Within Family Gamete Donation

The committee considered this information in relation to the *Guidelines on Donation of Gametes between Certain Family Members* and the principles of the HART Act 2004.

Issues discussed included:

- The previous procedure was successful and RW has a child who was born through this arrangement
- All parties consent to the procedure and there have been no significant changes in circumstances.
- The recipient woman's BMI may put her at risk of carrying a pregnancy. She has stated that she would lose weight before trying for a further pregnancy.

Decision

- the committee has made their decision taking into account the requirements in guideline 2(a)(i) that *"the recipient or recipient's partner must have a medical condition affecting his or her reproductive ability, or a medical diagnosis of unexplained fertility, that makes egg or sperm donation appropriate"*.
- the committee was satisfied that RW has a medical condition affecting her reproductive ability.
- each party has received appropriate counselling and medical advice.

The committee agreed to **defer** this application and assigned a sub-committee to review the original file before making a decision.

Actions

Secretariat to request the file for the original application for review by sub-committee. Deborah Payne and Carolyn Mason.

15. Request for extension of approval for application E10/09 for Clinic-Assisted Surrogacy

The committee considered this information in relation to the *Guidelines on Surrogacy Arrangements involving Providers of Fertility Services* and the principles of the HART Act 2004.

Issues discussed included:

- The intended parents had a break from treatment after their first attempt was unsuccessful and the birth parents had a child during this time.
- The reasons for a period of depression the birth mother had have been identified and worked through.
- ECART would need to consider whether the birth mother's plan to stop taking her medication before commencing with the procedure would impact on her health in a significant way. The committee would support her involvement as long as she is mentally well and would like to see evidence that the decision to stop taking her medication would not be detrimental to her health.
- In the original application, approval was given as the committee was satisfied that the IM has a medical condition that prevents her from carrying a pregnancy. It appears that the birth mother has in the past donated her eggs to IM and they were replaced into the IM.
- It is not clear from the documentation provided whether the birth mother intends to use her own eggs for the surrogacy arrangement.
- Given the above, ECART would like to seek further clarification on the details of the arrangement and has requested the file for the original application before a decision will be made.

Decision

- the committee has made its decision taking into account the guideline in 2(a)(ii) that "*the intending mother has a medical condition that prevents pregnancy or makes pregnancy potentially damaging to her and/or any resulting child*".
- each party has received appropriate counselling, medical and legal advice.
- the committee was satisfied that there is no coercion apparent within this application and that all parties are entering the agreement fully informed of the potential risks and of their own free will.

The committee agreed to **defer** this application and has requested review of the original file before making a decision.

Actions

Secretariat to request the file for the original application for review by the committee.

16. Correspondence

The committee **noted** the correspondence to and from ECART since the meeting of 29 November 2012:

- a query from a member of the public about whether ECART sets a maximum age for a woman to act as a surrogate mother. In response, ECART advised that ACART's surrogacy guidelines do not set a maximum age for a surrogate. However, ECART must take into account and weigh up a number of factors, including the health and well-being of women involved in procedures.
- a letter from a Fertility Associates clinic counsellor requesting advice from ECART about how to proceed with an intended application for within family gamete donation for a couple who reside in Noumea. In response, ECART advised that as it considers and determines applications for New Zealand based fertility clinics to carry out assisted reproductive procedures, the committee is happy to accept and consider an application in this case from Fertility Associates.
- a letter from a Fertility Associates clinic asking whether a proposed counselling process for counselling and gaining legal advice for a couple who live offshore would be acceptable to ECART. In response, ECART advised that it would accept an application with reports had via video conferencing.
- a letter from a Fertility Associates clinic advising that a surrogacy arrangement previously approved by ECART is no longer proceeding.
- an annual report from a researcher for a previously approved study.
- a query from a fertility clinic asking what ECART would require for a surrogacy application for which treatment will be given in New Zealand, a child born in New Zealand and then to enter and offshore country to live with the intended parents. In response, the secretariat advised that ECART might wish to see information about the intended adoption process and some notification from a relevant authority that the parents have been assessed as suitable adoptive parents. In addition, ECART might want some evidence that the child will be able to enter and remain in the offshore country with the intending parents.
- correspondence from ACART and from fertility clinics that addressed the proposed draft application forms for extending the storage period for gametes and embryos. ECART expressed appreciation for the feedback and asked that the secretariat acknowledge this in letters to ACART and the fertility clinics.
- The committee **noted** the decision letters from the ECART 29 November meeting.

17. ACART minutes

The unconfirmed minutes from the forty-first ACART meeting held on 23 November 2012 were **noted**.

18. General business

The committee discussed the proposed form for applications to extend the storage period of gametes and embryos. Four main concerns were raised about:

1. ECART's position of not wanting identifying information about participants on the application form.
2. Who can make an application to ECART.
3. The difficulties that clinics will experience when attempting to contact gamete donors.
4. The issue of consent and why it is needed for storage of gametes and embryos.

1. The committee discussed the likelihood that many applications will be made and that this will prove logistically challenging. The importance of having identifying details to minimise the potential risk for mistakes to be made was stressed. Emphasis was placed on the need to have identifying details on the application form so that clinics could readily and accurately link an application back to the gamete and or embryo donor. The point was made that an application to extend the storage of embryos and gametes is distinct from an application for an assisted reproductive treatment from clinics and as such identifying details could be provided on the application form without risk of ECART linking them back to a specific application.

2. The ACART guidelines state that an application to extend the storage period of gametes and embryos may be made by any person, clinic or others interested in an extension. The committee was concerned that this could give rise to difficulties, especially if anonymity continues to apply. Therefore it was suggested that only those who have provided gametes be able to apply through fertility clinics.

3. Fertility clinics gain consent from the donor for the use of gametes at the time of donation. In the case of gamete donation, the donor loses the right to have a say once the gamete is used. It was noted that the guidelines for embryo donation is at variance to this as consent is up to the time the embryo is replaced in a recipient woman's uterus. The clinics tend not to go back to a donor for further consent and trying to contact donors who have contributed to embryos could be problematic. The committee discussed what would constitute 'reasonable effort' to gain consent and the point was made that the clinics could find the practicalities of some of the examples given problematic. For example, there may be multiple names given in the white pages and that could potentially mean compromising patient confidentiality when phoning to seek confirmation of donor identity.

4. The question of why consent was being sought for storage was raised. The committee noted that consent may be sought because of a change in the basis for which consent was originally sought.

The committee noted that the storage extension period is not defined and a decision would need to be made about this aspect taking into account such issues as intergenerational problems associated with the length of storage.

17. Conclusion of meeting

The committee confirmed the next ECART meeting date of 30 May 2013 to be held at Deloitte House, Wellington. Deb Rowe will open the meeting.

The committee confirmed the next ACART meeting date of Friday 17 May. Attendance by either Deborah Payne or Carolyn Mason is to be confirmed.

Actions

Secretariat to write to ACART and the Fertility clinics and thank them for the correspondence dated 5 October 2012.

Secretariat to arrange a working group meeting to discuss and finalise the proposed storage extension application forms.

The meeting closed at 3.00pm.