**ADVISORY COMMITTEE ON ASSISTED REPRODUCTIVE TECHNOLOGY (ACART)**

**BRIEFING TO THE INCOMING MINISTER OF HEALTH**

**INTRODUCTION**

1. The purpose of this Briefing is to introduce the Advisory Committee on Assisted Reproductive Technology, known as ACART. ACART is an independent committee, set up under the Human Assisted Reproductive Technology Act 2004 (the HART Act). The Minister of Health appoints ACART members.
2. ACART is part of the regulatory framework for assisted reproduction services and human reproductive research in New Zealand. The Committee prepares and issues guidelines that set out the criteria for ethical approval of certain procedures – eg, embryo donation and the use of surrogacy – and for human reproductive research. ACART also provides advice to the Minister of Health. Its work programme is agreed with the Minister of Health.
3. This cover paper describes ACART’s membership and how the Committee works. We note actions that are required and reports that you will receive from ACART in the next six months. We also note current issues.
4. Six associated papers are attached to the Briefing:
5. Biographies of members
6. ACART’s Terms of Reference
7. A background to assisted reproductive technology (ART) in New Zealand
8. New Zealand’s ART regulatory framework
9. ACART’s work programme
10. Human reproductive research.

**MEMBERSHIP**

1. ACART currently has eight members, the minimum number required by legislation. The current members, their area of specialisation, and length of appointment are as follows:

* Alison Douglass – appointed in May 2011 for three years, Acting Chair since 1 July 2014. Legal expertise, current term has ended (note members with terms ended remain as members until a new appointment is made).
* John Angus – appointed as member in November 2010, Chair from October 2011, resigned as Chair on 30 June 2014 for health reasons but remains on the Committee. Children’s interests as a representative of the Children’s Commissioner, current term ends December 2016.
* Karen Buckingham – appointed in November 2010. Expertise in assisted reproduction, current term ends December 2016.
* Jonathan Darby – appointed in April 2013. Disability perspective, current term ends April 2016.
* Nikki Horne – appointed in November 2010. Consumer perspective, current term ends December 2015.
* Michael Legge – appointed October 2011. Human reproductive research and ethics expertise, current term ends October 2015.
* Sue McKenzie – appointed in April 2013. General layperson, current term ends in April 2016.
* Barry Smith - appointed in April 2013. Expertise in Māori customary values and perspectives, current term ends April 2016.

1. Further information about members is attached (Associated paper 1).
2. As noted in paragraph 5, the current number of ACART members is the minimum required by the HART Act, although past membership has been up to the maximum of 12 members. We ask that you consider increasing the number of members for the following reasons:

* Maintaining and expanding expertise: While the HART Act sets down statutory member roles, other expertise is also a valuable contribution to ACART’s work, in particular relevant social science expertise and public policy expertise. It would also be useful to have additional ethics expertise: one member at present carries both the role of expertise in human reproductive research and ethics expertise. Another member with the ability to articulate issues from a Māori perspective would complement the significant contribution of the member who already has that role.
* Maintaining ACART’s work programme and staggering turnover of members: With a small membership, there is a significant impact when two or more new members are appointed to ACART at the same time. Regardless of new members’ prior experience, they need time and support to come up to speed with the context of ACART’s work and the complexity of the regulatory framework.

**ACART’S ROLES AND RESPONSIBILITIES**

1. ACART’s functions are set out in the HART Act (s.35). These include:

* issuing guidelines and providing advice to the Ethics Committee on Assisted Reproductive Technology (ECART) on assisted reproductive procedures requiring case by case ethical approval (eg, embryo donation, surrogacy), human reproductive research, and extending the storage period of gametes and embryos. ECART is a specialist Health and Disability Ethics Committee.
* keeping such guidelines and advice under review
* providing independent advice to the Minister on matters concerned with human reproductive research and human assisted reproduction. The scope of such advice includes:
* specific matters set out in sections 37 and 38 of the HART Act (eg, informed consent, import and export of gametes and embryos, gametes derived from deceased persons)
* whether a procedure should require ethical review on a case by case basis (“assisted reproductive procedure”)
* whether a procedure should be declared an “established procedure” and thus not require ethical review
* whether the HART Act or other legislation should be amended to prohibit or provide for a procedure or human reproductive research
* whether a moratorium should be imposed on any kind of assisted reproductive procedure or human reproductive research
* whether regulations should be made to regulate the performance of any kind of assisted reproductive procedure or human reproductive research.
* monitoring the application and outcomes of assisted reproduction, and monitoring developments in human reproductive research.

1. ACART must undertake public consultation before issuing guidelines to ECART and before giving significant advice to ECART and the Minister of Health.
2. ACART does not have any functions associated with public funding of fertility treatment or auditing fertility services.

**HOW ACART WORKS**

**Terms of Reference**

1. ACART operates under Terms of Reference. These include ACART’s formal functions under the HART Act, the operation of meetings, and expectations of members. A copy of the Terms of Reference is attached (Associated paper 2).

**ACART’s work programme**

1. An associated paper discusses ACART’s work programme (Associated paper 5). The paper describes completed projects since 2011, current projects, and projects ACART wishes to undertake.
2. ACART meets as a full committee six times a year. Small working groups meet between the full meetings to progress key work items, reporting to ACART which makes final decisions.

**How ACART works with the Minister of Health**

***Agreement to a work programme***

1. The Terms of Reference require that ACART agree its work programme with the Minister of Health. ACART seeks the Minister of Health’s agreement to all significant projects, including where public consultation is likely to be required. ACART briefs the Minister and may request that the Minister meet with the Chair to discuss the work programme.

***Public consultations***

1. ACART provides the Minister of Health with a copy of public consultation documents, for information, in advance of publication and beginning public consultation.

***Issuing guidelines***

1. ACART is required to consult with the Minister of Health before issuing guidelines. The Minister of Health does not have the role of approving guidelines. To date ACART has not issued any guidelines before completing consultation with the Minister of Health.
2. ACART must advise the Minister of Health when guidelines are issued.

***Advice to the Minister***

1. The HART Act sets down matters where ACART is required to advise the Minister of Health, within timeframes agreed with the Minister of Health (s.37 and s.38).
2. ACART also briefs the Minister of Health:

* on any other matters where the Minister requests advice or information
* on any matters which ACART considers may be of interest to the Minister or where the Minister’s agreement is needed.

***Regular reports***

1. Under s.42 of the HART Act, ACART is required to give the Minister a report after each 12 month period ending on the 30 June on its progress in carrying out its functions; and on the number and kinds of decisions given by ECART in that period.
2. ACART also provides a copy of the annual reports *Assisted Reproductive Technology in New Zealand,* commissioned from the University of New South Wales, and drawing on data reported by New Zealand fertility services providers.

**ACART’s relationship with the Ministry of Health**

1. The Ministry of Health provides policy analysis and administrative support to ACART through Secretariat staff members who sit in the Policy Business Unit within the Ministry. The Ministry has responsibility for the budget that supports ACART.
2. ACART has an open relationship with the Ministry of Health. It gives the Ministry copies of all correspondence and reports to the Minister on a “no surprises” basis, and so that the Ministry is able to provide parallel advice to the Minister if requested.
3. ACART must advise the Director-General of Health when issuing guidelines.
4. The Ministry provides ACART with legal advice when requested, including on interpretations of the HART Act, and also provides communications support. The Ministry assists with any requests under the Official Information Act for ACART information.

**ACART’s relationship with ECART**

1. The HART Act requires ACART to liaise with ECART on general and specific matters relating to assisted reproductive procedures and human reproductive research. The Chairs of each committee or another member attends the meetings of the other committee in the role of member-in-attendance. The Chairs meet together as needed to discuss matters of mutual interest.
2. ACART issues guidelines to ECART, and ECART uses ACART’s guidelines to consider, determine and monitor applications made by fertility clinics for certain assisted reproductive procedures, extending storage of gametes and embryos, and human reproductive research. ECART must report to ACART about approvals, giving ACART a copy of the application and approval.
3. If ECART receives an application for an activity which is not covered in guidelines issued or advice given to it by ACART, ECART must decline the application and refer the application to ACART. The HART Act does not prescribe any specific action that ACART must take in such a situation. In practice, ACART considers whether there are grounds to review the guidelines.

**ACART’s relationships with the fertility sector and other stakeholders**

1. An associated paper (Background to assisted reproductive technology in New Zealand, Associated paper 3) discusses stakeholders that provide feedback to ACART’s public consultations.
2. ACART must advise fertility services providers when it issues guidelines.
3. Outside formal public consultations and contacts, ACART’s ongoing relationships include fertility services providers. Providers are consistently helpful in providing information needed for ACART’s policy development. An example is recent interviews with staff at three Auckland providers as part of a project to assist ACART to understand the informed consent processes used by providers.
4. Providers have also given ACART members tours of their facilities as part of orientations. Training days for new members include presentations by fertility counsellors and members of Fertility New Zealand (national consumer group).
5. ACART has developed relationships with New Zealand researchers who are working in areas relevant to ACART’s policy development. For example, Professor Ken Daniels at Canterbury University (a former member of ACART) is an international expert on families formed by donor insemination. Sonja Goedeke at the Auckland University of Technology has recently completed doctoral work on embryo donation. Professor John McMillan and other staff members at Otago University have interests that include bioethics and law related to ART.

**ACART’s website**

1. ACART has a website maintained by the Ministry of Health [www.acart.health.govt.nz](http://www.acart.health.govt.nz). Items published on the website include agendas and minutes of meetings; guidelines; public consultation documents and submissions; Annual Reports; and other publications. ACART also has a public email address.

**CURRENT REQUIRED ACTIONS FROM YOU**

1. The table below and on the following pages sets out actions required in the next six months. The actions are in three categories:

* Decisions about membership
* Decisions in respect of ACART’s work programme
* Statutory functions.

**Decisions about membership**

| **Action** | **Timing** | **Comment** |
| --- | --- | --- |
| Appointment of new Chair | Over the next 3 – 4 months | Chair is appointed by you from existing or new members. |
| Appointment of member with legal expertise | Processes associated with member appointments are managed by the Ministry of Health.  Member whose term has expired is able to be reappointed. |
| Appointment of additional members | As discussed above in paragraph 7. |

**Decisions in respect of ACART’s work programme**

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| --- | --- | --- |
| **Action** | **Timing** | **Comment** |
| Acting Chair of ACART to meet with the Minister to discuss and agree ACART’s work programme for 2015 | Over the next 3 – 4 months | Note two priority items for decision: work to review “biological link” policy and work to revise the human reproductive research guidelines.  Also two other projects for future decision: advice or guidelines on cryopreserved ovarian and/or testicular tissue; guidelines or advice on posthumous use of gametes and embryos.  See Attached papers 5 and 6. |
| Respond to advice on import and export of gametes and embryos for human reproductive research and human assisted reproductive procedures | ACART will provide you with its advice before the end of 2014.  ACART will publish the advice on its website in March 2015, to give you time to consider the advice. | The advice is in final preparation. It will include advice on initiatives to increase the supply of gametes for donation within New Zealand.  See Attached paper 5. |
| Consider draft consultation document on informed consent in relation to human assisted reproductive technology | ACART will send you a copy of the discussion document for public consultation, for your information before consultation begins in first half of 2015. | ACART will provide you with the finalised advice on informed consent requirements in the second half of 2015.  See Attached paper 5. |

**Statutory functions**

|  |  |  |
| --- | --- | --- |
| **Action** | **Timing** | **Comment** |
| Consider and table ACART’s Annual Report 2013/14 | ACART will provide you with the Report within the next 2 months. | The Secretariat will contact your Office to arrange tabling, after you have considered the Report. |

(continued on next page)

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| --- | --- | --- |
| **Action** | **Timing** | **Comment** |
| Table *Guidelines on Surrogacy involving Assisted Reproductive Procedures, Guidelines on Donation of Eggs or Sperm between Certain Family Members,* and *Guidelines on Preimplantation Genetic Diagnosis with Human Leucocyte Antigen Tissue Typing.* | Over the next 3 months. | The HART Act requires guidelines to be tabled. The Secretariat will contact your Office to arrange.  See Attached paper 5. |
| Respond to proposals to amend ACART’s Terms of Reference | In early 2015 ACART will send you proposed amendments for your decision. | The proposed changes will reflect a 2010 amendment to the HART Act. |

**CURRENT ISSUES**

**Extending storage of gametes and embryos**

1. Last year ACART issued *Guidelines on Extending the Storage Period of Gametes and Embryos.* The HART Act prohibits storing gametes and embryos for longer than 10 years unless ECART approves an extension. Gametes and embryos must be discarded otherwise.
2. The 10 year period is counted from 22 November 2004 for gametes and embryos stored before or on that date, and from the date of original storage for gametes and embryos stored after that date. ECART has begun receiving and deciding applications for samples of gametes and embryos where storage is due to expire in November 2014 or soon after. The HART Act requires that applications to extend storage must be received by ECART before the lawful storage period expires, and ECART must give any approval while gametes and embryos are lawfully stored.
3. Fertility services providers have been making significant efforts to contact people affected by the deadline, to ascertain their wishes in regard to the future of the gametes and embryos in which they have an interest. The provider most concerned is Fertility Associates because it has a substantial quantity of sperm stored before 22 November 2004 as well as after that date, and it has been unable to make contact with about 300 of the people affected.
4. A particular concern for Fertility Associates is where sperm has been stored for young men before cancer treatment which was likely to affect their fertility, and where the provider has been unable to make contact. For these men, the stored sperm is likely to be their last chance to have a genetically related child.
5. ACART wrote to the Ministry of Health asking that it complement providers’ efforts to contact people whose gametes and embryos are approaching the end of the 10 year storage period. The Ministry of Health has advised that it is making a grant to Fertility Associates to assist in publicity, conditional on publicity being on behalf of all providers.

**The use of cryopreserved ovarian and testicular tissue**

1. ACART has been keeping a watching brief on the use of cryopreserved ovarian and testicular tissue internationally. Currently the use of cryopreserved ovarian tissue requires ECART approval using ACART guidelines. However, ACART has not issued guidelines to date, and this means that women with stored tissue are unable to use it in New Zealand. After receiving a technical report in 2010 on the use of cryopreserved ovarian tissue, members concluded there was insufficient evidence at that time about the safety of the procedure.
2. ACART has commissioned an updated technical report, to include the use of cryopreserved testicular tissue from an international expert. The report is due to be received in December 2014. More details about the project are included in the attachment about ACART’s work programme (Associated paper 5). We will report to you early next year about the findings of the review and our views about whether there should be further work to enable the use of cryopreserved ovarian and/or testicular tissue.

**Limitation on human reproductive research under current guidelines**

1. ECART must consider and decide applications to undertake human reproductive research using gametes and embryos. The current guidelines provide for ECART to approve research using gametes and non-viable embryos. These guidelines were issued in 2004 by a former committee, the National Ethics Committee on Assisted Human Reproduction.
2. An attached paper to this Briefing discusses human reproductive research (Attached paper 6) and discusses limitations of the current research guidelines.
   1. The guidelines, and the HART Act, fail to define non-viable embryos or to define embryo viability.
   2. Not allowing the use of viable embryos has effects that appear to be unintended.

* ECART declined a recent research application where researchers proposed to investigate if embryos transferred after day three or five (both currently used in IVF cycles) yielded a higher chance of pregnancy success. This study would use the women’s own embryos and would not alter the embryos.
* The Ministry of Health has been recently contacted by researchers who wanted to compare different media for culturing embryos, by culturing embryos for three to five days before transferring the embryos to patients. This research cannot be conducted in New Zealand, because the research would be using viable embryos.

*[Note: The paragraph above has been edited to maintain legal privilege.]*

1. Consumers affected by the 10 year storage period in some cases would like to donate their stored embryos for research in the hope that others can benefit.
2. In the attached paper about ACART’s work programme (Attached paper 5) we have requested that you meet with the Acting Chair to discuss including a review of the research guidelines in ACART’s work programme.

**Developments in genetic testing techniques**

***Preimplantation genetic diagnosis (PGD)***

1. Preimplantation genetic diagnosis (PGD) is able to be used in New Zealand to select embryos that do not have a specific inheritable condition or chromosomal abnormalities. This use of PGD does not require ethical approval. In 2011 PGD was performed in 40 cycles, representing 0.9 percent of all cycles in which embryos were created or thawed.[[1]](#footnote-1)
2. An increasing number of serious inheritable conditions will become testable, including late onset conditions (conditions that are established in adulthood eg, breast cancer associated with the BRCA genes). We anticipate that demand for uses of PGD that do not require ethical approval will increase in the future.

***Preimplantation genetic screening (PGS)***

1. The development of new technologies or refinement of current technologies has provided increasingly sophisticated diagnostic tools for the use in preimplantation embryos. PGS is a relatively recent development whereby cells can be removed from the embryo and analysed for overall chromosome numbers and related abnormalities. Linked with the use of PGS is the development of Whole Genome Screening (WGS), although this technique is still in its development stage. These techniques are part of ongoing research in preimplantation embryo development.

*[Note: The final section of five paragraphs in this paper has been removed to maintain legal privilege.]*

1. The most recent figure available, from *Assisted Reproductive Technology in New Zealand 2011* (ACART, 2014). [↑](#footnote-ref-1)