Minutes of the Eighty-eighth Meeting of the Advisory Committee on Assisted Reproductive Technology

Held on 10 December 2020, at the Rydges Airport Conference Centre, Wellington.

Present

Kathleen Logan (Chair)
Colin Gavaghan (Deputy Chair)
Calum Barrett
Rosemary de Luca
Seth Fraser
Karen Reader
Catherine Ryan
Karaitiana Taiuru
Analosa Veukiso-Ulugia
Sarah Wakeman

Non-members present

Michele Stanton, ECART Member (1.00pm – 3.00pm)
Hayley Robertson, ACART Secretariat
Tristan Katz, ACART Secretariat
Lucy Campbell, ACART Secretariat

1. Welcome

1.1 The Acting Chair opened the meeting at 9.00am and welcomed the new Committee members appointed to ACART on 6 August 2020.

1.2 On this occasion, the ECART member in attendance was Michele Stanton who joined the meeting at 1.00pm following the morning sessions of working group

meetings.

1.3 This meeting was held in person with some members joining online via zoom. The Secretariat noted that the following meeting in February will be held via zoom.

1.4 Members briefly discussed the recent media interest in the BMI limit for fertility treatment and the issues related to equity of access that this causes, particularly for Māori and Pacifica families.

Actions:

- *Sarah to circulate a published paper related to BMI to members.*
- *Secretariat to email members instructions about how to export meeting papers from diligent boards into a pdf.*
- *Members to ensure they have access to diligent boards for meeting papers.*

2. Apologies

2.1 Apologies were received from Martin Kennedy and Judge Andrew Becroft.

3. Approval of the agenda

3.1 Members approved the agenda and the Chair reiterated that the morning of the meeting will be spent working on ACART's two current projects, the consultation on guidelines for posthumous reproduction and the consultation for guidelines for extending the storage of gametes and embryos. The Committee then came together for the afternoon to discuss other matters on the agenda.

Action:

- *Secretariat to add the agenda to the ACART website.*

4. Declarations of Interests

4.1 No conflicts of interest were declared at this meeting.

5. Minutes of ACART's meeting of October 2020

5.1 The minutes were approved subject to amendments.

Action:

- *Secretariat to amend the minutes and add the minutes to the ACART website.*

6. Actions arising from ACART's October meeting

6.1 Members noted the status of the actions from the October meeting, including those actions that were carried over to this meeting.

6.2 The Secretariat noted that public consultation for the new standards for fertility services has begun and asked that members consider the draft response to the public consultation.

7. Work programme status

7.1 Members noted the status of items on the work programme.

8. Briefing to the Incoming Minister

8.1 This agenda item asked members to read and discuss the draft Briefing to the Incoming Minister and to direct the Secretariat to make any amendments.

8.2 Members were advised that with the new government formed and ministerial portfolios assigned, it is standard practice for new Ministers to be briefed on their portfolios and ACART is one party who will brief the Minister of Health.

8.3 Members were advised that, in the past, ACART has briefed new Ministers about ACART's role and current work. The briefing explains the following matters:

a. ACART's statutory position and functions

b. How ACART interacts with ECART, the Ministry of Health, and the fertility sector

c. ACART's current work programme

d. Any specific actions ACART would like the Minister to take in the near future

e. Membership.

8.4 Several appendices are also included to give more context that the Minister might find useful.

8.5 Members discussed the order of the drafted content and how to best advise the Minister of the work programme and the urgency of some matters. Members directed the secretariat to make minor amendments before the briefing is sent to the Minister.

Action:

- *Secretariat to make minor amendments to the BIM and organise for the briefing to be sent to the Minister of Health.*

WORKING GROUP MEETINGS: Two Projects

9. Guidelines for posthumous reproduction – working group

9.1 The secretariat advised members that at the October meeting, the public consultation had recently closed and the secretariat gave members a verbal overview of the main themes and policy positions from submitters at that meeting.

9.2 At this meeting, the secretariat presented members with a first draft of the submissions analysis for approval and a working group paper of policy proposals to consider or revise. The secretariat noted that both the raw submissions and ACART's summary of submissions will be published on ACART's website.

9.3 Members thanked the Secretariat for collating the submissions into a comprehensive summary and agreed that all main themes and voices were captured in the summary of submissions. Members then agreed to refine the policy proposals for the next iteration of the draft guidelines alongside the feedback received in the public consultation.

9.4 The Māori representative member abstained from supporting the findings on the consultation because he considered Māori were not appropriately consulted. He also asked the minutes note he does not endorse previously made policy positions or consultations that occurred without an adequate Māori consultation framework and (for the past almost two years) without Māori representation on the Committee.

Oral consent to posthumous use

9.5 It was noted that submitters expressed that retrieval of gametes or tissue after death could not meet the threshold of informed consent in almost all cases, but also thought that some sort of evidence of consent was vital. They suggested many forms that verbal or inferred consent could take, such as an affidavit confirming conversations had with family or a partner. It was thought by a few submitters that there should be a level of formality to that oral consent such as an affidavit and/or and independent witness to consent given, say, to a presiding doctor. Alternatively, some fertility providers did not agree that oral consent was acceptable and thought that consent should always be in writing for posthumous use of gametes or tissue. It was noted that freely given, informed consent to posthumous retrieval will be difficult to determine in emergency situations such as accidents.

9.6 The working group noted that some people with disabilities may not be able to provide written consent, and that oral consent is therefore acceptable for some people. The working group noted that the guidelines should give ECART the discretion to decide what kinds of consent are acceptable while also giving clear consent requirements. Members decided to draft guidance on what this could be, while ensuring the guidelines do not inadvertently exclude people whose situations don't fit the examples that are given.

9.7 Members discussed how prior and transparent discussion in relation to posthumous use will be key to ensuring that there is robust and informed consent to ensure people understand what they are agreeing to on the consent forms especially. It was agreed that consent forms will continue to be an important part of the process as evidence of consent to the posthumous use of stored gametes or embryos.

9.8 Members wished to reiterate that regardless of what form the consent takes, there needs to be evidence of consent to posthumous reproduction in keeping with the spirit of the HART Act and respecting the dignity of the deceased and of future generations.

9.9 It was suggested that the guidelines be amended to include a note about options for families to dispose of material. This was thought to be consistent with the cultural and spiritual considerations required by the HART Act.

Requirement for ECART approval for posthumous use

9.10 Most submitters and Fertility providers thought that ECART review should not be required for all posthumous uses of gametes or reproductive tissue, particularly that review is not necessary for cases where consent was given to the specific use of the gamete before the death of the gamete provider and there has been a clear and robust informed consent process.

9.11 It was also argued by some submitters that ethical review by ECART is an unfair and unjustifiable emotional and financial burden in cases where consent was given to the use of gametes stored while the individual was alive. A few fertility providers thought that there is nothing more to gain by requiring ethical review for those who have already undertaken a robust consent process at the time of consent and in cases where written consent has been provided before death.

9.12 Members agreed to rescind their proposed policy, and no longer require ECART

approval (unless an ARP such as surrogacy is needed) for the use of gametes or embryos retrieved and stored while the individual was alive, providing the consent is clear and specific, and agreed to propose a change to the HART Order to allow use in these cases to be an established procedure.

9.13 Members agreed that ECART approval should still be required for use in cases where gametes are retrieved posthumously and/or where consent to their retrieval and use is not clear.

9.14 Members then discussed how the HART Order must be clear about what cases are required to go to ECART. They discussed situations where a personal or clinic donor has subsequently died and whether the use of that person's gamete could still be in a potential child's best interests or if it would be best to use another donor who is still alive at the time of use.

9.15 Members agreed that ECART approval should still be required for posthumous use of gametes from a clinic donor on a case by case basis. This will allow ECART to consider whether having a living donor is more beneficial to the child's wellbeing. Conversely, cases where there is clear and robust evidence of informed consent to posthumous use has been given by a personal donor, this should not require ECART approval.

9.16 Members agreed that all cases of posthumous reproduction that require a surrogate should still require ECART approval due to the complex nature of surrogacy. These complexities include the surrogate as the legal mother of the child under law and that, where someone has consented to posthumous use, it is unlikely that they will know who the surrogate is.

Use of a minor's gametes after death

9.16 Members discussed diversity and acknowledged the diversity of views and values received during the consultation. It was reiterated that ensuring diverse consultation is crucial and that a small hui was convened in the stage one consultation in 2018.

9.17 Some cultural issues were raised, particularly the tension between individual versus collective rights in relation to continuation of an individual's genealogy. Members noted the strong theme from some submitters that they (as the whānau of a deceased child) should be allowed to authorise the use of that frozen material, even in situations where there was not consent to the specific use.

9.18 However, ACART has previously considered this is at odds with human rights of children, and societal expectations that parents are not normally involved in reproductive decisions of their children. It was ultimately agreed that gametes stored by minors for their own fertility preservation should not be able to be used by others, even family, in the event of their death. Members noted that this decision is consistent with the current legal requirements, principles and spirit of the HART Act.

Collective consent to a procedure

9.19 Members discussed the notion of collective decision making and the HART Act's emphasis that family and whānau can be involved in decisions about an individual's reproductive decisions but only when the individual invites them to be involved. Members also discussed the HDC requirement of informed consent from all people

undergoing procedures.

9.20 Members noted that ensuring family involvement in a culturally-relevant counselling process is a way to ensure family and whānau are supported to be part of decision-making, that also aligns with the HART Act.

Authorisation of posthumous retrieval of gametes or tissue

9.21 ACART proposed in the draft guidelines that the posthumous retrieval of gametes or reproductive tissue could be authorised by the High Court, or by ECART in very rare circumstances.

9.22 Members discussed the feedback from a few submitters that there is no legal mechanism in the HART Act for ECART to approve the posthumous retrieval of gametes, and that only the High Court may authorise the posthumous retrieval of gametes.

9.23 Members discussed the possibility of adding a note in the guidelines outlining that posthumous retrieval is legally complex area and that ACART believes that in very rare cases, ECART could make decisions about the posthumous retrieval of gametes or tissue. ACART see this inclusion in the guidelines as filling a gap in the law, but recognise that in almost all cases, it will be more practicable for the High Court to make decisions about posthumous retrieval. It was agreed that further discussion between legal experts was needed to agree on the final guidelines and the Chair asked the Secretariat to organise a meeting to discuss this issue.

The HART Act's 10-year storage period

9.24 Some submitters had critiqued the 10-year storage rule. The working group took this into account but agreed that ECART should not make decisions about disposal of material, and that the 10-year rule at least provides a route to disposal.

Actions:

- *Secretariat to organise a meeting to discuss authorisation and agree on a final position in the next meeting.*
- *Secretariat to progress amending the guidelines using tracked changes for consideration at the next meeting.*
- *Secretariat to email members the background paper of how different jurisdictions regulate posthumous reproduction for their revision.*
- *Secretariat to publish the summary of submissions with minor amendments.*
- *Secretariat to draft paper for ACART's rationale for decision-making for ACART's approval at the next full ACART meeting in February.*

10. Review the guidelines for extending the storage of gametes and embryos: confirm/approve the consultation document – working group

10.1 Members summarised the policy problem and ACART's position that once gametes have been used to create an embryo, the gamete-owners are no longer considered to have a significant interest in that embryo.

10.2 The working group discussed the four recommendations made by the Secretariat:

1. Confirm the removal of the provision that asks gamete donors to consent to extensions of storage of embryos after embryos have been formed from their gametes

2. Confirm that when the storage of gametes is to be extended, the gamete donors must consent

3. Confirm that the guidelines should state that when the storage of donated embryos is to be extended, the embryo donors must consent

4. Decide whether the guidelines should include notes about full genetic siblings and about donation and surrogacy scenarios.

10.3 The working group noted how the recommendations relate to and follow on from each other. It was noted that in creating the proposed guidelines, ACART would be creating a rule around whose interests should be considered when extending the storage of embryos; however, this rule would be in line with other rules that ACART has created for ECART.

10.4 It was noted that while ECART is required to follow ACART's guidelines, guidelines as a legal construct do not apply absolutely. It was confirmed that the HART Act mandates that ECART take into account advice and guidelines from ACART *as well as* the purposes and principles on which ACART makes its decisions. Consequently, in writing the guidelines for extending the storage of gametes and embryos ACART should provide ECART the latitude to apply them in situations which ACART may not have anticipated (by adding wording such as "in most cases", or "except in exceptional circumstances").

10.5 It was further noted that the Guidelines should more explicitly take into account the ethical principles of the HART Act, and other obligations, including under Te Tiriti o Waitangi.

10.6 The working group confirmed the first three proposals, and discussed proposal four. There was uncertainty as to whether on-donated embryos should be consented to by the original donors; the on-donors; or both, in addition to the current owners of the embryo. It was noted that requiring both the original donors and on-donors to consent to the extension of storage of embryos would be administratively burdensome, but would only occur in a few specific scenarios. It was noted that the Guidelines, in their current form, do not address re-donation and on-donation.

10.7 The working group discussed the ordering of paragraphs on the consultation document. They further noted the length of the document and the difficulty in understanding the information. It was suggested that diagrams could help to aid understanding.

10.8 It was decided not to include notes about full genetic siblings and about donation and surrogacy scenarios in the consultation document, as they do not constitute a policy position. It was also agreed to remove the corresponding consultation question.

10.9 The working group agreed to amend the consultation questions so as to specifically address the proposed changes, rather than seeking general opinions on the consent to extending the storage of embryos.

10.10 The Māori representative member asked for the committee to have a robust kaupapa Māori engagement framework before commencing any further public consultations. The Chair supported this stance.

Actions:

- *Secretariat to work with Calum to update the draft guidelines.*
- *Secretariat to update the draft consultation document.*
- *Consultation document to be reviewed at full ACART meeting in February.*

11. ACART's Consultation process

11.1 The HART Act (sections 28, 35, 41 and 76) requires ACART to consult the public and the Minister of Health when it develops advice on, or guidelines or regulations for, assisted reproduction. To date, ACART's consultations have elicited only limited responses. These responses have typically been from:

(a) interested public, who often have a personal connection to fertility treatment

(b) interest groups such as church groups and Fertility New Zealand (consumers)

(c) health and ethics professionals, such as the fertility clinics, the NZ Nurses Organisation, and the Bioethics Centre at Otago University.

11.2 ACART does not attempt to survey the opinions of the nation about its work. Rather, ACART's consultations are used to identify the matters that ACART should consider when developing advice, guidelines or regulations for fertility treatment and research.

11.3 ACART's current standard consultation process is to:

(a) publish a consultation document on its website, with links also from the Ministry of Health website

(b) present the document in both Word and PDF formats with the response form available as a separate document

(c) provide an online submission form (currently using "Citizenspace")

(d) meet any interested parties who request an oral submission (in person, online or by phone)

(e) invite service providers to bespoke meetings with ACART (in person, online or by phone)

(f) e-mail ACART's stakeholder list (people and groups who have already expressed an interest, or identified as likely to have an interest in ACART's work)

(g) publish a media statement / press release on the Ministry of Health website

(h) send a tweet on the Ministry of Health Twitter account

(i) advise the Minister of Health of the consultation.

11.4 The secretariat then collates the submissions, analyses the themes, and reports them back to ACART. ACART then considers the submissions and amends its guidelines or advice if it agrees with changes proposed by submissions (either in part or as a whole). The submissions are published on ACART's website and a summary of submissions is attached to any advice to the Minister.

11.5 Members also discussed fertility matters and how they affect the nature and development of society, and noted the publicity in the 1970's for assisted reproductive technologies.

11.6 Members discussed the need for more robust and relationship driven consultation to better inform policy development. Members agreed to pursue:

a) considering and implementing the Ministry's kaupapa Māori engagement framework
b) better ways to engage with the disability community
c) engagement and developing stronger relationships with the Ministry of Health Māori Treaty partners and internal policy experts, Māori health providers, and Te Arawhiti
d) a search on the charities register for more names for our consultation list.

Action:

- *Members to consider and suggest improvements to ACART's consultation list at the February meeting.*

12. Consultation on the use of Cyropreserved Testicular Tissue

12.1 Members were updated on the status of the consultation document on the use of cryopreserved testicular tissue. The secretariat advised members that they have finalised information from other countries about if and how they regulate the use of the material.

12.2 The secretariat advised that the consultation document has also been professionally edited and formatted through the Ministry of Health.

12.3 Members directed the Secretariat to make minor amendments and advise the Minister that ACART intends to consult. The Secretariat will also develop a communications plan for consultation and work with the Ministry's web team to publish the consultation.

12.4 Further to 10.10 above, a proper consultation process is to be agreed by all members at the next meeting before going out to consult on new advice to the Minister.

13. Review of the Standards

13.1 Members noted the draft response to the Fertility Services Standards consultation and agreed to submit on this consultation from the Ethics group on behalf of the ACART Secretariat.

13.2 Members wished to note two key parts to the revised standards that they felt was missing, including mention of the 10 family limit for gamete donation and incorporation of the Fertility Services Standard Audit Workbook.

14. ACART's 2019/20 Annual report

14.1 Members had approved the wording for the Annual Report in the October meeting, however in the meantime ACART has been considering wording to add regarding ACART's obligations under Te Tiriti o Waitangi.

14.2 Members noted that they are not able to publish the 2018/19 and the 2019/20 report until ECART data is available and agreed to contact the Manager in Ethics to enquire about resourcing this issue so ACART can fulfil their statutory obligations to monitor the decisions of ECART.

Actions:

- *Secretariat to make minor amendments to the Annual Report.*
- *Chair to enquire about the resource needed to collate ECART data.*

15. 2021 meeting dates

15.1 Members agreed meeting dates for the first half of 2021, including:

- 19 February
- 15 April
- 11 June.

15.2 Members proposed that some future meetings be used as working groups; and requested these should occur in person.

15.3 Members proposed that some online-only meetings should take place on Fridays to account for members' teaching commitments.

Action:

- *Secretariat to put placeholders for these meetings in members calendars.*

Standing items

16. Report on ECART's October meeting

16.1 Members noted the report and discussed an application concerning the use of frozen embryos after the tragic death of one intending parent.

17. Chair's report

17.1 The Chair's report was taken as read.

18. Secretariat report

18.1 The Secretariat report was taken as read.

19. Attendance at ECART meetings

19.1 Calum Barrett confirmed that he will attend the next ECART meeting on 11 February 2021.

19.2 Seth Fraser confirmed that he will attend the ECART meeting on 8 April 2021.

The meeting closed at 3:00pm.