**ACART’S WORK PROGRAMME – ASSOCIATED PAPER 5**

**ACART’S WORK PROGRAMME - OVERVIEW**

1. ACART’s current work programme was agreed by the previous Minister of Health in February 2014.
2. The cover paper in this Briefing sets out required actions in the next six months, and includes our request for you to meet with the Acting Chair to discuss and agree ACART’s work programme for 2015.
3. In this attached paper we first briefly discuss work items for which ACART will seek your agreement. We then include tables summarising recently completed projects, current projects, and the future projects for which we seek your agreement.
4. Finally, we discuss an issue on the horizon.

**Work items for which ACART wishes to seek your agreement**

1. There are two priority matters on which ACART will seek your agreement for inclusion in the work programme.

* Work on the guidelines that apply to human reproductive research
* Work on the evidence base for the “biological link” policy in current ACART guidelines.

1. There are two other matters where ACART is currently undertaking preliminary work and is likely to seek your agreement to further work.

* Work on the use of cryopreserved ovarian and testicular tissue
* Work on the collection, storage and use of gametes and embryos from deceased and comatose individuals.

***Work on extending and updating the guidelines that apply to human reproductive research***

1. The guidelines currently limit embryo research in New Zealand, by requiring that such research be restricted to “non-viable” embryos.
2. In another associated paper to this Briefing (Associated paper 6) we make the case for reviewing the research guidelines, including enabling ECART to consider and decide applications to undertake research using viable embryos. We also include more details in the table on page 10 of this paper.

***Work on the evidence base for the “biological link” policy in current ACART guidelines***

1. The “biological link” policy across ACART guidelines requires that there be a “biological link” between resulting children and at least one intending parent. The biological link can be either genetic parenthood or gestation. The policy predates the HART Act, was continued by ACART, and is not part of the HART Act.
2. The effects of the biological link policy include:

* ECART is not able to approve a surrogacy where neither intending parent would be a genetic parent of a resulting child
* ECART is not able to approve the use of donated eggs with donated sperm by an infertile single man or where both men in a male couple are infertile
* ECART is not able to approve embryo donation where an intending mother is not able to carry the pregnancy.

1. We include more details of the proposed project in the table on page 7 of this paper.

***Work on the use of cryopreserved ovarian and testicular tissue***

1. In New Zealand it is currently permissible to store cryopreserved ovarian tissue: it is an established procedure and hence does not require ECART approval. However, the use of such tissue is an assisted reproductive procedure and thus requires ECART approval. To date ACART has not issued guidelines.
2. ACART commissioned a technical report in 2010 on the use of cryopreserved ovarian tissue only (the use of testicular tissue was not included). As a result of that report, ACART decided that the evidence did not support undertaking further work at that stage. ACART has maintained a watching brief on international evidence about outcomes of the procedure.
3. ACART has commissioned a technical report from an international expert about current peer reviewed evidence on the use of cryopreserved ovarian and testicular tissue. The report is due by the end of the year. ACART will then consider whether the evidence supports undertaking further work to enable the use of cryopreserved ovarian and/or testicular tissue, and will report to you on the matter in early 2015, including seeking your agreement to any proposed further work.
4. We include more details in the table on page 12 of this paper.

***Work on the collection and use of gametes and embryos from deceased and comatose individuals***

1. Current guidelines enable ECART to consider applications for the storage, use and disposal of sperm from a deceased man. These guidelines were issued by the former National Ethics Committee on Assisted Human Reproduction in 2000. The guidelines thus predate the HART Act, and reflect the technologies of the time: techniques for successful cryopreservation of eggs were not yet established.
2. The HART Act includes provisions for ACART to give advice to the Minister of Health in two matters related to deceased persons:

* in relation to human reproductive research, the use of human gametes derived from foetuses or deceased persons (s.37(1)(d))
* in relation to human assisted reproductive technology, gametes derived from deceased persons (s. 38(c)).

1. ACART is currently gathering information about the regulatory framework which addresses the collection, storage and use of gametes and embryos from deceased and comatose individuals. At this stage, we expect to find some gaps.
2. We will then report to you about our conclusions and seek your agreement to proposed further work. We include more details from page 13 of this paper.

**GUIDELINES ISSUED SINCE 2011**

***Guidelines on Surrogacy involving Assisted Reproductive Procedures***

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| *Subject* | Surrogacy is facilitating the birth of a child through a surrogate mother gestating the pregnancy. The surrogate is legally the mother of the resulting child until legal parenthood passes to the intending parent through an adoption order. |
| *Mandate* | The HART Act requires ACART to issue guidelines to ECART on any matter relating to any kind of assisted reproductive procedure (s.35(1)(a)). Surrogacy in itself is not an assisted reproductive procedure, but cases must be approved by ECART where it involves the use of an assisted reproductive procedure. |
| *Background* | ACART originally issued surrogacy guidelines in 2007. Amended guidelines were issued in December 2013, following a review of the guidelines that arose from a complaint that the guidelines discriminated on the basis of sex and sexual orientation. |
| *Changes to previous guidelines* | Key changes in the amended guidelines are:   * The guidelines no longer require that there be an “intending mother”. ECART can decide applications where single men or male couples wish to become parents with the assistance of a surrogate. * The guidelines no longer require that there is a medical need for surrogacy, but include factors to be considered by ECART in determining whether a surrogacy is justified. * The guidelines explicitly apply only to surrogacy facilitated by a fertility services provider, and where the embryo gestated is created from the gametes of two intending parents or the gametes of one intending parent and the gametes of a third party. * Neither ACART nor ECART has a role in regard to surrogacies where the surrogate or her partner has contributed gametes. * Nor do ACART and ECART have a role in regard to informal surrogacy arrangements outside a fertility services provider. |
| *Date of issue* | ACART issued new guidelines on 12 December 2013. |
| *Comment* | ACART will amend the guidelines as necessary to reflect any changes following the proposed review of the “biological link” policy. |

***Guidelines on Donation of Eggs or Sperm between Certain Family Members***

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| *Subject* | The HART Order requires most intrafamily gamete donation to be approved by ECART. Donation between some relationships (brother, sister, cousin) do not require ECART approval. |
| *Mandate* | The HART Act requires ACART to issue guidelines to ECART on any matter relating to any kind of assisted reproductive procedure (s.35(1)(a)). |
| *Background* | ACART originally issued family gamete donation guidelines in 2007, and issued amended guidelines in December 2013. The eligibility criteria in the guidelines were reviewed at the same time as the surrogacy guidelines, to ensure that there was no discrimination where single men or male couples wished to use eggs donated by a family member. |
| *Changes to previous guidelines* | Key changes in the amended guidelines are:   * A fuller, plain language description of the family relationships covered by the guidelines. * The guidelines no longer require that there is a need for the donation on the basis of a medical condition. |
| *Date of issue* | ACART issued new guidelines on 12 December 2013. |
| *Comment* | ACART’s current review of the three donation guidelines [discussed on page 6] includes considering whether these guidelines should be incorporated into one set of guidelines to cover all gamete and embryo donation cases requiring ECART review. |

***Guidelines on Extending the Storage Period of Gametes and Embryos***

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| *Subject* | Gametes and embryos can be stored no longer than 10 years unless ECART approves extending the storage time. The guidelines set out the matters ECART must take account of when considering applications to extend storage. |
| *Mandate* | The HART Act was amended in 2010 to clarify some matters in regard to the 10 year storage limit. The amendment gave ACART a mandate to issue guidelines in regard to the matters that ECART should take into account in making decisions about extending storage applications (s.35(1)(aa)). The 2010 amendment also clarified that the 10 years should be counted from 22 November 2014 or later, depending on the time of first storage. |

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| *Background* | The guidelines are not prescriptive: instead, they set out the questions ECART must consider in accord with the statutory mandate. |
| *Changes to previous guidelines* | The guidelines are new. ECART is directed to consider the length of time gametes or embryos have already been stored, the purposes of the extension, informed consent, and the period of extension. |
| *Date of issue* | ACART issued new guidelines in September 2012. |
| *Comment* | The statutory storage periods begin to run out from 22 November 2014, 10 years after the commencement of the HART Act. Fertility clinics have been contacting people with stored material to ascertain what they want to do. See discussion in Current Issues section of the covering paper in this Briefing. |

***Guidelines on Preimplantation Genetic Diagnosis (PGD) with Human Leucocyte Antigen (HLA) tissue typing***

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| *Subject* | The HART Act allows the use of PGD in some circumstances. Most lawful uses of PGD do not require ECART approval eg, to select an embryo which does not carry the gene for a specific inheritable disorder. ECART must approve the use of PGD to select an embryo to be a tissue match for an existing ill child, with a view to a donation from the resulting child. |
| *Mandate* | The HART Act requires ACART to issue guidelines to ECART on any matter relating to any kind of assisted reproductive procedure (s.35(1)(a)). The HART Order requires ECART to approve the use of PGD when the use is other than the uses that are declared to be established procedures (Part 2 s.6). |
| *Background* | The new guidelines replace guidelines issued before implementation of the HART Act. |
| *Changes to previous guidelines* | The new guidelines have extended:   * the circumstances where ECART can approve PGD with HLA tissue typing, to include non-heritable conditions (eg, leukaemia) as well as heritable conditions. It did not appear reasonable to allow access to the procedure for a seriously ill sibling with a heritable condition, but not for non-heritable conditions. Sibling to sibling bone marrow transplants are current practice. * the type of tissue intended to be donated from the planned child: ie, allows the possible future donation of bone marrow from the planned child to the ill sibling, as well as donation cord blood. This provides for cases where bone marrow is the best option for treating the ill child. |
| *Date of issue* | ACART issued new guidelines in August 2014. |
| *Comment* | The new guidelines are in effect. The procedure is rarely used: ECART has had only one application, under the previous guidelines, since ECART’s establishment in 2005. The guidelines require ECART to consider that the procedure is justified, in view of various clinical factors and ethical considerations. |

**CURRENT WORK REVIEWING GUIDELINES**

***Review of donation guidelines, with proposed inclusion of review “biological link” policy***

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| *Subject* | There are currently three guidelines covering gamete and embryo donation procedures that require case by case approval by ECART: family gamete donation, embryo donation, and the use of donated eggs with donated sperm. |
| *Mandate* | The HART Act requires ACART to keep guidelines under review (s.35(1)(a)). ACART must address the risk of a complaint that a policy is discriminatory. |
| *Background* | There are common ethical issues across the three donation procedures. It may be simpler and clearer to have one set of guidelines covering the three circumstances.  ACART reviewed and amended the eligibility criteria in the surrogacy and family gamete donation guidelines in 2012-2013. As noted above, this review arose out of a complaint that the surrogacy guidelines discriminated on the basis of sex and sexual orientation  A review of eligibility criteria in two other guidelines is already on ACART’s work programme: the *Guidelines on Embryo Donation for Reproductive Purposes* (embryo donation guidelines) and the *Guidelines on the Creation and Use, for Reproductive Purposes, of an Embryo created from Donated Eggs in conjunction with Donated Sperm* (donated eggs/donated sperm guidelines). |

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| *Work to date* | ACART has begun to consider the feasibility of one set of guidelines to cover the three assisted reproductive procedures involving donation, extending the original scope of the project.  ACART wishes to include in the project a review of ACART’s “biological link” policy to determine if there is a justification for requiring that there be a genetic or gestational link between at least one intending parent and a resulting child.  While the current review of the donation guidelines can be undertaken separately from reviewing the “biological link” policy, our view is that the most efficient way forward is to package the projects together, since the biological link policy is an integral part of the current donation guidelines.  *“Biological link” policy*  ACART has given some preliminary consideration to ACART’s policy to date to require at least one biological link (genetic parenthood or gestation) between at least one intending parent (where intending parents are a couple) and a resulting child. This policy is set out in existing guidelines.  ACART wants to review the policy, to consider whether the absence of both gestational and genetic parenthood links between intending parents and a resulting child would risk the health and wellbeing of children. This review would be consistent with the HART Act requirement that ACART keep guidelines under review, and also address the risk of a complaint that the policy is discriminatory.  ACART’s preliminary view is that there are potentially two factors more significant for the wellbeing of children born from third party assistance than how an embryo is created or gestated:   * Preparation before fertility treatment, when an individual or couple is looking at the implications for themselves and the child of having a child through gamete or embryo donation or using surrogacy, and * Once a child is born, the way in which the family deals with the child’s identity. |
| *Next steps* | The inclusion of a review of the “biological link” policy requires agreement from the Minister. Any proposed amended guidelines would be subject to the statutory public consultation process before consultation with the Minister of Health and the issuing of new guidelines. |
| *Comment* | *[Note: This cell has been removed to maintain legal privilege.]* |

**CURRENT WORK ON ADVICE TO THE MINISTER OF HEALTH**

***Advice to the Minister of Health on import and export of gametes and embryos for human reproductive research and human assisted reproductive procedures***

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| *Subject* | ACART is required to give the Minister of Health advice on the policies and regulation of the import and export of *in vitro* human gametes and embryos for human reproductive research and human assisted reproductive technology. |
| *Mandate* | The HART Act requires ACART to advise the Minister of Health on the import and export of *in vitro* human gametes and embryos for human reproductive research and human assisted reproductive technology (s.37(1)(g) and s.38(f)). The advice may include recommendations about requirements, including whether regulations should be made. |
| *Background* | New Zealander is experiencing growth in transborder reproduction, mainly where New Zealanders use fertility treatments in other countries. The impact of transborder reproduction includes conflicts between standards and laws in different countries.  A common example of this conflict is when a woman has *in vitro* fertilisation overseas creating embryos from commercially sourced donated eggs, possibly from a donor who is not identifiable, and then wants to bring surplus embryos back in New Zealand. However, the embryos have been created in circumstances inconsistent with New Zealand law which prohibits buying and selling eggs, sperm and embryos, and requires donors to be identifiable to donor offspring.  Fertility services providers generally refuse to import and use such embryos, basing their decision on Ministry of Health advice which gives providers discretion to make decisions about importing and exporting gametes and embryos. The HART Act does not address specific requirements. |
| *Work to date* | For this project ACART had two rounds of public consultation. A preliminary public consultation in March 2013 captured views on various ethical and policy issues associated with the import and export of gametes and embryos. A second consultation in February 2014 captured feedback on ACART’s proposed advice. |
| *Next steps* | ACART’s forthcoming advice is about policy intent, not the mechanics of achieving the policy. The advice makes recommendations about requirements for importing and exporting gametes and embryos, including making regulations. The advice also makes recommendations about areas where there is potential to address factors contributing to New Zealanders travelling overseas for fertility treatment. |
| *Comment* | ACART anticipates providing the advice to the Minister late 2014. |

***Advice to the Minister of Health on informed consent in relation to human assisted reproductive technology***

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| *Subject* | One of the HART Act principles is that procedures and research should not happen unless the individuals concerned have given informed consent. In ART consent is complicated by the number of interested parties involved in procedures and outcomes, and the long periods of time covered by consent eg, consent to use donated gametes.  The current project focuses only on human assisted reproductive technology. ACART will address the human reproductive research context when it reviews the human reproductive research guidelines. |
| *Mandate* | The HART Act requires ACART to advise the Minister of Health on informed consent in relation to human reproductive research and human assisted reproductive technology (s.37(1)(f) and section 38(d)). ACART’s advice may include recommendations about requirements, including whether regulations should be made. |
| *Background* | There is a well-established body of law and practice on informed consent in the context of medical treatment procedures. This generally involves autonomous individuals making decisions about treatment carried out on them. In contrast, decisions about fertility treatment can be complex because of the impacts on and interests of other parties and children who may be born from procedures.  The complexities of informed consent in this area include consents involving different parties with different interests (eg, donors and recipients), consents unrelated to medical treatment (eg, consent to storage and disposal of gametes), varying and withdrawing consent, and parties providing consent for the future (eg, consent in advance for the use of gametes).  The HART Act does not address in detail many of the specific issues that arise in regard to informed consent issues. An impact of this lack of detail is that ACART has needed to consider informed consent requirements each time it has developed guidelines. The informed consent provisions in guidelines apply only to the specific guidelines. |

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| *Work to date* | To inform the development of proposals, ACART undertook an information gathering phase in the first half of 2014. This included meeting with Auckland fertility clinics in May 2014 to better understand the policies, rules and processes clinics have established to give effect to informed consent requirements.  ACART is currently developing proposals for public consultation in the first half of 2015. |
| *Next steps* | ACART will send you a copy of the discussion document for public consultation, for your information, before consultation begins. ACART will provide you with the finalised advice on informed consent requirements in the second half of 2015. |
| *Comment* | ACART is considering the best way to elicit consumer feedback about the proposals. While the basis of ACART public consultations involves publishing a discussion document that is sent to individuals and organisations on ACART’s mailing list, ACART also holds some targeted meetings as part of consultations. |

**FUTURE GUIDELINES AND ADVICE PROJECTS**

**Priority projects for which ACART is seeking agreement to include in its work programme**

***Review of the “biological link” policy***

1. This review is discussed earlier in the context of the review of the donation guidelines, on page 7 of this paper.

***Guidelines on human reproductive research***

1. Associated paper 6 in this Briefing discusses the issues below more fully.

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| *Subject* | The HART Act defines human reproductive research as research that uses or creates a human gamete, a human embryo or a hybrid embryo. The Ministry of Health advised in 2008 that this definition applies to research using gametes and embryos in any way, including in clinical trials of assisted reproductive procedures |
| *Mandate* | The HART Act requires ACART to issue guidelines to ECART on any matter relating to human reproductive research (s.35(1)(a)). |

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| *Background* | The current *Guidelines for Research on Gametes and Non-viable Embryos* were issued in 2005 by the former National Ethics Committee on Assisted Human Reproduction before implementation of the HART Act and establishment of ACART. These guidelines allow for research on gametes and non-viable embryos, but do not allow for research on viable embryos. |
| *Work to date* | ACART issued a discussion document in 2006 on proposed advice to the Minister of Health on aspects of human reproductive research.  ACART’s finalised advice to the Minister of Health in 2007 included recommending the development of new guidelines on research to allow research on “surplus” viable embryos ie, embryos left over from consumers’ IVF treatments, with informed consent by the consumers concerned. |
| *Comment* | There are problems with the guidelines that can create confusion during their application.   * The guidelines, and the HART Act, fail to define non-viable embryos or to define embryo viability. * The wording in the HART Act can be construed as covering viable embryos. For example, clause 15.4.2 states “any risks (particularly any long-term risks to persons born) should be minimal”. If embryos are non-viable then they cannot give rise to an individual.   Not allowing the use of viable embryos has effects that appear to be unintended. For example, ECART declined a recent research application where researchers proposed to investigate if embryos transferred after day 3 or 5 (both currently used in IVF cycles) yielded a higher chance of pregnancy success. This study would use women’s own embryos and would not alter the embryos. *[Note: This cell has been edited to maintain legal privilege.]* |
| *Next steps* | The HART Act requires ACART to agree its work programme with the Minister of Health. To date, the development of new guidelines has not been included in the work programme.  If ACART was to develop new guidelines, public consultation on proposed guidelines would be required. We anticipate that new guidelines would be produced within 12-18 months. |

**Other projects for which ACART will seek your agreement for any further work**

1. For both these projects, ACART is undertaking preliminary work to assess the scope of any future work for which your agreement is sought.

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

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| *Subject* | Fertility preservation is now routinely discussed with individuals before beginning cancer treatment or other treatment that is likely to impair future fertility. Sometimes the best option for fertility preservation is to obtain and store ovarian or testicular tissue eg, where it would be risky to use hormones to obtain eggs for storage, or because of the age of the individual. |
| *Mandate* | The HART Act requires ACART to provide the Minister with advice if a treatment should be declared an established procedure (s.6(1)), and to issue guidelines on any kind of assisted reproductive procedure (s.35(1)(a)).  The HART Act also requires ACART to monitor the application and health outcomes of assisted reproductive procedures and established procedures, and also developments in human reproductive research (s.35(2)). |
| *Background* | In New Zealand, it is currently permissible to store cryopreserved ovarian tissue (it is an established procedure and does not require ethical approval from ECART). However, it is not possible to *use* the material, because the procedure requires case by case ECART approval and ACART has not yet issued guidelines. The HART Order is silent on the status of the storage of testicular tissue and the current use of such tissue.  ACART commissioned a technical report in 2010 on the use of cryopreserved ovarian tissue only (the use of testicular tissue was not included). As a result of that report, ACART decided that the evidence did not support undertaking further work at that stage. However, ACART has maintained a watching brief on international evidence about outcomes of the procedure. |
|  | In April 2014, ACART agreed to update the previous report due to potential future demand in New Zealand for the use of cryopreserved ovarian and testicular tissue, and developments in this area since the original report was commissioned. The update will include:   * an updated review on the use of ovarian tissue, including any developments in this area * comment on the use of testicular tissue.   Work on the updated technical report has commenced. It is being prepared by Professor Claus Andersen at the University of Copenhagen and is due in December 2014. |
| *Next steps* | The updated technical report will give ACART the information needed to decide if there is merit in continuing work to either draft guidelines on the use of cryopreserved ovarian and/or testicular tissue, or to develop advice to the Minister of Health that the procedures should become established procedures. Either project would require ACART to issue a discussion document with proposals for public consultation  The technical report will be delivered to ACART in late 2014. We will report to you in the next three months about the report, including our views about any future work. |
| *Comment* | At present New Zealanders wishing to use stored tissue must go to Australia or another country if they wish to try to conceive a child using the tissue. |

***Work on the collection and use of gametes and embryos from deceased and comatose individuals***

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| *Subject* | There are situations where people may have an interest in collecting and/or using gametes and embryos from deceased and comatose individuals, including:   * using gametes stored before an individual’s death * using embryos where one gamete provider has died * collecting gametes from an individual shortly after death * collecting and/or using gametes from a comatose individual. |

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| *Mandate* | The HART Act requires ACART to keep guidelines under review (s.35(1)(a)).  The HART Act also requires ACART to provide the Minister of Health with information, advice and if it thinks fit, recommendations:   * in relation to human reproductive research, the use of human gametes derived from foetuses or deceased persons (s.37(1)(d)) * in relation to human assisted reproductive technology, gametes derived from deceased persons (s.38(c)). |
| *Background* | Current guidelines enable ECART to consider applications for the storage, use and disposal of sperm from a deceased man. These guidelines were issued by the former National Ethics Committee on Assisted Human Reproduction in 2000.  The guidelines thus predate the HART Act, and reflect the technologies of the time. For instance, techniques for successful cryopreservation of eggs were not yet established. No guidelines have been developed that address the use of stored eggs after an individual’s death.  The HART Order requires that ECART approve some cases related to dead individuals: the use of gametes of a person who has since died eg, use of eggs collected from a woman who is dead when the eggs are collected or dies before the procedure is carried out; and use of sperm collected from a man who has since died and did not give consent to the specific use of the sperm he died.  ACART will be considering in December 2014 a descriptive report of the regulatory framework, including the Code of Health and Disability Services Consumers’ Rights, as it applies to the collection and use of gametes and embryos from deceased and comatose persons. We anticipate that there are gaps in the regulatory framework that will justify further work. |
| *Next steps* | We will report to you in the first half of 2015 with our views about the adequacy of the regulatory framework in respect of the collection and use of gametes and embryos from deceased and comatose individuals.  Our report is likely to include proposed further work. Further work to develop guidelines and/or to develop significant advice to you would in both cases require that ACART issue a discussion document for public consultation. |
| *Comment* | As noted in the context of cryopreserved ovarian and testicular tissue, fertility preservation is now routinely addressed in cases where individuals, including children and young people, are having treatment that is likely to impair their future fertility.  This means that there are instances where people will die and others will have an interest in using the stored material. A core issue is the nature of informed consent given by the individual before his or her death.  ECART recently received an application to extend the storage period of sperm which was obtained from a minor, now deceased. *[Note: This cell has been edited to maintain the confidentiality of an application to ECART.]* |

**ISSUE ON THE HORIZON**

***Mitochondrial donation***

1. Mitochondrial donation is an IVF technique for mothers at risk of passing on incurable genetic diseases, such as muscular dystrophy, to their children. The intention is to allow women carrying mitochondrial disorders, the opportunity to have healthy, genetically-related children, born free of those disorders.
2. The technique involves replacing an egg’s faulty mitochondria with healthy mitochondria from a donor’s egg. The resulting embryo would carry genetic material from a man and a woman, and a mitochondrial donor. The technique has been met with some debate, as it involves three people having genetic links to a baby, and is often referred to as creating “three-parent embryos”. However, the amount of genetic material contributed by the donor is minute compared to that of the two parents.

*International recognition*

1. No country, including New Zealand, currently permits the use of mitochondrial donation. However, with increasing research supporting the development and progress of the technique, both the United Kingdom and the United States have taken steps towards allowing it.
2. In early 2014 the United Kingdom government commissioned the Human Fertilisation and Embryology Authority (ART regulatory body) to convene an expert panel of scientists to conduct a review into the safety and efficacy of mitochondrial replacement techniques. The panel reported that it had seen no evidence which suggested that mitochondrial replacement is unsafe and that good progress was being made on the science.
3. The United Kingdom government then announced in July 2014 its intentions to put before Parliament regulations relating to mitochondrial replacement. If regulations are made, the Human Fertilisation and Embryology Authority would then need to design and implement a process for licensing clinics to use mitochondrial replacement therapies.
4. In February 2014, the United States Food and Drug Administration also considered whether to allow human clinical trials of this technique. A decision remains pending.

*ACART’s view*

1. ACART recognises the increasing international interest in the use of mitochondrial donation and will continue to maintain a watching brief on the technique. It will be of particular interest to see what happens next in the United Kingdom and the United States.
2. ACART is not aware of any demand to date to use the procedure in New Zealand.