

**Advisory Committee on
Assisted Reproductive Technology**

Import and Export of
Gametes and Embryos:

Proposed advice
to the Minister of Health

**Consultation Document**

* Citation: Advisory Committee on Assisted Reproductive Technology. 2013. *Import and Export of Gametes and Embryos: Proposed advice to the Minister of Health.* Wellington: Advisory Committee on Assisted Reproductive Technology.
* Published in January 2014 by the Advisory Committee on Assisted Reproductive Technology, PO Box 5013, Wellington 6145, New Zealand
* ISBN 978-0-4787-41577-3 (print)
ISBN 978-0-4787-41578-0 (online)
HP 5779
* This document is available on the ACART website:
www.acart.health.govt.nz



# Foreword

The Advisory Committee on Assisted Reproductive Technology (ACART) was established under the Human Assisted Reproductive Technology Act 2004 (the HART Act). ACART’s functions include advising the Minister of Health on the import and export of *in vitro* human gametes and embryos (“import/export”).

In March 2013, we issued a background paper asking for views on various ethical and policy issues associated with import/export.[[1]](#footnote-1) We wanted to know whether stakeholders thought there should be flexibility or change in regard to any of the current requirements associated with import/export. We also sought the reasons for people’s views.

As noted in that paper, transborder reproduction by New Zealanders is part of an established and growing international phenomenon. However, jurisdictions vary in regard to requirements associated with the sourcing and use of gametes and embryos. A key group affected by this lack of harmonisation is New Zealanders who want to import and use here embryos created in circumstances that are not acceptable in New Zealand.

From March to early June 2013, we received 24 submissions. Members held 19 meetings with organisations and individuals in Auckland, Hamilton, Wellington, Christchurch and Dunedin. On behalf of ACART, I thank everyone who generously took time to share and explain their views, in writing or in person. While all the feedback was useful and appreciated, the opportunity for discussion at meetings was especially valuable. I am grateful to the consumers who shared personal stories that contributed to our understanding of the reasons why some New Zealanders look offshore for assistance in creating their families.

As required by the HART Act, we are now formally consulting on our proposed advice and look forward to hearing your views. After reviewing the feedback received, we will then finalise our advice to the Minister.

John Angus

**Chair, Advisory Committee on Assisted Reproductive Technology**

#

# How to have your say

Please take this opportunity to have your say. A feedback form is included in this document.

You may give feedback on your own behalf or as a member of an organisation. You can contribute your views in either of these ways:

email a completed feedback form or your comments to acart@moh.govt.nz, or

post a completed feedback form or your comments to:

Secretariat

Advisory Committee on Assisted Reproductive Technology

PO Box 5013

Wellington.

We will place all feedback on ACART’s website as it is received, and therefore prefer that feedback is submitted electronically if possible. However, we will accept and consider all feedback regardless of how we receive it.

Where you give feedback on your own behalf, we will remove your contact details before placing the feedback on ACART’s website. Alternatively, you may request that all or part of your feedback is withheld from publication for reasons of confidentiality.

**The closing date for feedback is 21 March 2014.**

After receiving and considering feedback, we will finalise our advice to the Minister of Health on the import and export of human *in vitro* gametes and embryos. We anticipate forwarding our finalised advice to the Minister during the first half of 2014.

You can obtain additional copies of this paper and feedback form from the ACART website ([www.acart.health.govt.nz](http://www.acart.health.govt.nz)). If you require a hard copy, please contact the ACART Secretariat (email acart@moh.govt.nz or telephone 04 816 3931 or 04 816 2782).

Contents

Foreword iii

How to have your say iv

Executive summary vii

Import and export requirements vii

Related matters viii

1 Background 1

1.1 Context 1

1.2 Why is ACART developing advice to the Minister of Health on the import and export of gametes and embryos? 2

1.3 What are the current requirements for import and export of human gametes and embryos? 2

1.4 What is the scope of ACART’s import/export work? 4

2 ACART’S consultation March–June 2013 6

2.1 Our consultation process 6

2.2 What we heard 6

3 ACART’S proposed advice 8

3.1 Summary 8

3.2 The principles and requirements of the HART Act should apply in all cases where people wish to import into and use in New Zealand gametes and embryos sourced or created in other countries 9

3.3 Export of gametes and embryos should be possible, provided that the subsequent use of the gametes and embryos will be consistent with the principles and requirements of the HART Act, including any prohibitions, and all gamete providers, including donors, have given informed consent to the export of their gametes or of embryos created from their gametes 11

3.4 Fertility services providers should continue to make decisions about whether the import and export of gametes and embryos for assisted reproductive procedures is consistent with the principles of the HART Act and New Zealand requirements 12

3.5 The role of ECART in respect of human reproductive research should explicitly include considering and deciding applications to undertake research involving imported and exported gametes and embryos 14

3.6 Regulations should be made about the requirements for the import and export of gametes and embryos 15

3.7 The Ministry of Health should be asked to consider guidance to fertility services providers that allows for increased levels of donor compensation, particularly for egg donors (for consistency, the expenses available for surrogates should also be considered) 16

3.8 The Ministry of Health should be asked to consider public health information about the impact of age and other factors on fertility, and about gamete donation 19

3.9 The Ministry of Health should be asked to consider strategies for collecting data about the use and outcomes of offshore fertility treatment by New Zealanders 21

4 Prohibitions in the HART Act 24

5 Import and export requirements in some comparable jurisdictions 25

5.1 United Kingdom 25

5.2 Australia 26

5.3 Canada 27

Glossary 28

Appendix 1: Members of ACART 29

Feedback form 31

Questions about the proposals discussed in the paper 32

Question 1: Import and subsequent use of gametes and embryos 32

Question 2: Export of gametes and embryos 32

Question 3: Decisions about import and export for assisted reproductive procedures 33

Question 4: Decisions about import and export for human reproductive research 34

Question 5: Regulations 35

Question 6: Donor compensation 36

Question 7: Public health information 37

Question 8: Data about offshore fertility treatment and outcomes 38

Question 9: Comments or suggestions 38

# Executive summary

ACART is required to advise the Minister of Health about the import and export of human *in vitro* gametes and embryos for assisted reproductive procedures and human reproductive research.

During March–June 2013, ACART undertook preliminary public consultation focused on eliciting views on various ethical and policy issues associated with the import and export of gametes and embryos. The submissions received and meeting notes are on ACART’s website, except where submitters asked that all or part of submissions be withheld.

ACART is now inviting feedback on its proposed advice to the Minister of Health. The proposals, below, are a package that supports New Zealand standards while addressing some of the drivers pushing people to look overseas for fertility treatment.

## Import and export requirements

The principles and requirements of the Human Assisted Reproductive Technology Act (HART Act) should apply in all cases where people wish to import into and use in New Zealand gametes and embryos sourced or created in other countries.

Export of gametes or embryos should be possible, provided that:

the subsequent use of the gametes or embryos will be consistent with the principles and requirements of the HART Act including any prohibitions, and

all gamete providers, including donors, have given informed consent to the export of their gametes or of embryos created from their gametes.

Fertility services providers should continue to make decisions about whether the import and export of gametes and embryos for assisted reproductive procedures is consistent with the principles of the HART Act and New Zealand requirements.

The role of the Ethics Committee on Assisted Reproductive Technology in respect of human reproductive research should explicitly include considering and deciding applications to undertake research involving imported and exported gametes and embryos.

Regulations should be made about the requirements for the import and export of gametes and embryos.

## Related matters

The Ministry of Health should be asked to consider:

guidance to fertility services providers that allows for increased levels of donor compensation, particularly for egg donors and, for consistency, also guidance about expenses available for surrogates

public health information about the impact of age and other factors on fertility

public health information about gamete donation

strategies for collecting data about the use and outcomes of offshore fertility treatment by New Zealanders.

The closing date for feedback is 21 March 2014. ACART will then finalise its advice to the Minister, for submission in mid-2014.

# Background

## Context

Information from fertility services providers and consumers indicates that New Zealand, in common with many countries, is experiencing growth in the numbers of people accessing assisted reproductive procedures in other countries. This phenomenon is sometimes called transborder reproduction or cross-border reproductive care. In some cases, transborder reproduction involves sending, or wanting to send, *in vitro* gametes or embryos between countries.

The impacts of transborder reproduction include conflicts between standards and laws in different countries; concern about the potential exploitation of donors and surrogates in developing countries; and managing the entry of children born from overseas surrogacy arrangements into the home countries of intending parents. New Zealand is not alone in exploring how to address such conflicts.[[2]](#footnote-2)

When we issued our background document earlier in 2013, we noted that a common situation in New Zealand is where a woman has had *in vitro*[[3]](#footnote-3) fertilisation (IVF) treatment overseas with embryos created using commercially sourced donated eggs, and then wants to bring surplus embryos back to New Zealand for further treatment. Currently she could not use the embryos in New Zealand because the embryos have been created in circumstances that are inconsistent with New Zealand requirements. New Zealand prohibits buying and selling eggs, sperm and embryos.

Feedback during our consultation this year confirmed that this situation is the one of greatest concern for providers and consumers in regard to import/export. A key driver for New Zealanders to travel overseas is to access donated eggs because of the shortage of egg donors in this country. However, eggs obtained in other countries (for instance, the United States) are frequently from commercial sources.

## Why is ACART developing advice to the Minister of Health on the import and export of gametes and embryos?

The HART Act requires ACART to provide specific advice to the Minister of Health (the Minister) on:

the import into, or export from, New Zealand of *in vitro* human gametes or *in vitro* human embryos, in respect of human reproductive research

the import into, or export from, New Zealand of *in vitro* donated cells or *in vitro* embryos, in respect of human assisted reproductive technology.

ACART must provide the Minister with information, advice, and if it thinks fit, recommendations on these matters (s37(1)(g) and s38(f) of the HART Act).

ACART’s role of advising the Minister is significantly different from ACART’s role of developing and issuing guidelines. While ACART must consult with the Minister before issuing guidelines, the responsibility for the guidelines lies with ACART.

In contrast, where ACART advises the Minister, as it will about import/export matters, the Minister decides whether to accept any or all of the advice. Depending on the nature of advice that is accepted, any further work is likely to be the responsibility of the Ministry of Health (eg, development of regulations).

## What are the current requirements for import and export of human gametes and embryos?

New Zealand’s requirements associated with import/export are set out in:

the HART Act

Ministry of Health advice to fertility services providers

the Fertility Services Standard.

### The HART Act

The HART Act is the key law that regulates human assisted reproductive technology and human reproductive research in New Zealand. The HART Act prohibits import and export of cloned and hybrid embryos, and gives Customs Officers powers to detain any item or material if Customs has concerns that the item or matter may be prohibited.[[4]](#footnote-4)

The HART Act is otherwise silent on rules for import/export. Instead, the HART Act requires ACART to provide the Minister of Health with advice about import/export. The HART Act also says that regulations may be made for the purpose of prescribing requirements for import/export, including requirements for the giving of informed consent by persons from whom gametes are obtained overseas.[[5]](#footnote-5) No such regulations have been made.

### Ministry of Health advice to fertility services providers and individuals

In response to queries from providers and individuals, the Ministry of Health has said that there are no legal barriers to gametes and embryos being imported into and exported out of New Zealand. However, any treatment in New Zealand using imported gametes or embryos must meet the same requirements for the use of gametes and embryos sourced or created in New Zealand.

In addition, the Ministry of Health has advised providers that if they are involved in importing or exporting gametes and embryos, the Ministry expects providers to act ethically in relation to the following considerations:

HART Act principles

HART Act requirements (particularly requirements that describe prohibited actions, including commercial supply and sex selection, and requirements about keeping information about donors and donor offspring)

legislation and regulations in countries of origin and their similarity to that in New Zealand

informed consent requirements as in the HART Act and the Code of Health and Disability Services Consumers’ Rights.

### Fertility Services Standard

Fertility services providers in New Zealand must operate in accord with the Fertility Services Standard,whichsets out the requirements for the safety and quality of fertility services in New Zealand. Providers are audited and certified against the Standard.

TheStandard contains only one requirement specific to import/export. Providers must have a written procedure outlining requirements for the safety and quality of gamete and embryo transport, including obtaining consent of consumers before transport.[[6]](#footnote-6) Our understanding is that the Standard applies to all treatment in New Zealand regardless of the origin of gametes or embryos.

## What is the scope of ACART’s import/export work?

### In scope

Import means to bring or carry *in vitro* gametes (eggs and sperm, including reproductive tissue containing gametes) or embryos into New Zealand from another country.

Export means to carry or send *in vitro* gametes or embryos out of New Zealand to another country.

In practice, import/export means transporting human sperm, eggs or embryos in liquid nitrogen in special containers. People may carry gametes and embryos across borders in the containers, or the gametes and embryos may be freighted in the containers. Where gametes and embryos are shipped by plane, the packaging must comply with requirements of the International Air Transport Association.[[7]](#footnote-7)

Our proposed advice to the Minister addresses the import and export of human gametes and embryos, including:

an individual’s own sperm or eggs

donated sperm and donated eggs

embryos created from the sperm and eggs of a couple

embryos created from an individual’s own eggs or sperm, in conjunction with donated eggs or sperm

embryos created from donated eggs in conjunction with donated sperm

donated embryos

ovarian and testicular tissue.

Our proposed advice covers import/export for both treatment and research purposes.

The HART Act says that ACART’s advice on import /export for treatment purposes must address *donated* gametes and *donated* embryos. However, some policy and ethical issues related to import/export arise regardless of who provided the gametes and embryos. For this reason, the scope of our proposals includes individuals’ *own* sperm and eggs, and also embryos made from a couple’s *own* sperm and eggs, in cases where individuals and couples intend to use the material for their own treatment.

Our proposed advice includes some matters that are not directly associated with import/export but where we see potential to address some of the factors contributing to New Zealanders travelling overseas for fertility treatment.

### Out of scope

Our proposals do *not* address requirements associated with movements of *people* between countries, for example where:

people travel overseas for treatment

people travel overseas to be involved in human reproductive research projects

pregnant women return to New Zealand after treatment overseas

people come to New Zealand for fertility treatment

children created from assisted reproduction enter or leave New Zealand (for instance, as a result of surrogacy arrangements).

Such movements may, of course, be associated with import/export.

Our advice does *not* address import/export of embryonic stem cell lines. The HART Act definition of an embryo excludes stem cells derived from an embryo.

However, we will inform the Minister about any key issues not related to import/ export that we note in this consultation and in the consultation earlier this year.

#

# ACART’S consultationMarch–June 2013

ACART’s consultation March to June 2013 focused on seeking feedback about various ethical and policy issues associated with import/export. We asked the following questions:

If New Zealand’s regulatory framework was amended to facilitate import/export, where might change or flexibility be justified?

On the other hand, are there areas where there should be no flexibility in New Zealand requirements?

We discussed several specific areas where New Zealand requirements and policies may be a barrier to the use here of imported gametes and embryos.

## Our consultation process

We notified a broad range of individuals and organisations about the release of the background paper, and invited feedback. Those contacted included regular submitters to ACART, and also individuals and organisations we thought might have particular insights.

We also asked a variety of people and groups if they were interested in meeting with the Chair to discuss the matters raised in the background paper.

We received 24 submissions, and the Chair held 19 meetings. Some submitters also met with the Chair. Feedback came from a wide variety of sources eg, fertility services providers, consumers of fertility services here and overseas, bioethicists, professional groups, and researchers.

## What we heard

The consultation was useful for eliciting information as well as views about New Zealanders going offshore for fertility treatment and the implications for import/export policy. Consumers told us that treatment overseas was a last resort, particularly to obtain donated eggs. The costs associated with overseas treatment can be substantial, including significant payments to donors.[[8]](#footnote-8) Social costs include distance from support networks.

Consumers and providers tended to advocate for a more liberal approach to enabling the import and use of gametes and embryos that do not meet New Zealand requirements. Often this position was based on harms and injustice to parents and potential parents if gametes and embryos stored overseas could not be used in New Zealand. These views were at times associated with a view that New Zealand’s assisted reproduction policies are overly restrictive and limit the exercise of autonomy.

Another cohort of submitters argued that New Zealand should insist that overseas sourced gametes and embryos must comply with domestic standards applying to sourcing and use. This perspective was often argued in terms of the importance of adhering to principles and law that reflect New Zealand values and that extend beyond assisted reproductive technologies.

A majority view placed a high value on donor offspring having access to identifying information about donors, and said this should be possible in all circumstances. A minority of submitters saw access to identifying information as either “nice to have” depending on circumstances, or not essential. Some of this group said that parents were able to deal with situations where children had been born from anonymous donations.

Most submitters thought there was scope for more generous compensation to donors, particularly egg donors, and this would contribute to increasing the supply of donated eggs in this country. This view was held both by submitters who wanted no change to New Zealand requirements for import/export and by submitters who wanted exceptions and/or flexibility in regard to statutory requirements.

Even where submitters advocated for a more flexible regime that included exceptions or the exercise of discretion, most accepted the principles of theHART Act.

There were four key themes in feedback, not all mutually exclusive:

Arguments for retaining the status quo requirements applying to import/export. These arguments were often presented as protecting the interests of children and women, individually and collectively.

Arguments for supporting the exercise of individual autonomy generally or in specific areas. From this perspective, policy should be flexible in order to recognise that consumers were acting with good intentions and from desperation to have a child by whatever means available.

Arguments for domestic initiatives that might contribute to reducing the numbers of people going offshore for fertility treatment and thus reducing the associated impacts.

Arguments for taking into account wider public policy issues. From this perspective, the HART Act was part of a constellation of related public policy principles and requirements and should not be considered in isolation.

Submissions and meeting notes are placed on ACART’s website [www.acart.health.govt.nz](http://www.acart.health.govt.nz). Some submissions and notes are withheld in full or part where requested.

#

# ACART’S proposed advice

## Summary

Our proposed advice is summarised below. Some proposals are specifically about proposed requirements for import/export. Other proposals are about broader related matters.

While the proposals are presented and discussed individually, they are jointly intended to be a package that supports New Zealand standards while addressing some of the drivers pushing people to look overseas for fertility treatment.

### Import and export requirements

The principles and requirements of the Human Assisted Reproductive Technology Act should apply in all cases where people wish to import into and use in New Zealand gametes and embryos sourced or created in other countries.

Export of gametes and embryos should be possible, provided that:

the subsequent use of the gametes or embryos will be consistent with the principles and requirements of the HART Act, including any prohibitions, and

all gamete providers, including donors, have given informed consent to the export of their gametes or of embryos created from their gametes.

Fertility services providers should continue to make decisions about whether the import and export of gametes and embryos for assisted reproductive procedures is consistent with the principles of the HART Act and New Zealand requirements.

The role of the Ethics Committee on Assisted Reproductive Technology (ECART) in respect of human reproductive research should explicitly include considering and deciding applications to undertake research involving imported and exported gametes and embryos.

Regulations should be made about the requirements for the import and export of gametes and embryos.

### Related matters

The Ministry of Health should be asked to consider:

a) guidance to fertility services providers that allows for increased levels of donor compensation, particularly for egg donors (for consistency, the expenses available for surrogates should also be considered)

b) public health information about the impact of age and other factors on fertility

c) public health information about gamete donation

d) strategies for collecting data about the use and outcomes of offshore fertility treatment by New Zealanders.

In the following sections we discuss each proposal in turn.

## The principles and requirements of the HART Act should apply in all cases where people wish to import into and use in New Zealand gametes and embryos sourced or created in other countries

In essence, this proposal continues the status quo as set out in the Ministry’s advice to providers. The key difference is that we consider that import of gametes and embryos should not happen unless the circumstances and intended use are consistent with New Zealand requirements. There is little point in importing material that cannot be used here.

We appreciate that this proposal will not be welcomed by those submitters who advocated strongly that public policy should provide for flexibility in the use of gametes and embryos that do not meet New Zealand requirements. However, we think there are significant public policy and ethical arguments in support of our proposal.

### Public policy

The principles and requirements in the HART Act are consistent with core values in other domestic policy and in New Zealand’s international obligations. The HART Act reflects wider well-established important legal and policy positions and cultural values. Examples include:

altruistic tissue donation, prohibition on trading in human tissue (eg, blood donation, organ donation, Human Tissue Act 2008)

informed consent (in Code of Health and Disability Services Consumers’ Rights)

protection of children (eg, Care of Children Act 2004)

access to identifying information about one’s origins (Adult Adoption Information Act 1985, role of knowledge of whakapapa for iwi membership and personal identity)

New Zealand’s ratification of the United Nations Convention on the Rights of the Child, which includes respecting the rights of children to preserve their identity.

We consider that any changes to New Zealand standards in regard to import/export requirements should not take place outside the context of wider public discussion about the principles of the HART Act, their links to other well-established principles in public policy, and the HART Act itself.

We recognise that import/export requirements are important to people who are affected, particularly those prevented from bringing embryos back to New Zealand. However, allowing for flexibility in New Zealand requirements would be out of proportion to the scale of the issue. New Zealanders involved in transborder reproduction appear to be a small proportion of those using assisted reproductive procedures in this country.

Migrants to New Zealand may want to bring with them gametes or embryos stored in their home country. Our proposal would mean that those gametes and embryos could not be brought here if they were sourced or created in circumstances that do not meet New Zealand requirements.

However, this is one of the many factors that migrants must take into account when making the decision to live in another country. New Zealand has a right to decide what is lawful and acceptable in this country, regardless of what is lawful elsewhere.

### Health and wellbeing of women and children

We recognise there are significant concerns associated with the health and wellbeing of women and children. Continuing restrictions on import may be an incentive for women to have multiple embryos replaced, and thus incur risks for themselves and children associated with multiple pregnancies. The New Zealand health system bears the costs that arise from adverse outcomes for women and children.

However, balanced against this is the broader public policy picture, discussed above. We think the ethical values and associated policy in the HART Act should be preserved and agree with the submitter who said that the HART Act could be seen as a taonga that protects women and children.

Some submitters argued that policy should provide for cases where there were compassionate grounds to ease restrictions on import. We think it would be very difficult to determine which cases met such a test and which cases did not.

### Justice and equality

We do not think it is fair or desirable to have a two-tier system in which people who travel offshore, or who obtain gametes or embryos from overseas, are then able to access treatment back in New Zealand under conditions that would not be lawful for consumers who do not leave New Zealand for treatment.

Some submitters noted that if people could not use embryos stored overseas, this would mean that such embryos would need to be discarded, which would be unfair. We do not see this as a compelling argument. The HART Act allows for gametes and embryos to be discarded, and requires that gametes and embryos are discarded where they have been stored for longer than 10 years or beyond an approved extended storage period.

### Autonomy

Our proposal does not undermine individuals’ existing freedom to choose from the options available to them. People will continue to be able to weigh up the costs and benefits of going overseas for treatment and returning overseas for further treatments.

**Question 1:** Do you agree that the principles and requirements of the HART Act should apply in all cases where people wish to import into and use in New Zealand gametes and embryos sourced or created in other countries?

## Export of gametes and embryos should be possible, provided that the subsequent use of the gametes and embryos will be consistent with the principles and requirements of the HART Act, including any prohibitions, and all gamete providers, including donors, have given informed consent to the export of their gametes or of embryos created from their gametes

There are various reasons why people might wish to export gametes and embryos, including:

emigration to another country

to use in a procedure prohibited in New Zealand (see page 25 for a summary of prohibitions)

to use in a procedure that is precluded in New Zealand but not prohibited. This may be because the procedure is not offered by fertility services providers or ACART has not issued guidelines or the provisions of guidelines exclude particular circumstances.

We know that a key area related to export is the use of cryopreserved ovarian tissue. In New Zealand, storing ovarian tissue (eg, before cancer treatment that is likely to impair fertility) does not require ethical approval. However, the subsequent use of such tissue is subject to ECART approval. ACART has not issued guidelines on the use of cryopreserved ovarian tissue, and so ECART cannot consider applications to use the tissue. We have been told that, in some cases, New Zealanders have exported their tissue to Australia so that it can be implanted in an attempt to have a child.

### Public policy

We think there are important differences between a procedure being prohibited and a procedure not being available. Where New Zealand has imposed prohibitions on the use of gametes and embryos, such prohibitions are part of the protections afforded by the HART Act and should operate as far as possible where people wish to export gametes and embryos.

However, where prohibitions are not in place, people should be able to export their own material provided the use is consistent with the principles and requirements of the HART Act.

### Informed consent

Where gametes and embryos go offshore, New Zealand has no control or jurisdiction over their use. Informed consent processes need to include informing consumers, including donors, about the limitations of any conditions set as part of consent to export. For instance, once sperm leaves this country, conditions set by a sperm donor about the maximum number of families able to use his donated sperm may not be upheld.

**Question 2:** Do you agree that export of gametes and embryos should be possible provided that the subsequent use of the gametes or embryos is consistent with the principles and requirements of the HART Act, including any prohibitions?

Do you agree that all gamete providers, including donors, should give informed consent to the export of gametes or of embryos created from their gametes?

## Fertility services providers should continue to make decisions about whether the import and export of gametes and embryos for assisted reproductive procedures is consistent with the principles of the HART Act and New Zealand requirements

Currently, providers make decisions about import/export, and the use of imported gametes and embryos, on the basis of Ministry of Health advice.

Some submitters assumed ECART has or would have a role in determining whether or not import/export should take place, perhaps using guidelines developed by ACART. However, import/export is not classified as a procedure requiring ethical approval, and thus neither ACART nor ECART currently has a role in determining whether or not import/ export should take place.

We have concluded that providers should continue to make decisions about import/export, with the support of more detailed information about requirements. Providers already make a range of decisions about the provision of fertility services in accord with the HART Act and are regulated under the Health and Disability Services (Safety) Act 2001. Providers must operate in accord with requirements set out in the Fertility Services Standard.

As noted in our proposal for regulations below, further detail about import/export processes could be added to the Fertility Services Standard. Any risks associated with the current approach to import/export can be managed by introducing more detailed and transparent requirements.

### Public policy

We do not think there is a case to charge an existing or new regulatory body with deciding case-by-case applications to import and export gametes and embryos. Such a body would require resourcing. For instance, decision-making by ECART on import/export cases could be a significant enlargement of and change to ECART’s existing functions.

In order to make decisions about import/export, providers would need to obtain full information about gametes and embryos that clients seek to import and export, including about the intended use of the gametes and embryos. This would enable providers to identify situations that would preclude import or export and to advise clients about options and implications. Providers would need to make it clear that even if the intended subsequent use was lawful, any procedure in New Zealand requiring ethical approval could not be carried out unless approved by ECART.

**Question 3:** Do you agree that fertility services providers should continue to make decisions about whether the import and export of gametes and embryos for assisted reproductive procedures is consistent with the principles of the HART Act and New Zealand requirements?

If you disagree with the proposal, who or what should make decisions about whether the import and export of gametes and embryos for assisted reproductive procedures is consistent with New Zealand requirements?

## The role of ECART in respect of human reproductive research should explicitly include considering and deciding applications to undertake research involving imported and exported gametes and embryos

While above we have proposed that providers have a formal mandate to continue making decisions about import/export, we think the situation is different in regard to human reproductive research. ECART’s role already includes considering and deciding applications to undertake human reproductive research, using ACART guidelines.[[9]](#footnote-9)

### Transparency

It is not clear whether the scope of ECART’s role includes situations where New Zealand material is to be exported for research purposes or where a New Zealand researcher wants to import material from an overseas colleague. We consider that ECART’s role should include considering such cases and that this should be explicit for the sake of transparency.

We recognise limits to the operation of the function, given that the HART Act has no effect outside New Zealand. For instance, ECART could not place conditions on overseas researchers that apply to New Zealander researchers, such as supplying research reports (s8(5) of the HART Act).

### Public policy

ECART scrutiny would ensure that New Zealand researchers were not participating in research that was not acceptable in this country, or using material obtained in circumstances that are not acceptable here, including without informed consent.

**Question 4:** Do you agree that ECART’s role in respect of human reproductive research should explicitly include considering and deciding applications to undertake research involving imported and exported gametes and embryos?

If you disagree with the proposal, who or what should be responsible for making decisions about research using imported and exported gametes and embryos?

## Regulations should be made about the requirements for the import and export of gametes and embryos

The HART Act provides for regulations to be made about the import and export of *in vitro* gametes and *in vitro* embryos (s.76(I)(iii)). The regulations can prescribe requirements or conditions or impose restrictions, and include addressing the giving of informed consent by overseas gamete donors.

No such regulations have been made to date. We think there are good arguments for making such regulations. If the Minister of Health agrees, ACART would not draft the regulations. We understand that the Ministry of Health would be responsible for further work associated with regulations.

### Transparency

A detailed set of rules for import/export would contribute to ensuring people understand New Zealand’s import/export requirements before undertaking offshore fertility treatment.

Regulations would provide transparency by collating requirements in one place, backed by the force of law. We suggest that any regulations should be explained in supporting guidance.

Some requirements could also be included in the Fertility Services Standard when it is revised. This would enable audits of providers to capture a wider range of processes associated with import and export.

### Equity

If interest in offshore fertility treatment grows, there will be an increasing need for consumers, providers and researchers to have a shared and accurate understanding about import/export requirements as they apply to human assisted reproduction and human reproductive research.

The current approach of relying on providers’ interpretation of high level Ministry advice carries the risk that import/export may not be carried out in a consistent way. As discussed above, we propose that providers continue to decide if import/export for assisted reproductive procedures is consistent with New Zealand requirements. Regulations would support providers in making decisions.

### Public policy

During public consultation we learnt that providers in New Zealand are often involved in services to patients who are planning to go offshore for treatment, particularly where providers here have entered into a relationship with an overseas clinic.

However, it appears there may be a lack of clarity at times about the extent to which New Zealand providers should be supporting clients who plan to undertake procedures in other countries where the procedures would not be lawful or best practice if carried out in this country.

We suggest that regulations could set out any limits that should apply to services in New Zealand to consumers who plan to go offshore for treatment, taking into account the duty of care of clinicians to their patients.

**Question 5:** Do you agree that regulations should be made about the requirements for the import and export of gametes and embryos?

If you disagree with the proposal, how should requirements for import and export be set out?

## The Ministry of Health should be asked to consider guidance to fertility services providers that allows for increased levels of donor compensation, particularly for egg donors (for consistency, the expenses available for surrogates should also be considered)

The HART Act prohibits the commercial supply of gametes and embryos. The regulatory framework does not set out the amounts that can be paid.

Information on providers’ websites indicates that modest travelling expenses are offered to gamete donors – one provider offers $30 a visit, and another offers up to $200 using fuel vouchers. This level may leave donors out of pocket, for example from lost earnings. Some submitters noted a lack of clarity about what costs could be covered.

Most submitters, regardless of their views on other matters, said there was scope for more generous compensation to gamete donors, particularly egg donors. Where submitters suggested amounts, these ranged from $1000 to $3000.

Submitters thought that increased compensation had the potential to increase the number of donors in New Zealand, and thus reduce the number of New Zealanders who travel overseas to obtain donated gametes, in particular donated eggs.

We agree that increased compensation may contribute to increasing the supply of donated gametes, and in turn decreasing the number of New Zealanders who undertake fertility treatment overseas using commercially sourced gametes.

We therefore propose to advise the Minister that the Ministry of Health should be asked to consider guidance to providers about acceptable levels of compensation, taking into account the opportunity costs associated with donation.

Compensation levels in New Zealand are modest compared to that available in the United Kingdom (UK), which also prohibits commercial supply of gametes and embryos.

After public consultation in 2011 on gamete and embryo donation, the UK Human Fertilisation and Embryology Authority (HFEA) raised the level of expenses payable to donors.

Egg donors can receive compensation of up to £750 per cycle of donation, to reasonably cover any financial losses incurred in connection with the donation, with the provision to claim an excess to cover higher expenses (such as for travel, accommodation or childcare).

Sperm donors can receive compensation of up to £35 per clinic visit, to reasonably cover any financial losses incurred in connection with the donation, with the provision to claim an excess to cover higher expenses (such as for travel, accommodation or childcare).

### Public policy

The matter of specific levels of compensation to donors is outside ACART’s jurisdiction. We think the state has the important role of determining what is acceptable. This would ensure that providers could be confident that the amounts offered do not breach the HART Act.

### Altruism

Our proposal retains the distinction between the altruistic and commercial supply of gametes and embryos. The aim is to remove disincentives to donate, and to support people who are considering donation by not leaving donors out of pocket.

A 2011 report by the UK Nuffield Council on Bioethics, *Human bodies: donation for medicine and research*,[[10]](#footnote-10) usefully distinguishes between various uses of money in the context of donation:

**purchase** of a thing

**reward** to a person for donating e.g. remuneration that is reward calculated as a wage

**recompense** of a person for losses incurred. This can involve both **reimbursement** for financial losses and **compensation** for non-financial losses such as discomfort.

Our proposed approach is intended to fall under the third category of recompense, recognising that donation involves both financial and non-financial losses. An increase in the level of expenses should be at a rate that does not leave donors in a significantly better position than they would have been in without donating.

### Justice

Egg donation is intrusive and carries risks for donors. A comment by a submitter who had used donated eggs from both overseas and local sources captured the perspectives of many submitters:

* “An egg donor goes through so much physically to do a donor cycle – the hormone ups and downs, the injections, the invasive procedures, anaesthetics, etc, etc.”

Another consumer noted the significant amount she had spent in her successful efforts to advertise for egg donors in New Zealand, arguing that she would rather have spent the money compensating a donor.

### Supply

While increased compensation to donors may contribute to increasing the supply of donated gametes in New Zealand, we cannot quantify how many more donors would be likely to come forward. As noted by some submitters, the level of donation would not fall.

However, an increased supply of donated eggs may in turn increase interest in using donated eggs in this country, whether or not consumers would have looked overseas for donated eggs.

### Decisions about who pays

An increased level of available donor expenses would require decisions about who would bear the costs.

Where procedures are publicly funded, expenses paid to donors might decrease the number of people able to be treated from the pool of available funding.

Where procedures are privately funded, providers might pass on to intending parents the additional costs associated with a higher rate of expenses.

### Expenses paid to surrogates

If egg donors in particular could receive a higher rate of expenses on the basis of opportunity costs and the risks involved, for consistency the expenses available for surrogates should also be addressed. Surrogates incur substantial opportunity costs and risks. ECART has made some determinations about the scope of support to surrogates, eg, life insurance can be paid on the basis that if the surrogate dies, she would not benefit from the insurance.

One submitter argued that consideration needed to be given to the boundaries between commercial and altruistic surrogacy, including what constitutes a payment or fee and what is deemed to be reasonable reimbursement for expenses incurred by a surrogate. This comment was in the context of overseas surrogacy arrangements and decisions about the entry to New Zealand of children born from such arrangements.

**Question 6:** Do you agree that the Ministry of Health should be asked to consider guidance to fertility services providers that allows for increased levels of donor compensation, particularly for egg donors?

If you agree with the proposal, do you have a view about appropriate maximum levels of compensation to donors?

Do you agree that, for consistency, the Ministry should also be asked to consider guidance about expenses available for surrogates?

## The Ministry of Health should be asked to consider public health information about the impact of age and other factors on fertility, and about gamete donation

Fertility services providers have taken the initiative from time to time to advertise about age and other impacts on fertility, and the merits of donation. The Ministry of Health’s Service Specification to District Health Boards for Assisted or Artificial Technology includes a requirement that providers “will provide advice to increase awareness of infertility, its prevention, and the minimisation of its impact among the general public”.

We think that information about fertility matters is a public health obligation. While the effects of age on fertility are not the only reasons that people seek fertility treatment in New Zealand or overseas, we think there is scope to mitigate some of the impacts of age and lifestyle factors on fertility by giving information that enables people to make informed decisions about their parenting intentions. Information is also needed that raises public awareness of the need for donated gametes, in the same way that the need for donated blood is regularly advertised.

Research here and overseas indicates that people often have poor or inaccurate information about the impact of age on fertility. They may also overestimate the chances that assisted reproduction will result in the birth of a child (see box).

Research in **New Zealand** looked at university students’ knowledge of fertility decline in women, and found that most overestimated the rates of pregnancy for both natural and IVF conception. Most students were aware of assisted reproductive technologies but overestimated their effectiveness.[[11]](#footnote-11)

A national survey in **Australia** found that only 20 percent of respondents could correctly identify the point at which women’s fertility begins to decline (early 30s) and only nine percent knew that men’s fertility begins to decline from 45 years.[[12]](#footnote-12)

A **United States** survey of women’s fertility knowledge in 2011 found that most of the respondents (aged 25–35 years) underestimated the magnitude of fertility decline with age.[[13]](#footnote-13)

Research in the **United States** from 2009 to 2011 found that women over the age of 40 years who were first time parents did not accurately understand, before giving birth, the relationship between age and fertility.[[14]](#footnote-14)

An **international** survey of over 10,000 men and women in 79 countries who were trying to conceive found that fertility knowledge was modest, with 57 percent average correct score. However, on a country level, New Zealanders had the highest score at 79 percent.[[15]](#footnote-15)

We have noted some overseas information initiatives.

### United Kingdom

The **National Gamete Donation Trust** is a government-funded charity to raise awareness of and seek ways to alleviate the national shortage of gamete and embryo donors. The Trust provides information to prospective donors, consumers, and health professionals about what is involved in donation. In 2011 and 2012, the Trust surveyed donors about their experiences when they approached clinics, and the results are published on the Trust’s website: <http://www.ngdt.co.uk/>

The **National Donation Strategy Group** is a recent initiativeestablished by the HFEA for an initial two years, with review at the end. The Strategy Group, comprising a wide range of experts, was set up following an HFEA public consultation that looked at barriers to egg and sperm donation. While one of the outcomes of the consultation was to raise the level of expenses payable to donors, the HFEA identified other barriers to donation where regulation was not an appropriate mechanism.

The three core objectives of the group are to:

increase awareness of donation and the information that donors receive

improve the ‘customer service’ that donors receive when they contact clinics

help donors provide better information about themselves for future families.

The website is <http://www.hfea.gov.uk/7138.html>

### Victoria, Australia

The **Fertility Coalition** is a partnership between the Victorian Assisted Reproductive Treatment Authority, a not-for-profit women’s health organisation, Andrology Australia, and a research institute at The University of Adelaide. The Coalition is supported by funding from the Australian Department of Health and Ageing and the Victorian Department of Health.

The Coalition has a Your Fertility campaign that focuses on five key factors that affect getting pregnant and having a healthy baby: age, smoking, weight, alcohol and timing intercourse to coincide with the most fertile time of a woman’s cycle. <http://yourfertility.org.au/fertility-coalition>

Question 7: Do you agree that the Ministry of Health should be asked to consider public health information about the impact of age and other factors on fertility, and about gamete donation?

## The Ministry of Health should be asked to consider strategies for collecting data about the use and outcomes of offshore fertility treatment by New Zealanders

Our proposal is concerned with two types of information:

data about use of overseas fertility treatment and outcomes

access to information by donors and donor offspring.

### Data about use of overseas fertility treatment and outcomes

During the consultation, we heard concerns from foetal medicine specialists that there is a lack of data about outcomes where New Zealanders travel overseas for treatment.

Our understanding is that the Australia-New Zealand Assisted Reproduction Database (ANZARD) report, issued annually, includes only cases reported by providers where treatment is undertaken in Australia and New Zealand.[[16]](#footnote-16) Although annual New Zealand-specific reports are now being published,[[17]](#footnote-17) these reports do not address the lack of information about outcomes where New Zealanders go overseas for treatment.

The foetal medicine specialists argued that information is needed about antenatal and postnatal outcomes for pregnancies, babies and women. Many of the women going overseas are older and likely to have high-risk pregnancies, with substantial risks to themselves and babies. This includes, but is not restricted to, cases where multiple pregnancies result from treatment. Outcomes information could contribute to supporting informed decisions about overseas fertility treatment.

We note that the collection of limited information has begun in some overseas countries. The most recent report of the use of assisted reproductive technology in Europe says that six European countries – Croatia, Ireland, Iceland, Macedonia, Spain and Poland – reported data on cross-border reproductive care (cycles involving women from other countries).[[18]](#footnote-18) Only one country, Spain, included complete data about countries of origin for the women being treated. The main reason reported by patients was to seek access to procedures not legally available in their home countries.

### Access to information by donor offspring and donors

At an individual level, donors and donor offspring have an interest in being able to access information. We think that the rights applying to donor offspring and donors where children are born in New Zealand from treatment here (as in Part 3 of the HART Act) should also apply, as far as is practical, where children are born in a different country from the donor. Those rights should include:

donor offspring having the right from the age of 18 years to access identifying information about donors, for instance where children are born in New Zealand from the use of overseas donated gametes

donors having the right to know whether, to the best of a provider’s knowledge, a child has been born from the donation and the sex of the child, for instance where a child is born overseas from donated gametes exported from New Zealand.

In Victoria, Australia, applicants to export donated gametes or embryos created from donated gametes (to another state or another country) must sign a declaration that they will notify the Victorian clinic should a live birth result from the use of the exported gametes or embryos.

### Public policy

We recognise the challenges and limitations involved in systematically obtaining the proposed information, at a population level and a personal level.

People are free to leave New Zealand. The proportion of those travelling for fertility treatment will constitute a tiny proportion of all departures from New Zealand and so would not justify amending departure cards to capture such information.

Providers here will not have been involved in all cases where New Zealanders go overseas for treatment.

Women who return to New Zealand pregnant may choose not to disclose that the pregnancy is the result of fertility treatment.

New Zealand has no jurisdiction offshore. Where people are treated in New Zealand, providers are required to record information about donors to ensure donor offspring can access information about their genetic origins (s47 of the HART Act). New Zealand providers must also have systems in place to ensure they are notified of births of donor offspring (s52). However, overseas clinics are not bound by these requirements. This means that New Zealand providers may not know about births overseas from donated gametes, donated embryos or embryos created from donated gametes that have been exported from New Zealand.

Nevertheless, there is potential to capture data and information in cases where New Zealand providers have played a role, particularly where providers here are in some type of partnership with an overseas clinic. New Zealand providers could establish processes to ensure, as far as possible, that collaborating clinics in other countries would notify them of any births. Providers could then link these births to the HART register in New Zealand.

There are substantial risks associated with solely relying on overseas providers and sperm banks as a source of information about donors, regardless of undertakings given. There may be challenges for New Zealanders seeking access to information from an overseas source. If an overseas provider or sperm bank goes out of business, the records may not be secure. In contrast, New Zealand has centralised statutory registers held by a government agency (Department of Internal Affairs).

### Health and wellbeing of children

Our proposal would protect any resulting children by providing the opportunity for donor offspring born outside New Zealand to access information about their whakapapa/genetic origins.

Children born in New Zealand from the use of donated gametes and embryos overseas would also have the opportunity to access identifying information about donors.

### Health and wellbeing of women

Improved information would assist consumers in making informed decisions that took into account the merits and risks associated with overseas treatment.

Question 8: Do you agree that the Ministry of Health should be asked to consider strategies for collecting data about the use and outcomes of offshore fertility treatment by New Zealanders?

If you agree, do you have ideas about how such data could be collected?

\

#

# Prohibitions in the HART Act

The HART Act includes prohibited activities and actions.

*Part 2: Prohibited activities (see the HART Act for details)*

Development of an *in vitro* embryo beyond 14 days and import or export of such an embryo.

Storage of embryos or gametes beyond 10 years or beyond an approved extended period without approval by ECART.

Sex selection of human embryos (though a defence is that the act was performed to prevent a genetic disease or disorder).

Obtaining gametes from an individual under the age of 16 years (though a defence is that the act was performed to preserve the gamete or to bring about the birth of a child likely to be raised by the person from whom the gamete was obtained).

Commercial supply of gametes and embryos.

Commercial surrogacy arrangements.

*Schedule 1: Prohibited actions*

Artificially form a cloned embryo.

Artificially form a hybrid embryo.

Implant into a human being a cloned embryo.

Implant into a human being an animal gamete or embryo.

Implant into a human being a hybrid embryo.

Implant into an animal a human gamete or embryo.

Implant into a human being a genetically modified gamete, human embryo or hybrid embryo.

Implant into a human being gametes derived from a foetus or an embryo formed from a gamete or gametes from a foetus.

#

# Import and export requirements in some comparable jurisdictions

## United Kingdom

The United Kingdom provides for clinics to decide if the import and export of gametes and embryos is consistent with directions issued by Human Fertilisation and Embryology Authority (HFEA). The directions include the following points.

Clinics must be licensed to import and export.

Transfer must be clinic to clinic.

Gamete providers, including in the event that an embryo has been created, must give informed consent.

Informed consent must include a written notice that the law in the other jurisdiction about the use of the material and the parentage of a resulting child may be different to that of the sending country.

Clinics must report import and export within a set period to the HFEA, using standard documents.

Gametes and embryos cannot be exported if they could not be lawfully used in the United Kingdom in the same way as proposed in the receiving country.

While the directions apply to import and export for research as well as treatment, import and export for research purposes requires an application to the HFEA for Special Permission.

The formal General directions covering import and export are available at: http://www.hfea.gov.uk/docs/2009-09-09\_General\_directions\_0006\_-\_Import\_and\_export\_of\_gametes\_and\_embryos\_-\_version\_2.pdf[[19]](#footnote-19)

## Australia

### Victoria

The Assisted Reproductive Treatment Act 2008 requires that the Victorian Assisted Reproductive Treatment Authority (VARTA) decide applications for import and export, for treatment purposes, of donated gametes and embryos created from donated gametes. VARTA’s guidelines are available at: [http://www.varta.org.au/ import-export-of-gametes-embryos/](http://www.varta.org.au/%20import-export-of-gametes-embryos/)w1/i1003328/[[20]](#footnote-20)

The requirements apply whether the import and export is between Victoria and another Australian state or between Victoria and overseas, and include the following points.

Generally, approval will be given to export only where the intended use is consistent with a purpose that is lawful in Victoria. The recipients of the donated material must be counselled by a fertility counsellor.

Conditions for import are that the same conditions apply as for donated gametes and embryos created in Victoria. Donors must be counselled by a fertility counsellor, and information about the donor must be lodged with the clinic that will store the imported material.

Donors must consent to import and export.

### New South Wales

The Assisted Reproductive Technology Act 2007 (s22) says that a fertility services provider must not export, or cause to be exported, a gamete or embryos from New South Wales except with the consent of the gamete provider and in a manner that is consistent with the consent of the gamete provider.

### Western Australia

The Reproductive Technology Council issued advice in 2009 on the import of donated reproductive material. Compliance with requirements is left to clinics. The advice particularly notes that consents associated with imported material must comply with requirements in the Human Reproductive Technology Act 1991 and Directions issued under the Act. The advice also says that there should be no more than five known donor families, including within and outside Western Australia, from the use of imported donated human reproductive material, and notes that this limit may be less than in some jurisdictions from which donated material is imported.

Further information is available at: [http://www.rtc.org.au/faqs/docs/ Import\_Donor\_Notice.pdf](http://www.rtc.org.au/faqs/docs/%20Import_Donor_Notice.pdf)

### South Australia

The Assisted Reproductive Treatment Act 1988 and the Assisted Reproductive Treatment Regulations 2010 do not include any references to import or export.

## Canada

The Assisted Human Reproduction Act 2004 does not include any specific requirements for import and export. The Processing and Distribution of Semen for Assisted Reproduction Regulations 1996 (regulations under the Food and Drugs Act) include requirements for the import of semen. The requirements focus on health and safety issues. Establishments (eg, clinics) that import, or intend to import, semen for distribution are required to notify Health Canada in writing at least 10 days before the date on which they begin importing semen. Information can be found at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/don/ gui\_41‑eng.php\](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/don/%20gui_41eng.php%5C)

#

# Glossary

**Cryopreserved tissue** means frozen ovarian or testicular tissue.

**Donor** means a person from whose cells a donated embryo is formed or from whose body a donated cell is derived.

**Fertility services provider** means a provider, clinic or sperm bank that is regulated under the rules in the country where it is situated.

**Fertility Services Standard** is a document issued by Standards New Zealand thatsets out the requirements for the safety and quality of fertility services in New Zealand. Clinics are audited and certified against the Standard.

**Gamete** is defined in the HART Act 2004 as:

(a) an egg or a sperm, whether mature or not; or

(b) any other cell (whether naturally occurring or artificially formed or modified) that –

(i) contains only one copy of all or most chromosomes; and

(ii) is capable of being used for reproductive purposes.

ACART considers that “human gametes” includes ovarian tissue and testicular tissue, as the purpose of obtaining, storing and using the tissue is to use the eggs or sperm the tissue contains.

**Intending parent** means a person who hopes to become a parent following fertility treatment.

***In vitro*** means outside a living organism.

**Researcher** means a person who conducts human reproductive research that is subject to the requirements of the Human Assisted Reproductive Technology Act 2004.

# Appendix 1: Members of ACART

The members of ACART are:

Dr John Angus (Chair)

Alison Douglass (Deputy Chair)

Dr Karen Buckingham

Jonathan Darby

Nikki Horne

Associate Professor Mike Legge

Sue McKenzie

Dr Barry Smith

Further information about the members and ACART can be found on ACART’s website [www.acart.health.govt.nz](http://www.acart.health.govt.nz)

#

#

# Feedback form

Please provide your contact details below.

|  |  |
| --- | --- |
| Name: |  |
| If this feedback is on behalf of an organisation, please name the organisation: |  |
| Please provide a brief description of the organisation if applicable: |  |
| Address/email: |  |
| Interest in this topic (eg, user of fertility services, health professional, researcher, member of the public): |  |

We will place all feedback on ACART’s website, except where we are asked that feedback be withheld in full or part for reasons of confidentiality. We will remove contact information from all feedback.

|  |  |
| --- | --- |
|  | I **request** that my feedback be withheld in full or part from publication on ACART’s website (if you wish a part to be withheld, please clearly indicate which part). |

Please note that all feedback may be requested by any member of the public under the Official Information Act 1982 (the Act). If there is any part of your feedback that you consider should be properly withheld under the Act, please make this clear in your feedback, noting the reasons.

If information from your feedback is requested under the Act, the Ministry of Health (the Ministry) will release your feedback to the person who requested it. The Ministry will remove your name and/or contact details from the feedback if you check one or both of the following boxes. Where feedback is on behalf of an organisation, the Ministry will not remove the name of the organisation.

|  |  |
| --- | --- |
|  | **I do not** give permission for my name to be released to persons under the Official Information Act 1982. |
|  |  |
|  | I **do not** give permission for my contact details to be released to persons under the Official Information Act 1982. |

We will acknowledge all feedback.

#

# Questions about the proposals discussed in the paper

## Question 1: Import and subsequent use of gametes and embryos

Do you agree that the principles and requirements of the Human Assisted Reproductive Technology Act 2004 should apply in all cases where people wish to import into and use in New Zealand gametes and embryos sourced or created in other countries?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No |  |

Please give reasons for your views.

|  |
| --- |
|  |

## Question 2: Export of gametes and embryos

Do you agree that export of gametes and embryos should be possible, provided that:

the subsequent use of gametes or embryos is consistent with the principles and requirements of the Human Assisted Reproductive Technology Act 2004, including any prohibitions, and

all gamete providers, including donors, have given informed consent to the export of their gametes or of embryos created from their gametes?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No |  |

Please give reasons for your views.

|  |
| --- |
|  |

## Question 3: Decisions about import and export for assisted reproductive procedures

Do you agree that fertility services providers should continue to make decisions about whether the import and export of gametes and embryos for assisted reproductive procedures is consistent with the principles of the Human Assisted Reproductive Technology Act 2004 and New Zealand requirements?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No |  |

If you disagree with the proposal, who or what should make decisions about whether the import and export of gametes and embryos for assisted reproductive procedures is consistent with New Zealand requirements?

|  |
| --- |
|  |

Please give reasons for your views.

|  |
| --- |
|  |

## Question 4: Decisions about import and export for human reproductive research

Do you agree that the role of the Ethics Committee on Assisted Reproductive Technology in respect of human reproductive research should explicitly include considering and deciding applications to undertake human reproductive research involving imported and exported gametes and embryos?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No |  |

If you disagree with the proposal, who or what should be responsible for making decisions about research involving imported and exported gametes and embryos?

|  |
| --- |
|  |

Please give reasons for your views.

|  |
| --- |
|  |

## Question 5: Regulations

Do you agree that regulations should be made about the requirements for the import and export of gametes and embryos?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No |  |

If you disagree with the proposal, how should requirements for import and export be set out?

|  |
| --- |
|  |

Please give reasons for your views.

|  |
| --- |
|  |

## Question 6: Donor compensation

Do you agree that the Ministry of Health should be asked to consider guidance to fertility services providers that allows for increased levels of donor compensation, particularly for egg donors?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No |  |

Do you agree that such guidance should, for consistency, include the expenses available to surrogates?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No |  |

If you agree with the proposals, do you have a view about appropriate maximum levels of compensation to donors?

|  |
| --- |
|  |

Please give reasons for your views.

|  |
| --- |
|  |

## Question 7: Public health information

Do you agree that the Ministry of Health should be asked to consider public health information about:

the impact of age and other factors on fertility, and

gamete donation?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No |  |

Please give reasons for your views.

|  |
| --- |
|  |

## Question 8: Data about offshore fertility treatment and outcomes

Do you agree that the Ministry of Health should be asked to consider strategies for collecting data about the use and outcomes of offshore fertility treatment by New Zealanders?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No |  |

If you agree, do you have ideas about how such information could be collected?

|  |
| --- |
|  |

Please give reasons for your views.

|  |
| --- |
|  |

## Question 9: Comments or suggestions

Do you have any other comments or suggestions about the issues discussed in this proposed advice paper?

|  |
| --- |
|  |

1. Advisory Committee on Assisted Reproductive Technology. 2013. *Import and Export of Gametes and Embryos: Background paper for stakeholder discussion.* Available at www.acart.health.govt.nz [↑](#footnote-ref-1)
2. For example, in 2011, the European Society for Human Reproduction and Embryology issued a good practice guide for cross-border reproduction <http://nuevo.sefertilidad.com/ESHREspractice-guide-practitioners.pdf>; in 2012, the Hague Convention on Private International Law issued a report about issues arising from international surrogacy arrangements, including the mismatch between requirements in different jurisdictions <http://www.hcch.net/upload/wop/gap2012pd10en.pdf>; and in 2013, the Ethics Committee of the American Society for Reproductive Medicine issued an opinion on cross-border reproductive care [http://www.asrm.org/uploadedFiles/ASRM\_Content/News\_and\_ Publications/](http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_%20Publications/)Ethics\_Committee\_Reports\_and\_Statements/Cross-border%20reproductive%20care2013.pdf [↑](#footnote-ref-2)
3. *In vitro* means outside a living organism. [↑](#footnote-ref-3)
4. See s8(2) and s73 of the HART Act 2004. [↑](#footnote-ref-4)
5. s76 of the HART Act 2004. [↑](#footnote-ref-5)
6. 4.2.11 of the Fertility Services Standard. Note that the definition of ‘consumer’ in the Standard covers everyone involved in a procedure: “A user or participant in the service, including client, patient, gamete or embryo donor. Where appropriate, this may include the family/whānau or other representatives”. [↑](#footnote-ref-6)
7. http://www.ncsu.edu/ehs/dot/Bio\_shipping.pdf [↑](#footnote-ref-7)
8. The Ethics Committee of the American Society for Reproductive Medicine says that total payments above US$5,000 to egg donors require justification and sums above US$10,000 are not appropriate:

http://www.asrm.org/uploadedFiles/ASRM\_Content/News\_and\_Publications/Ethics\_Committee\_Reports\_and\_Statements/financial\_incentives.pdf [↑](#footnote-ref-8)
9. ECART must currently use the *Guidelines for Research on Gametes and Non-viable Embryos,* issued by the former National Ethics Committee on Assisted Human Reproduction in 2005. [↑](#footnote-ref-9)
10. http://www.nuffieldbioethics.org/donation [↑](#footnote-ref-10)
11. Lucas N, Rosario R, Shelling AN. New Zealand university students’ knowledge of fertility decline in woman via natural pregnancy and IVF, submitted for publication. [↑](#footnote-ref-11)
12. Hammerberg K, Setter T, et al. 2013. Knowledge about factors that influence fertility among Australians of reproductive age: a population-based survey. *Fertility and Sterility* 999(2): 502–7. [↑](#footnote-ref-12)
13. Velez FF, et al. *Fertility Knowledge Among US Women Currently Using Birth Control or Not Currently Trying to Conceive: Findings from the Fertility IQ 2011 Survey*. Presentation at 2011 meeting of the American Society for Reproductive Medicine. http://www.marketwired.com/press-release/media-alert-new-data-presented-american-society-reproductive-medicine-annual-meeting-1582984.htm [↑](#footnote-ref-13)
14. MacDougall K, Beyene Y, Natchigall RD. 2013. Age shock: misperceptions of the impact of age on fertility before and after IVF in women who conceived after age 40. *Human Reproduction* 28(3): 350–6. [↑](#footnote-ref-14)
15. Bunting L, Tsibulsky I, Boivin J. 2013. Fertility knowledge and beliefs about fertility treatment: findings from the International Fertility Decision-making Study. *Human Reproduction* 28(2): 385–97. [↑](#footnote-ref-15)
16. [www.npesu.unsw.edu.au/data-collection/australian-new-zealand-assisted](http://www.npesu.unsw.edu.au/data-collection/australian-new-zealand-assisted)-reproduction-database-anzard [↑](#footnote-ref-16)
17. The reports for 2009 and 2010 are available on ACART’s website. ACART is currently contracting for the 2011 report. [↑](#footnote-ref-17)
18. Ferraretti AP, Goossens V, Kupka M, et al. 2013. Assisted reproductive technology in Europe, 2009: results generated from European registers by ESHRE. 2013. *Human Reproduction* 28(9): 2318–31. [↑](#footnote-ref-18)
19. Import and export of gametes and embryos: General Directions Ref. 0006, Version 3, 6 April 2010. [↑](#footnote-ref-19)
20. *Guidelines on the Import and Export of Donor Gametes and Embryos Produced from Donor Gametes*. December 2009. [↑](#footnote-ref-20)