133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
+64 4 496 2000

11 April 2019

[redacted]

Response to your request for official information

Thank you for your request for information under the Official Information Act 1982 (the Act) on 12 March 2019 for:

> *"Date scope of request: from 23 September 2017 to the 12 March 2019.*
> *Nature of request: We are seeking copies of all:*
>
> *briefings made to the Minister of Health or Associate Minister of Health regarding assisted reproduction / fertility treatment in NZ. This should include policy advice, thinking / discussion papers that relate to the provision or funding of fertility treatment, changes / potential changes to eligibility criteria, access to fertility treatment, use of or disposal of embryos, donor compensation & access.*
>
> *Officials' notes from conversations with the Minister of Health / Associate Minister Health relating to fertility treatment or assisted reproduction. This includes (but is not limited to) eligibility criteria, use of donors, donor compensation, funding.*
>
> *A list of all papers received or requested by MoH / AMoH regarding assisted reproduction and fertility treatment in NZ."*

Nine documents have been identified within scope of your request. These are itemised in Appendix 1 to this letter, and copies of the documents are enclosed. Where information has been withheld, the grounds under the Act are noted in Appendix 1 and in the relevant document.

I trust that this information fulfils your request. Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request.

Yours sincerely

Keriana Brooking
Deputy Director-General
Health System Improvement and Innovation

MINISTRY OF HEALTH
MANATŪ HAUORA

Appendix 1: List of documents proposed for release

#	Date	Title	Decision on release
1	22 February 2018	Email: Briefing re surrogacy for Minister Clark 2018 February	Released with some information withheld under section 9(2)(a) of the Act to protect personal privacy
2	24 February 2018	HR20180329: Compensation for surrogacy arrangements	Released with some information withheld under section 9(2)(a) of the Act
3	April 2018	HR20180637: Meeting to discuss surrogacy arrangements	Released with some information withheld under section 9(2)(a) of the Act and section 9(2)(f)(iv) of the Act, to maintain the constitutional conventions for the time being which protect the confidentiality of advice tendered by Ministers of the Crown and officials
4	3 May 2019	Email: Fw: Actions from meeting with ACART Chair 2/5/18	Released with some information withheld under section 9(2)(a) of the Act
5	11 May 2018	HR20180924: Advice on gamete (egg and sperm) donations and recent media interest	Released with some information withheld under section 9(2)(a) of the Act of the Act
6	15 May 2018	HR20180973: Law on Research on Embryos and Making the Environment more permissive	Released with some information withheld under section 9(2)(a) of the Act
7	29 January 2019	HR20182140: Request from the Advisory Committee on Assisted Reproductive Technology	Released with some information withheld under section 9(2)(a) of the Act; section 9(2)(f)(iv) of the Act; and section 9(2)(h) of the Act, to maintain legal professional privilege
8	31 January 2019	HR20182242: Compensation for egg and sperm donors	Released with some information withheld under section 9(2)(a) of the Act; section 9(2)(f)(iv) of the Act; and section 9(2)(h) of the Act. Appendix 1 withheld under section 18(d) of the Act as publicly available on the ACART website Appendix 3 withheld under section 9(2)(b)(ii) on the grounds that releasing the information would be likely to prejudice the commercial position of the person who supplied the information
9	21 February 2019	Official's notes from meeting with Minister	Released in full

Sent By: Hayley Robertson/MOH on 22/02/2018 4:31:12 p.m.
To: john.hobbs@parliament.govt.nz
Copy To: Philippa Bascand/MOH, Martin Kennedy/MOH
Subject: Briefing re surrogacy for Minister Clark 2018 February

Hello John,

Attached is a briefing for Minister Clark regarding payment for surrogacy arrangements, paper copies to follow in the bag tomorrow. Pasted below is the relevant email trail that led to this briefing.

HR report Minister Clark Surrogacy.docx

Media article: 22022018163433-0001.pdf

Kind regards,

Hayley Robertson | Policy Analyst | Ethics | Protection, Regulation and Assurance | Ministry of Health
DDI: 04 816 4353

MINISTRY OF HEALTH
MANATŪ HAUORA

From: Tara Forde <Tara.Forde@parliament.govt.nz>

To: Sarah Webster <Sarah.Webster@parliament.govt.nz>,
Cc: "Charlotte_Gendall@moh.govt.nz" <Charlotte_Gendall@moh.govt.nz>
Date: 16/02/2018 03:12 p.m.
Subject: surrogacy issues

I have supplied the Herald with the below lines:

“Surrogacy is important for New Zealand families, particularly those who have struggled with fertility or who have two same sex parents.
“These families, the parents and the children, are important to me.
“There needs to be further work undertaken to work out what is a “reasonable expense” for women who act as a surrogate.
“I understand that the Ministry of Health is working towards providing the responsible Minister with advice about ACART’s recommendations.

I have also discussed this with Minister Clark’s adviser Julia.

Can I please get a timeline from the Ministry about providing the Minister with advice so that we can proceed?
I would like this by 23/02/2018.

Thanks
Tara

Tara Forde | **Ministerial Adviser - Press and Policy**
Office of Hon Julie Anne Genter | Women | Associate Health | Associate Transport
6.14 Bowen House, Parliament Buildings, 80 Lambton Quay | Private Bag 18041 | Wellington 6160 | New Zealand
M: s 9(2)(a)
E: tara.forde@parliament.govt.nz

MINISTRY OF HEALTH
MANATŪ HAUORA

Database number: 20180329

Security classification: In-Confidence

File number: AD62-14-2018
Action required by: routine

Compensation for surrogacy arrangements

To: Hon Dr David Clark, Minister of Health

Purpose

1. This report informs you of the Ministry of Health's (the Ministry) position on surrogates receiving valuable consideration and explains why this matter has been brought to your attention.
2. On 16 February 2018 Associate Minister Julie Anne Genter asked the Ministry to advise her when advice would be received about what constitutes a "reasonable and necessary expense" for women who act as surrogate mothers.
3. Associate Minister Genter requested this information after being advised that the Ministry would provide advice about compensation for gamete donors. This was conflated with the issue of compensation for surrogates in New Zealand in a recent media article about surrogacy published on Saturday 17 February 2017. t quoted Associate Minister Genter as saying the Ministry would provide such advice. The media article is attached as **Appendix One**.
4. We have provided this information to you as the area of ethics advice and decisions on surrogacy applications on assisted human reproductive technology sit within your portfolio.

ACART's original advice

5. The Advisory Committee on Assisted Reproductive Technology (ACART) advised the former Associate Minister in 2015 on *Requirements for importing and exporting in vitro gametes and embryos for human reproductive research and human assisted reproductive technology,* and recommended that the Ministry carry out work under the remit of the HART Act that would allow:

    a) people to be compensated for their sperm or egg donations to address the gamete shortage in New Zealand and,

    b) people to be compensated for other reasonable necessary expenses (such as time off work) incurred as a result of a voluntary surrogacy arrangement.

Associate Minister Genter received advice

6. The advice to Associate Minister Genter, that the Ministry would provide advice about compensation for surrogates, was taken from the 2014/15 annual report of ACART. That advice had subsequently been responded to by the Ministry in its advice to the former Associate Minister in 2016. The Ministry's position is summarised below.

The Ministry's advice about compensating surrogates

7. Providers can be reimbursed for reasonable and necessary expenses under s.14 of the Human Assisted Reproductive Technology Act 2004 (HART Act). These reimbursements are for specific services only, and may be paid to the service provider(s), not to the surrogate herself. There is a

Contacts:	Philippa Bascand, Manager Ethics Committees, Protection Regulation and Assurance.	s 9(2)(a)

prohibition on commercial surrogacy arrangements or for any form of valuable consideration to be exchanged outside the permitted expenses listed under s.14, with significant penalties attached for breaches.

8. The HART Act does not allow for surrogates to receive any compensation for their time or risk in carrying a pregnancy. Any changes to this policy would require a legislative change to the HART Act.

9 In December 2016, the Ministry submitted parallel advice to Associate Minister Dunne on ACART's recommendations. The Ministry's position is that the narrow scope of reimbursement for reasonable and necessary expenses provided for in surrogacy arrangements are already sufficient.

10. In reviewing applications for surrogacy, the Ethics Committee on Assisted Reproductive Technology (ECART) is bound by the provisions of the HART Act, the HART Order, and the Committee's Terms of Reference. Applicants attest to entering into voluntary arrangements as surrogates and ECART relies on such attestations when reviewing ethics applications.

11. In regards to sperm and egg donations, the Ministry has recently written to all private fertility providers advising them of the limitations around valuable consideration under s.13 of the HART Act.

No further advice on compensation for surrogates

12. While the Ministry is not currently progressing any further information on this particular matter we would be willing to brief you on the subject given the complex arrangements and public interest in the matter.

Recommendation

It is recommended that you:

a)	**Agree** to meet with officials to discuss previous advice and the complexity of arrangements that exist when considering compensation for surrogates and gamete donors, given the ongoing public interest.	**Yes/No**
b)	**Note** that advice was provided to the former Associate Minister in December 2016 and that public interest in this matter is on-going.	**Yes/No**
c)	**Agree** to forward this advice to Associate Minister Genter for her information	**Yes/No**

Dr Stewart Jessamine
Director
Protection, Regulation and Assurance.

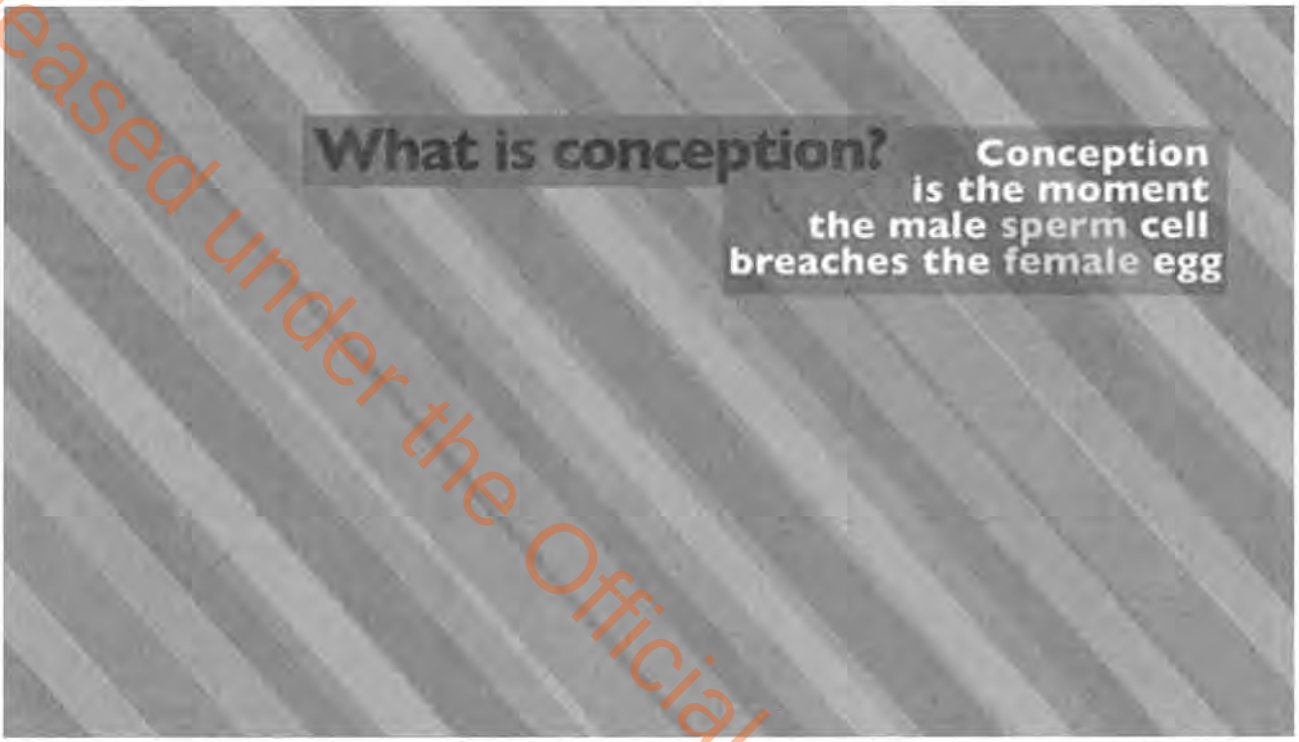
END.

LIFESTYLE

Calls for surrogates to be compensated - as Toni Street announces baby news

17 Feb, 2018 5:00am

11 minutes to read



A video explaining conception during sexual reproduction.

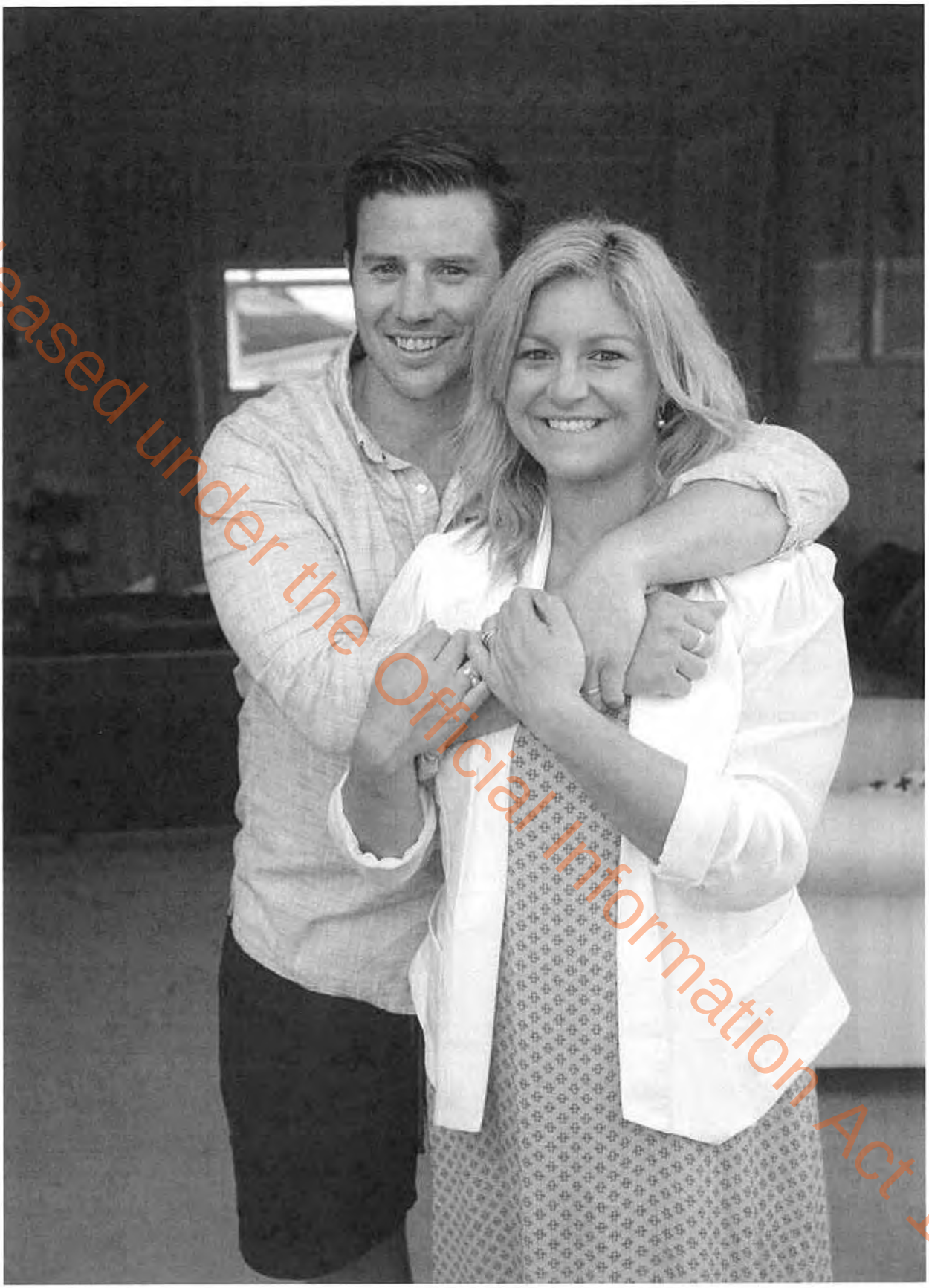
By: **Anna Leask**
Anna Leask is senior police reporter for the New Zealand Herald.
anna.leask@nzherald.co.nz @AnnaLeask

A leading surrogacy lawyer and doctor have called for a law change to allow compensation to be paid to women who bear a baby for someone else.

Broadcaster Toni Street last night went public on how she and her husband Matt France's third child is being carried by a surrogate – Street's best friend Sophie Braggins.

The couple turned to a surrogate after Street was diagnosed with a rare and incurable auto-immune condition shortly after she gave birth to Mackenzie in mid-2015.

Zandra Wackenier, who has represented surrogate mothers and "intending parents" in dozens of applications to authorities, says she supports a continuation of commercial surrogacy in New Zealand, but she also believes surrogates should be compensated for their out-of-pocket expenses.



Toni Street and husband Matt France are expecting a baby via a surrogate. Photo / Doug Sherring

"The big one is to be put back in the position she [the surrogate] would have been in but for the surrogacy," Wackenier told the Weekend Herald.

"If she needs to take time off work because she ends up having a caesarean section or gets pre-eclampsia and is off work, the loss of earnings should be covered."

The only payments permitted by the Human Assisted Reproductive Technology Act are "reasonable and necessary expenses" for counselling, fertility-related treatment, and the surrogate's legal advice.

Fertility specialist Dr Mary Birdsall said many intending parents interpreted the "necessary expenses" of treatment to include medical care for the surrogate, such as hiring a private obstetrician, but this was a legal grey area.

She supported a change to allow intending parents to compensate a surrogate for loss of income.

This would be in line with the Government's approval last year of loss-of-earnings compensation to be paid to live kidney or liver donors - except that live organ donors would be paid by the state.

Related articles:

LIFESTYLE

Toni Street announces surrogacy baby news

16 Feb, 2018 5:30pm
2 minutes to read

LIFESTYLE

Baby joy for Toni Street - via surrogacy

17 Feb, 2018 5:00am
4 minutes to read

Toni Street and her best mate Sophie Braggins. Braggins is acting as Street's surrogate and carrying her third child. Photo / Supplied

Associate Health Minister Julie Anne Genter is awaiting advice from officials on compensation for surrogates.

"There needs to be further work undertaken to work out what is a 'reasonable expense' for women who act as a surrogate," Genter said.

"Surrogacy is important for New Zealand families, particularly those who have struggled with fertility or who have two same sex parents."

On average since 2004 the Ethics Committee on Assisted Reproductive Technology has approved 17 applications a year. The provisional annual tally has been increasing since 2013/14 and reached 30 in 2016/17.

Street revealed her exciting baby news on Friday night.

In an exclusive interview in today's Weekend Herald, she and France have talked through the surrogacy and the health battle that lead to the decision.

The couple, both 34, are already parents to two daughters - Juliette, 5, and Mackenzie, 2-and-a-half.

They always planned to add to their brood but their dream of a big family was almost cut short when Street was diagnosed with a rare and incurable auto-immune condition.

Shortly after Mackenzie's birth Street became severely unwell - so sick she was in the early stages of organ failure.

Specialists revealed she had life-threatening Churg-Strauss syndrome - which causes auto-immune systems to overreact, leading to allergies, tissue damage and death.

Street underwent six months of intensive treatment and was facing a course of chemotherapy - but managed to get her symptoms under control and is now in remission.

She may be fit and well now, but the syndrome can reappear at any time without warning.

Last year she sat down with her doctor to discuss having a third baby.

"I said to him, can I have a third child and he said 'I don't think you should'," Street said.

"My doctor said I'd be risking my life, risking not being around for Juliette and Mackenzie and I decided I can't do that to them - so I wouldn't have a third child."

Street said the decision had a surprising impact on her.

"I tried to reason with myself that it wasn't happening for me, I wasn't having a third baby - but I felt really down," she revealed.

"I didn't expect that, I thought it would just go away, but I felt this constant nagging, kind of like I was grieving the fact that I couldn't have a third baby."

France said the news also hit him hard.

"Ideally, we would have liked to have more kids, but I just wanted Toni well," he said.

"I could see Toni was grieving the fact that she wouldn't be able to have any more babies."

It was then that Braggins made an offer Street and France could not refuse.

She had raised the idea of being their surrogate in the past, but Street had never seriously entertained it, thinking she would be able to bear more children.

Braggins, who has been Street's best friend since intermediate, persisted with her offer.

"I had mixed emotions," Street said.

"It's a massive thing for someone to do for you - this is my best friend having to go through another pregnancy, me having to watch her be sick, deliver a child and recover.

"All of that just so I could have another child, it was a big decision.

"I initially dismissed it, but Sophie came back and said 'I am serious, I really want to do this' and she bombarded me with text messages to reiterate that this wasn't a pie in the sky offer.

"So, we sat down to have a serious discussion about a year ago."

Braggins, the chief executive of a New Plymouth law firm and the chair of the Taranaki Chamber of Commerce, is now 14 weeks pregnant with Street and France's son and is due in August.

Toni Street, with husband Matthew France, at home in Auckland. Photo / Doug Sherring

She is married to Michael Braggins and the couple have two children of her own.

The couple attended university with Street and France and the four lived together when they all moved to Auckland to pursue careers.

Braggins told the Weekend Herald that she was thrilled to be able to help her friends.

"I'm over the moon that this is happening for my most special friends, Toni and Matt," she said.

"It's been a wonderful journey so far"

Street and France also wanted to share their story to raise awareness around surrogacy in New Zealand and clear up any misconceptions about their choice to go down that path.

They explained that the approval phase of the process took about six months.

The couples had to undergo counselling - both together and individually - and meet with specialists and lawyers to ensure each person in the process was up to it.

Then, Street and France had to be vetted.

The way New Zealand law works, even though the baby is biologically their own, Braggins will be the legal guardian when he is born.

Street and France then have to adopt their son.

As with any adoption, they had to be screened by Oranga Tamariki, the Ministry for Children, and police.

Street said the first six months was a "long drawn out" process and it was a relief to get approval from the authorities.

After that though, they had to go through the IVF and implantation process.

After IVF, Street and France had just one viable embryo and were told that the chances of it taking in Braggins' womb were about 40 per cent.

Once implantation happened, another highly risky process that could have ended their baby dream, they had an agonising wait to find out if they were pregnant.

"We only had one shot," said Street.

"We were extremely lucky to even have that one embryo so it was a very nervous wait."

The news was good, and they were thrilled to share it with close family and friends.

"It was kind of like we needed a whole lot of little miracles to happen to get to that point - and we got there," said France.

The couple are relieved that they can finally share their big secret - and their daughters cannot wait to tell everyone who will listen about their new baby brother.

"I never thought I would have a boy," said Street.

"That was the icing on the cake for us, we have the two girls and to have a boy and

complete the family was just a miracle really."

Street said Braggins had suffered some morning sickness, but was feeling good now.

She said it was an incredible bonding experience having her best friend as a surrogate - but she also had to find a balance between being interested and supportive of the pregnancy and hovering like a nervous parent-to-be.

It is illegal for Street and France to pay Braggins any remuneration for being a surrogate.

But they can pay any and all medical costs.

"We would love to pay Sophie and her family back for this, not in money but by doing something amazing for them.

"But in reality, what do you give someone who is making this kind of sacrifice for you, we can't think of anything yet that we can do for them to show how grateful we are," said Street.

"I said to her 'you're going through nine months of pregnancy and at the end you don't get a baby out of it, you don't get any joy'

Toni Street is co-host of the The Hits popular morning radio show. Photo / Doug Sherring

"She said 'yes I do, the reason I am going through this is to give you your much-wanted third child'.

"I think it brings her a lot of joy to do this for us… she is a very special person to be doing this for us."

They have hired an obstetrician in New Plymouth and another in Auckland - the same one they had for Juliette and Mackenzie.

Braggins had her first scan in New Plymouth, which Street watched over a Facebook live stream and was able to ask questions and talk to her best mate.

The next scan will be in Auckland and Street and France are excited to attend.

Street will be at the birth, but whether France or Braggins' husband will join are

undecided.

Street said she felt "incredibly calm" about the pregnancy and baby.

"I thought I would feel find it really hard not actually being pregnant, but I don't find it that strange," she said.

France said it was "weird" for him knowing he was having a baby but not having a wife with a pregnant belly.

But he was used to the idea and just excited for August to roll around.

The couple have had a positive reaction to their news with most people they have told asking many questions.

"There have been tears from our close friends, and others have just been shell shocked," said Street.

"I think most people who know how sick Toni really was after Mackenzie are extremely accepting of this, and relieved," France added.

"It was pretty dark times for that six months and the next 18 months while she was having treatment weren't easy either."

Their biggest supporters for the newest baby France were their daughters.

"Mackenzie is just overjoyed that she's going to be a big sister," Street laughed.

"She's asking when the baby can sleep in her big girl bed, when the baby can play with her toys and when she can give him the bottle.

"Juliette is a lot more inquisitive, she asked 'what does this mean for our family' - but she loves the fact that it's a boy.

"We took them out last week and told them they could buy one little present each for the baby and we ended up with a basket filled with everything blue they could find."

Street and France said the journey to announcing the pregnancy was long, drawn out and intense - for them and the Braggins'.

But the two couples, and their families who they are extremely close to, are now enjoying the pregnancy together and can't wait to meet baby France.

"I feel like we have gotten to the point now that we can get excited," Street said.

"It's been quite an anxious time because it was such an unknown process - being vetted, working with lawyers, counselling - but now I feel like we can be excited about this.

"I'm having a child that I'm not carrying, so I'm not going into this thinking it will be the

same as my other pregnancies.

"Obviously I would have loved to carry my own child, go through a pregnancy again and deliver it myself - but when I think about what I am getting at the end of it all.... As long as Sophie is ok and the baby is ok - I'm happy. "

- Additional reporting by Martin Johnston

MINISTRY OF HEALTH
MANATŪ HAUORA

Database number: 20180329

Security classification: In-Confidence

File number: AD62-14-2018
Action required by: routine

Compensation for surrogacy arrangements

To: Hon Dr David Clark, Minister of Health

Purpose

1. This report informs you of the Ministry of Health's (the Ministry) position on surrogates receiving valuable consideration and explains why this matter has been brought to your attention.
2. On 16 February 2018 Associate Minister Julie Anne Genter asked the Ministry to advise her when advice would be received about what constitutes a "reasonable and necessary expense" for women who act as surrogate mothers.
3. Associate Minister Genter requested this information after being advised that the Ministry would provide advice about compensation for gamete donors. This was conflated with the issue of compensation for surrogates in New Zealand in a recent media article about surrogacy published on Saturday 17 February 2017. It quoted Associate Minister Genter as saying the Ministry would provide such advice. The media article is attached as **Appendix One**.
4. We have provided this information to you as the area of ethics advice and decisions on surrogacy applications on assisted human reproductive technology sit within your portfolio.

ACART's original advice

5. The Advisory Committee on Assisted Reproductive Technology (ACART) advised the former Associate Minister in 2015 on *Requirements for importing and exporting in vitro gametes and embryos for human reproductive research and human assisted reproductive technology,* and recommended that the Ministry carry out work under the remit of the HART Act that would allow:

    a) people to be compensated for their sperm or egg donations to address the gamete shortage in New Zealand and,

    b) people to be compensated for other reasonable necessary expenses (such as time off work) incurred as a result of a voluntary surrogacy arrangement.

Associate Minister Genter received advice

6. The advice to Associate Minister Genter, that the Ministry would provide advice about compensation for surrogates, was taken from the 2014/15 annual report of ACART. That advice had subsequently been responded to by the Ministry in its advice to the former Associate Minister in 2016. The Ministry's position is summarised below.

The Ministry's advice about compensating surrogates

7. Providers can be reimbursed for reasonable and necessary expenses under s.14 of the Human Assisted Reproductive Technology Act 2004 (HART Act). These reimbursements are for specific services only, and may be paid to the service provider(s), not to the surrogate herself. There is a

Contacts:	Philippa Bascand, Manager Ethics Committees, Protection Regulation and Assurance.	s 9(2)(a)

prohibition on commercial surrogacy arrangements or for any form of valuable consideration to be exchanged outside the permitted expenses listed under s.14, with significant penalties attached for breaches.

8. The HART Act does not allow for surrogates to receive any compensation for their time or risk in carrying a pregnancy. Any changes to this policy would require a legislative change to the HART Act.

9. In December 2016, the Ministry submitted parallel advice to Associate Minister Dunne on ACART's recommendations. The Ministry's position is that the narrow scope of reimbursement for reasonable and necessary expenses provided for in surrogacy arrangements are already sufficient.

10. In reviewing applications for surrogacy, the Ethics Committee on Assisted Reproductive Technology (ECART) is bound by the provisions of the HART Act, the HART Order, and the Committee's Terms of Reference. Applicants attest to entering into voluntary arrangements as surrogates and ECART relies on such attestations when reviewing ethics applications.

11. In regards to sperm and egg donations, the Ministry has recently written to all private fertility providers advising them of the limitations around valuable consideration under s.13 of the HART Act.

No further advice on compensation for surrogates

12. While the Ministry is not currently progressing any further information on this particular matter we would be willing to brief you on the subject given the complex arrangements and public interest in the matter.

Recommendation

It is recommended that you:

a)	**Agree** to meet with officials to discuss previous advice and the complexity of arrangements that exist when considering compensation for surrogates and gamete donors, given the ongoing public interest.	**Yes/No**
b)	**Agree** to forward this advice to Associate Minister Genter for her information	**Yes/No**
c)	**Note** that advice was provided to the former Associate Minister in December 2016 and that public interest in this matter is on-going.	

Dr Stewart Jessamine
Director
Protection, Regulation and Assurance.

Ministers signature:

Date: 24/2/18

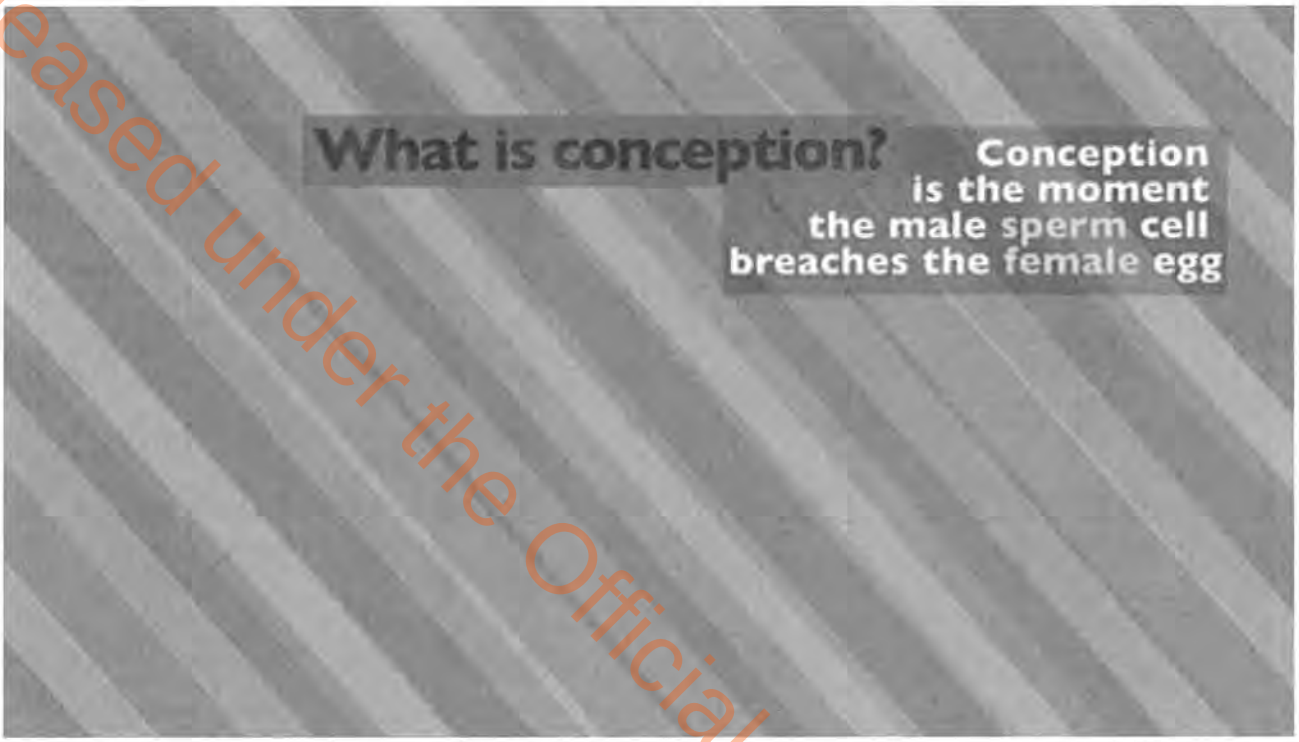
END.

LIFESTYLE

Calls for surrogates to be compensated - as Toni Street announces baby news

17 Feb, 2018 5:00am

11 minutes to read



A video explaining conception during sexual reproduction.

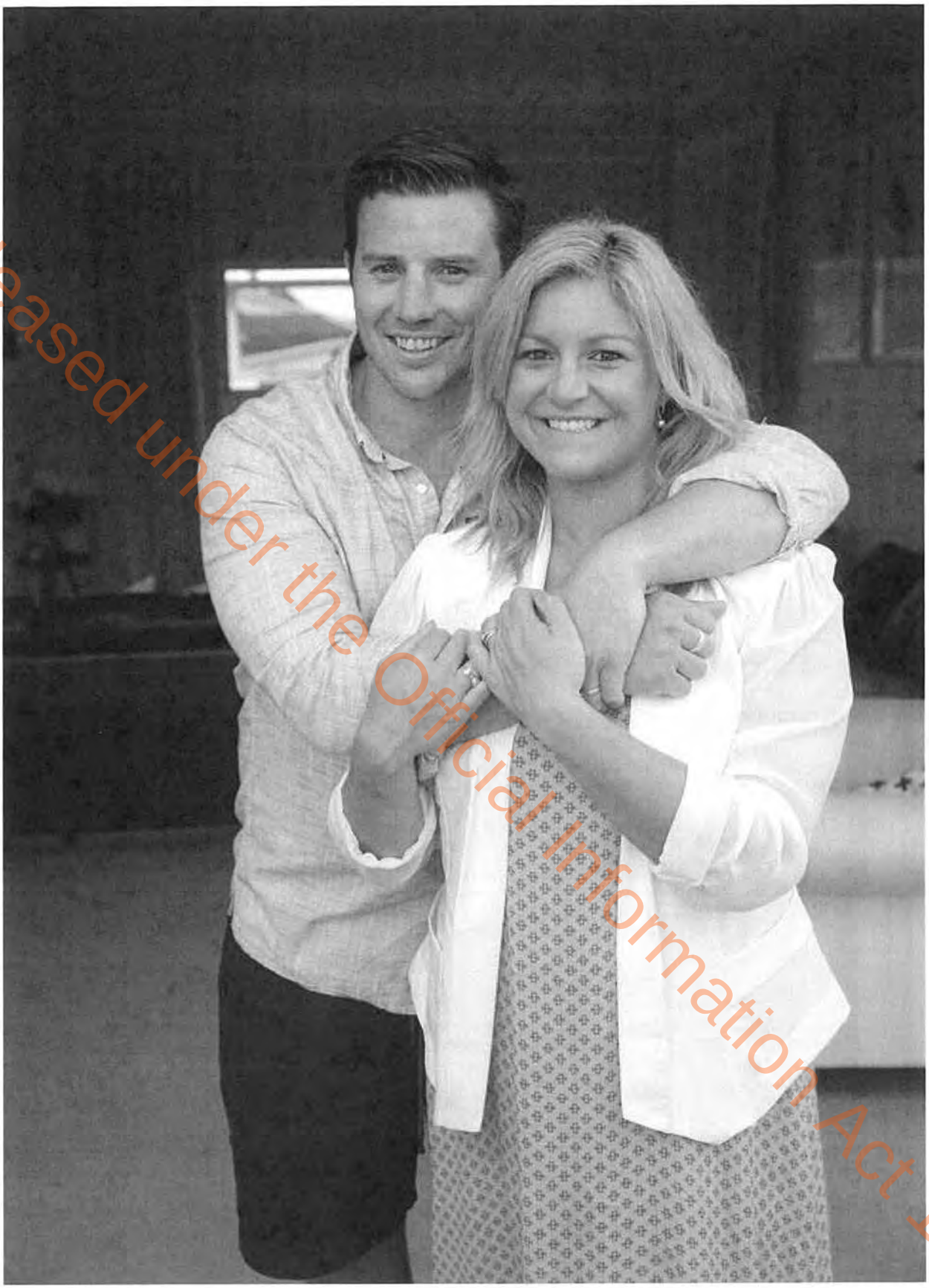
By: **Anna Leask**
Anna Leask is senior police reporter for the New Zealand Herald.
anna.leask@nzherald.co.nz @AnnaLeask

A leading surrogacy lawyer and doctor have called for a law change to allow compensation to be paid to women who bear a baby for someone else.

Broadcaster Toni Street last night went public on how she and her husband Matt France's third child is being carried by a surrogate – Street's best friend Sophie Braggins.

The couple turned to a surrogate after Street was diagnosed with a rare and incurable auto-immune condition shortly after she gave birth to Mackenzie in mid-2015.

Zandra Wackenier, who has represented surrogate mothers and "intending parents" in dozens of applications to authorities, says she supports a continuation of commercial surrogacy in New Zealand, but she also believes surrogates should be compensated for their out-of-pocket expenses.



Toni Street and husband Matt France are expecting a baby via a surrogate. Photo / Doug Sherring

"The big one is to be put back in the position she [the surrogate] would have been in but for the surrogacy," Wackenier told the Weekend Herald.

"If she needs to take time off work because she ends up having a caesarean section or gets pre-eclampsia and is off work, the loss of earnings should be covered."

The only payments permitted by the Human Assisted Reproductive Technology Act are "reasonable and necessary expenses" for counselling, fertility-related treatment, and the surrogate's legal advice.

Fertility specialist Dr Mary Birdsall said many intending parents interpreted the "necessary expenses" of treatment to include medical care for the surrogate, such as hiring a private obstetrician, but this was a legal grey area.

She supported a change to allow intending parents to compensate a surrogate for loss of income.

This would be in line with the Government's approval last year of loss-of-earnings compensation to be paid to live kidney or liver donors - except that live organ donors would be paid by the state.

Related articles:

LIFESTYLE

Toni Street announces surrogacy baby news

16 Feb, 2018 5:30pm
2 minutes to read

LIFESTYLE

Baby joy for Toni Street - via surrogacy

17 Feb, 2018 5:00am
4 minutes to read

Toni Street and her best mate Sophie Braggins. Braggins is acting as Street's surrogate and carrying her third child. Photo / Supplied

Associate Health Minister Julie Anne Genter is awaiting advice from officials on compensation for surrogates.

"There needs to be further work undertaken to work out what is a 'reasonable expense' for women who act as a surrogate," Genter said.

"Surrogacy is important for New Zealand families, particularly those who have struggled with fertility or who have two same sex parents."

On average since 2004 the Ethics Committee on Assisted Reproductive Technology has approved 17 applications a year. The provisional annual tally has been increasing since 2013/14 and reached 30 in 2016/17.

Street revealed her exciting baby news on Friday night.

In an exclusive interview in today's Weekend Herald, she and France have talked through the surrogacy and the health battle that lead to the decision.

The couple, both 34, are already parents to two daughters - Juliette, 5, and Mackenzie, 2-and-a-half.

They always planned to add to their brood but their dream of a big family was almost cut short when Street was diagnosed with a rare and incurable auto-immune condition.

Shortly after Mackenzie's birth Street became severely unwell - so sick she was in the early stages of organ failure.

Specialists revealed she had life-threatening Churg-Strauss syndrome - which causes auto-immune systems to overreact, leading to allergies, tissue damage and death.

Street underwent six months of intensive treatment and was facing a course of chemotherapy - but managed to get her symptoms under control and is now in remission.

She may be fit and well now, but the syndrome can reappear at any time without warning.

Last year she sat down with her doctor to discuss having a third baby.

"I said to him, can I have a third child and he said 'I don't think you should'," Street said.

"My doctor said I'd be risking my life, risking not being around for Juliette and Mackenzie and I decided I can't do that to them - so I wouldn't have a third child."

Street said the decision had a surprising impact on her.

"I tried to reason with myself that it wasn't happening for me, I wasn't having a third baby - but I felt really down," she revealed.

"I didn't expect that, I thought it would just go away, but I felt this constant nagging, kind of like I was grieving the fact that I couldn't have a third baby."

France said the news also hit him hard.

"Ideally, we would have liked to have more kids, but I just wanted Toni well," he said.

"I could see Toni was grieving the fact that she wouldn't be able to have any more babies."

It was then that Braggins made an offer Street and France could not refuse.

She had raised the idea of being their surrogate in the past, but Street had never seriously entertained it, thinking she would be able to bear more children.

Braggins, who has been Street's best friend since intermediate, persisted with her offer.

"I had mixed emotions," Street said.

"It's a massive thing for someone to do for you - this is my best friend having to go through another pregnancy, me having to watch her be sick, deliver a child and recover.

"All of that just so I could have another child, it was a big decision.

"I initially dismissed it, but Sophie came back and said 'I am serious, I really want to do this' and she bombarded me with text messages to reiterate that this wasn't a pie in the sky offer.

"So, we sat down to have a serious discussion about a year ago."

Braggins, the chief executive of a New Plymouth law firm and the chair of the Taranaki Chamber of Commerce, is now 14 weeks pregnant with Street and France's son and is due in August.

Toni Street, with husband Matthew France, at home in Auckland. Photo / Doug Sherring

She is married to Michael Braggins and the couple have two children of her own.

The couple attended university with Street and France and the four lived together when they all moved to Auckland to pursue careers.

Braggins told the Weekend Herald that she was thrilled to be able to help her friends.

"I'm over the moon that this is happening for my most special friends, Toni and Matt," she said.

"It's been a wonderful journey so far"

Street and France also wanted to share their story to raise awareness around surrogacy in New Zealand and clear up any misconceptions about their choice to go down that path.

They explained that the approval phase of the process took about six months.

The couples had to undergo counselling - both together and individually - and meet with specialists and lawyers to ensure each person in the process was up to it.

Then, Street and France had to be vetted.

The way New Zealand law works, even though the baby is biologically their own, Braggins will be the legal guardian when he is born.

Street and France then have to adopt their son.

As with any adoption, they had to be screened by Oranga Tamariki, the Ministry for Children, and police.

Street said the first six months was a "long drawn out" process and it was a relief to get approval from the authorities.

After that though, they had to go through the IVF and implantation process.

After IVF, Street and France had just one viable embryo and were told that the chances of it taking in Braggins' womb were about 40 per cent.

Once implantation happened, another highly risky process that could have ended their baby dream, they had an agonising wait to find out if they were pregnant.

"We only had one shot," said Street.

"We were extremely lucky to even have that one embryo so it was a very nervous wait."

The news was good, and they were thrilled to share it with close family and friends.

"It was kind of like we needed a whole lot of little miracles to happen to get to that point - and we got there," said France.

The couple are relieved that they can finally share their big secret - and their daughters cannot wait to tell everyone who will listen about their new baby brother.

"I never thought I would have a boy," said Street.

"That was the icing on the cake for us, we have the two girls and to have a boy and

complete the family was just a miracle really."

Street said Braggins had suffered some morning sickness, but was feeling good now.

She said it was an incredible bonding experience having her best friend as a surrogate - but she also had to find a balance between being interested and supportive of the pregnancy and hovering like a nervous parent-to-be.

It is illegal for Street and France to pay Braggins any remuneration for being a surrogate.

But they can pay any and all medical costs.

"We would love to pay Sophie and her family back for this, not in money but by doing something amazing for them.

"But in reality, what do you give someone who is making this kind of sacrifice for you, we can't think of anything yet that we can do for them to show how grateful we are," said Street.

"I said to her 'you're going through nine months of pregnancy and at the end you don't get a baby out of it, you don't get any joy'

Toni Street is co-host of the The Hits popular morning radio show. Photo / Doug Sherring

"She said 'yes I do, the reason I am going through this is to give you your much-wanted third child'.

"I think it brings her a lot of joy to do this for us… she is a very special person to be doing this for us."

They have hired an obstetrician in New Plymouth and another in Auckland - the same one they had for Juliette and Mackenzie.

Braggins had her first scan in New Plymouth, which Street watched over a Facebook live stream and was able to ask questions and talk to her best mate.

The next scan will be in Auckland and Street and France are excited to attend.

Street will be at the birth, but whether France or Braggins' husband will join are

undecided.

Street said she felt "incredibly calm" about the pregnancy and baby.

"I thought I would feel find it really hard not actually being pregnant, but I don't find it that strange," she said.

France said it was "weird" for him knowing he was having a baby but not having a wife with a pregnant belly.

But he was used to the idea and just excited for August to roll around.

The couple have had a positive reaction to their news with most people they have told asking many questions.

"There have been tears from our close friends, and others have just been shell shocked," said Street.

"I think most people who know how sick Toni really was after Mackenzie are extremely accepting of this, and relieved," France added.

"It was pretty dark times for that six months and the next 18 months while she was having treatment weren't easy either."

Their biggest supporters for the newest baby France were their daughters.

"Mackenzie is just overjoyed that she's going to be a big sister," Street laughed.

"She's asking when the baby can sleep in her big girl bed, when the baby can play with her toys and when she can give him the bottle.

"Juliette is a lot more inquisitive, she asked 'what does this mean for our family' - but she loves the fact that it's a boy.

"We took them out last week and told them they could buy one little present each for the baby and we ended up with a basket filled with everything blue they could find."

Street and France said the journey to announcing the pregnancy was long, drawn out and intense - for them and the Braggins'.

But the two couples, and their families who they are extremely close to, are now enjoying the pregnancy together and can't wait to meet baby France.

"I feel like we have gotten to the point now that we can get excited," Street said.

"It's been quite an anxious time because it was such an unknown process - being vetted, working with lawyers, counselling - but now I feel like we can be excited about this.

"I'm having a child that I'm not carrying, so I'm not going into this thinking it will be the

same as my other pregnancies.

"Obviously I would have loved to carry my own child, go through a pregnancy again and deliver it myself - but when I think about what I am getting at the end of it all.... As long as Sophie is ok and the baby is ok - I'm happy. "

- Additional reporting by Martin Johnston

MINISTRY OF HEALTH
MANATŪ HAUORA

Database number: 20180637

Security classification: In-Confidence

Quill record number: H201801311
File number: AD62-14-18
Action required by: N/A

Meeting to discuss surrogacy arrangements

To: Hon Dr David Clark, Minister of Health
Hon Julie Anne Genter, Minister of Health

Background

1. You are scheduled to meet Ms Philippa Bascand, Manager of Ethics, on 30 April 2018 from 4.30pm to 5.00pm to discuss the public interest in payment for surrogacy arrangements, and possible responses.

2. On 22 February 2018, the Ministry of Health (the Ministry) provided you with a health report regarding the current position surrounding payment to surrogates in response to a request from Minister Genter in her capacity as Minister for Women's Affairs (HR 20180329 refers). Minister Genter had asked for advice on what constitutes 'reasonable expenses' for women who act as surrogate mothers.

The Ministry's position and current legislation

3. Media interest and reporting concerning payments in assisted reproductive technology sometimes confuses payments for surrogacy arrangements with payments for sperm or egg donations.

4. The Human Assisted Reproductive Technology Act 2004 (HART Act) provides that:

   a) S.13: no person can be paid for their donation of eggs or sperm to another person. The Ministry's position is that this prohibition includes reimbursement for any expenses incurred as part of a donation.

   b) S.14: providers can be reimbursed for reasonable and necessary expenses incurred as part of the surrogacy process. These reimbursements are for specific services only (such as specialist medical appointments) and must be paid directly to the service provider(s), not to the surrogate herself.

5. Any changes to payments to sperm or egg donors, or additional payments to surrogates (i.e. other than the reimbursements that are already allowed) for carrying a pregnancy would require a change to sections 13 & 14 of the HART Act.

The sector is implementing their own measures for gamete donations

6. The media reported in 2016 that some fertility providers are implementing their own measures to address the shortage of egg and sperm donors in New Zealand by reimbursing them up to $2000 for costs and risk associated with their gamete donation. The Ministry has written to all providers reiterating the legislative requirements, and advising that in the event of a complaint legal action may be taken.

7. Similarly, the Ministry could readily issue advice to clinics on what constitutes reasonable and necessary expenses in surrogacy arrangements.

Contacts:	Philippa Bascand, Manager of Ethics, Protection, Regulation and Assurance.	s 9(2)(a)

Database number: 20180637

On-going interest and possible options

8. Surrogacy in New Zealand is frequently reported in the media with the most recent high profile article following TV presenter Toni Street using surrogacy to have her third child.

9. The former Associate Minister of Health agreed the Ministry should undertake the policy work to scope the effectiveness and parameters of reimbursing individuals for their sperm or egg donations, and for consistency, to also look at reimbursements in surrogacy arrangements. Because of competing priorities and internal restructuring, this work has not yet been undertaken.

10. s 9(2)(f)(iv) [redacted]

END.

Sent By: Philippa Bascand/MOH on 3/05/2018 1:59:41 p.m.
To: john.hobbs@parliament.govt.nz
Copy To:
Subject: Fw: Actions from meeting with ACART Chair 2/5/18 and MOH 3/5/18

Hi John ,

In addition to the items below ACART will add to their work programme a shorter project on advice on amending the provisions in the HART Act on extended storage of gametes which is resource intensive for ECART for little or no benefit (dependent on the decision to proceed on the research work below proceeding in some form or not).

3 May 2018 Actions from meeting today:

The Ministry to prepare advice for the Minister on options for and levels of compensation for donors of gametes and to work with the sector on this - and any spillover effects for surrogates - and what changes to the HART Act and Order may be necessary to give effect to any such changes - being mindful of balance between altruistic gifting, compensatory payments versus incentives (effects on equity) , and what is happening in like jurisdictions in terms of levels of compensation and median wage levels; and noting the law changes to live organ donation and compensation.

Further discussion with the Minister on the need for updating the law - either via amendment to address specific issues as above, or a major review. Will discuss with H Legal internally. ACART recommended a full review at their meeting.

If this is all satisfactory I will advise staff accordingly to proceed on the advice.

Regards
Philippa

Philippa Bascand
Manager, Ethics Committees
Protection, Regulation and Assurance
email: Philippa_Bascand@moh.govt.nz
Phone: 8162030
Cellphone s 9(2)(a)

Bascand_Philippa.vcf

Subject: Actions from meeting with ACART Chair 2/5/18

Hi John

just to confirm the actions from the meeting today:

The Ministry is to provide advice on which (like) jurisdictions have [recently] engaged in changing/clarifying the law on research from non-viable embryos to viable embryos or making the research environment more permissive? to be provided before the Minister attends the Commonwealth Health Ministers' meeting in Geneva. Include any thoughts from Maori on their views on the ethics of the matter (this will inform ACART's work below)

The Ministry is to provide advice on which (like) urisdictions have [recently] engaged in changing/clarifying the law on research from non-viable embryos to viable embryos or making the research environment more permissive? to be provided before the Minister attends the Commonwealth Health Ministers' meeting in Geneva. Include any thoughts from Maori on their views on the ethics of the matter (this will inform ACART's work below)

Advice from the Ministry on what advice, if any, should be issued to fertility clinics in relation to providing gender equity services in particular in relation to donating sperm or eggs (in compliance with the Human Rights Act) and whether there is an issue with the HART Act in this respect (there is not).

The Minister would like a regular meeting set up six monthly with the Chair of ACART.

ACART will write a further letter to the Minister in regard to the scope of work in relation to amending the guidelines on research on non-viable embryos

Discussion was had about the necessity of review of the HART Act but will be discussed further at the next meeting.

Philippa

Philippa Bascand
Manager, Ethics Committees
Protection, Regulation and Assurance
email: Philippa_Bascand@moh.govt.nz
Phone: 8162030
Cellphone s 9(2)(a)
[attachment "Bascand_Philippa.vcf" deleted by Philippa Bascand/MOH]

MINISTRY OF HEALTH
MANATŪ HAUORA

11 MAY 2018

Database number: 20180924

Security classification: In-Confidence

COPY

File number: AD62-14-18
Action required by: N/A

Advice on gamete (egg and sperm) donations and recent media interest

To: Hon Dr David Clark, Minister of Health

Purpose

1. In response to the recent media article by Logan Morton where a man with cancer was told by Fertility Associates that he was not able to donate his sperm for use by his same sex partner, you have asked for advice on what kinds of sperm donations are permitted between men.

2. The media article is attached as **Appendix one**.

Background

3. The Ministry of Health (the Ministry) and Minister of Health received some public interest in this article, notably a ministerial (below) where it appears that a member of the public believed that the Human Assisted Reproductive Technology Act 2004 prohibited men from donating sperm to other men. This is not the case, as the Act makes no such prohibitions.

4. Donors are able to place conditions on their gamete (egg or sperm) donations if they wish to. For example, a person may wish to donate their gametes to a nominated person, or people of the same religious affiliations as themselves.

5. The ministerial and final response are attached for your information as **Appendix two** (Minister's Office Reference Number C1800317 refers).

The current legislation and the clinic's forms

6. The Human Assisted Reproductive Technology Act 2004 and Human Assisted Reproductive Technology Order 2005 do not preclude a man from donating his sperm to another nominated man for him to use it.

7. Clinic consent forms are not standardised across New Zealand, so fertility clinics are able to choose the wording in their forms and policies, about the parameters that individuals can place on the use of their eggs or sperm. [redacted] s 9(2)(f)(iv) [redacted]

8. The Ministry has followed this issue up with Fertility Associates to ensure that they have amended their forms to account for a wider range of reproductive options, including the ability for sperm to be used by a specified partner or person. The updated form is attached as **Appendix three**.

9. It is the Ministry's view that the form could be further improved to allow reproductive material to be made availaible to an individuals male partner, instead of it needing to be specifically 'donated' in order to be used by a man's same sex partner.

Contact:	Philippa Bascand, Manager of Ethics, Protection, Regulation and Assurance.	s 9(2)(a) [redacted]

MINISTRY OF HEALTH
MANATŪ HAUORA

Database number: 20180924

Recommendation

It is recommended that you:

a)	**agree** the Ministry send out correspondance to all fertility clinics in New Zealand to ensure their forms are not discriminatory, and allow for donations between men.	**Yes/No**
b)	**agree** the Ministry advise Fertility Associates and other clinics amend their forms, so that same sex men are able to make their reproductive material available to their partners as easily as heterosexual men.	**Yes/No**

Dr Caroline McElnay
Acting Director
Protection, Regulation and Assurance

Minister's signature

Date

Appendix 1

stuff

Cancer patient outraged to discover he can only donate sperm to female partner

Logan Morton has written a first person piece about getting cancer aged 22

A gay man suffering severe pain from cancer was mortified to discover he was only able to donate sperm to a female partner.

Logan Morton, 22, received the shock diagnosis he had acute myeloid leukemia in April last year, and after being warned the treatment could make him infertile, arranged to store healthy sperm through Fertility Associates.

Severely debilitated from the cancer, Morton asked a nurse to fill out the paperwork, and noticed afterwards that he was only given the option of donating his sperm to a female partner.

Logan Morton was diagnosed with cancer at the age of 22 and had fertility treatment before chemotherapy

He later discovered his sperm would have been destroyed despite having a loving and supportive partner, Jeremy Young, who attended the clinic visit with him.

READ MORE:
* Cancer patient, 22, told he couldn't give sperm to gay partner
* Surrogate offers to be impregnated with dead teen's sperm
* Ethical debate over using deceased teen's sperm
* Hope for dead teen's sperm
* Two Kiwi woman want to have babies to their dead partners

Fertility Associates chair Dr Mary Birdsall said they would be changing their policy to accommodate gay male men after being alerted to Morton's experience.

Logan Morton was had just come back from a holiday backpacking around southeast Asia when the shock diagnosis came

"We really feel terrible that Logan was offended because we see ourselves as being an organisation that works really hard to meet all of our clients' needs, it's just that society is becoming more complicated in terms of reproductive options that are available and we just need to move with the times."

Birdsall said the Human Assisted Reproductive Technology (HART) Act 2000 which covers sperm donation was clearly not written with gay couples in mind.

The legislation provided for sperm to be "available for use only by a specified person within a specified timeframe".

He was dismayed to find he was denied the option of leaving his sperm to his partner, in the event of death. Logan Morton, left, with partner Jeremy Young

Fertility Associates interpreted this to mean that only a woman could be nominated to use the sperm as "only a woman can use sperm to make a baby".

Ad Feedback

Birdsall said the form would be changed, after they sought legal advice, to offer a potential alternative if the "female partner" option does not apply.

That would allow a gay man in Morton's situation to be able to choose to be a personal sperm donor and as such, nominate their partner to choose a woman to use the sperm with, in the event of their death.

Birdsall said it was the first time the issue had been raised with them, and she thanked Morton for bringing it to their attention.

Morton said the experience was deeply offensive, at a time when he was weakened and in severe pain, and showed how out of date the legislation was.

"Whether I would have chosen to write my partner's name in there or not I'm not sure, we would have had that discussion, it was the fact that I couldn't and I'm sure there are other people in the situation who would very much like to who are unable to."

He was pleased the company was making a change to ensure gay men were not discriminated against.

"Obviously I'm thrilled that it's been brought to their attention and they are willing to update the form and adapt their policy and definitely recognise they are working within legislation like they have to so I guess it boils down to an issue of... the legislation needs updating, doesn't it."

He planned to approach an MP to lobby for a members bill to bring about legislative change.

** Read Logan Morton's harrowing account of being given a less than even chance of surviving cancer here.*

**comments on this article have been closed*

- Sunday Star Times

Hon Dr David Clark

MP for Dunedin North

Minister of Health

Associate Minister of Finance

21 MAR 2018

s 9(2)(a)

Ref. C1800317

Dear Ms s 9(2)(a)

Thank you for your email of 11 February 2018 about the right of gay men to preserve their sperm for future use. I acknowledge how affected you were upon reading the article on Stuff by Logan Morton.

As chemotherapy is likely to reduce or destroy an individual's fertility, it is standard practice for an individual to have the option of preserving their reproductive material (in this case sperm) for future use.

Fertility clinics are regulated under the Human Assisted Reproductive Technology Act 2004 and must comply with Guidelines issued by the Advisory Committee on Assisted Reproductive Technology (ACART). I am advised that clinics may choose the wording in their forms, or their policies, about the parameters that individuals can place on the use of their frozen sperm. In this case, I am advised that the form stated that a man could donate sperm only to a female partner. I understand the clinic has amended its forms to account for a wider range of reproductive options, including the ability for sperm to be used by a specified person, in line with the ACART Guidelines.

The Human Assisted Reproductive Technology Act 2004 and Human Assisted Reproductive Technology Order 2005 do not preclude a man from leaving his sperm for another man to use it.

Thank you taking the time to write and raise these concerns with me.

Yours sincerely

Hon Dr David Clark
Minister of Health

+64 4 817 8709 Private Bag 18041, Parliament Buildings, Wellington 6160, New Zealand d.clark@ministers.govt.nz beehive.govt.nz

MINISTRY OF HEALTH
MANATŪ HAUORA

15 MAY 2018

Database number: 20180973

Security classification: In-Confidence

Quill record number: 201803558
File number: AD-62-14-18
Action required by: 14 May 2018

Law on Research on Embryos and Making the Environment More Permissive

To: Hon Dr David Clark, Minister of Health

Purpose

This briefing provides the information you requested on 2 May 2018 about whether the regulations for research using human embryos in other jurisdictions might have changed in the last few years.

You requested this information during your meeting with Gillian Ferguson (Chair of the Advisory Committee on Assisted Reproductive Technology, ACART), Kathleen Logan (Deputy Chair of that committee) and Philippa Bascand (Manager, Ethics Committees, Ministry of Health) as background to the World Health Assembly meeting in Geneva.

Background

1. Research on human embryos is permitted in numerous countries, including New Zealand, although the regulations vary from nation to nation.
2. New Zealand is anomalous in that although the Human Assisted Reproductive Technology Act 2004 permits research on surplus[1] human embryos, the research Guidelines[2] that apply to such research state that only non-viable embryos can be used. The definition of embryos as viable or non-viable is problematic and researchers in New Zealand are in effect unable to carry out research that several other countries permit.
3. The limits imposed by the Guidelines mean that researchers can carry out a restricted range of activities such as quality assurance processes. Activities such as comparing the effectiveness of transferring embryos to a woman's uterus at different stages of development (such as 3 days old versus 5 days old) are also precluded as they could be deemed 'research' on viable embryos.
4. If ACART is to amend the Guidelines it would consult the Minister of Health before issuing them. ACART is seeking your agreement to carry out an unlimited review of the Guidelines.

No notable changes to regulations in other jurisdictions

5. There have been no notable changes to the regulations used in countries comparable to New Zealand, for embryo research, since 2005 (when ACART published the Guidelines). During the same period New Zealand's Guidelines have also not changed and have remained restrictive.
6. Having said this, we note one particular change that has been proposed in the UK. The proposed change would be to their rule that embryos can be kept alive *in vitro* for a maximum of 14 days. If the change was made it would increase that maximum limit to 28 days. Such a change is not certain and is being considered by the UK government.

[1] Surplus in the context of assisted reproduction means that the intending parent(s) no longer needs or intends to use those embryos.

[2] Full title: "Guidelines for Research on Gametes and Non-viable Embryos."

Contacts:	Philippa Bascand, Manager, Ethics Committees, Protection Regulation and Assurance	s 9(2)(a)
	Martin Kennedy, Senior Policy Analyst, Ethics Committees	04 816 4459

International comparisons

7. Most countries that are comparable to New Zealand allow research on surplus embryos and most do not distinguish between viable and non-viable. New Zealand is unusual in distinguishing between viable and non-viable embryos when allowing research. Australia makes the distinction but does not restrict the use of viable embryos, rather it allows the use under certain conditions as defined in its *"Research Involving Human Embryos Act 2002."*

Surplus embryos can be used in research	Surplus embryos cannot be used in research
Australia, Belgium, Canada, Czech Republic, Denmark, Finland, France, Greece, Hungary, Netherlands, Russia, Singapore, Sweden, United Kingdom, United States of America (all but 5 states)	Austria, Germany, Ireland, Italy, Norway, Poland, Portugal

8. Few countries permit embryos to be created solely for use in research and we understand that ACART is not considering making such a proposal. New Zealand also has a statutory prohibition on implanting (into a woman) genetically modified embryos.

9. The UK has major fertility research sites that generate significant research benefit and revenue, for example the Wellcome Trust Centre for Mitochondrial Research in Newcastle.

Social and technological changes

10. Assisted reproduction is now more widely practiced than it was in 2004 and technological advances have out-paced the provisions of the HART Act and the Guidelines. In light of these factors, amongst others, a review of the Guidelines could be warranted.

Dr Caroline McElnay
Acting Director
Protection, Regulation and Assurance

Minister's signature

Date:

END.

MINISTRY OF HEALTH
MANATŪ HAUORA

Security classification: In-Confidence

Health Report: Request from the Advisory Committee on Assisted Reproductive Technology

Date:	29 January 2019	Report No:	20182140
		File Number:	AD62-14-18

Action Sought

	Action Sought	Deadline
Minister Clark	Agree	20/2/2019
Minister Genter	Note	

Contact for Telephone Discussion (if required)

Name	Position	Telephone	Contact Order
Rob McHawk	Acting Manager, Ethics, Health System Improvement and Innovation	s 9(2)(a)	2nd Contact
Martin Kennedy	Senior Policy Analyst, Ethics, Health System Improvement and Innovation	04 816 4459	1st Contact

Actions for the Minister's Office Staff

Return the signed report to Ministry of Health

Note any feedback on the quality of the report	

Health Report number: 20182140

Security classification: In-Confidence

File number: AD62-14-19
Action required by: 20 February 2019

Request from the Advisory Committee on Assisted Reproductive Technology

To: Hon Dr David Clark, Minister of Health
Copy: Hon Julie Anne Genter, Associate Minister of Health

Purpose

1. This briefing draws your attention to a request from the Advisory Committee for Assisted Reproductive Technology (ACART), to add a project to its work programme, and recommends a response.

Key points

You will meet the Acting Chair of ACART on 21 February 2019

2. You are scheduled to meet Dr Kathleen Logan, Acting Chair of ACART, on 21 February 2019 at 10.30 am.[1] Dr Logan's main interest is to ask you to agree that ACART should carry out a full review of the guidelines for human reproductive research.

3. Your office agreed to this meeting in response to a request Dr Logan had sent you on 9 October 2018 (letter from ACART and response from your office attached as **Appendix One**).

Earlier correspondence and meetings with ACART

4. At the meeting you had on 2 May 2018 with Gillian Ferguson and Dr Logan you discussed ACART's proposed work on human reproductive research. You asked the Committee for more information and they provided it on 11 May 2018 (**Appendix Two**).

5. Also, on 8 March 2018, ACART provided you a background briefing about its work programme, statutory functions, and relationships with other agencies (**Appendix Three**). That briefing explained ACART's reasons for wishing to carry out a full review of the guidelines for human reproductive research.

Previous advice, about human reproductive research, from the Ministry of Health

6. In recent years ACART has approached successive governments seeking agreement to add a review of the guidelines to its work programme. Some previous Ministers have agreed to consider the matter and some have requested further information, but a full review has not been done and the guidelines remain in the form published in 2005.

7. Our detailed analysis of embryo research is attached for your information (**Appendix Four)**. In this briefing we summarise the key points and your options.

Summary of ACART's proposed project

8. s 9(2)(f)(iv) [redacted]

[1] A member of ACART's Secretariat will also attend.

Contacts:	Rob McHawk, Acting Manager Ethics, Quality Assurance and Safety, Health System Improvement and Innovation	s 9(2)(a)
	Martin Kennedy, Senior Policy Analyst, Ethics, Quality Assurance and Safety, Health System Improvement and Innovation	04 816 4459

s 9(2)(f)(iv)

[redacted]

ACART does not need Ministerial or Parliamentary approval to publish its guidelines

16. The HART Act gives the responsibility and decision making power for the guidelines to ACART. Should ACART review the guidelines they would be obliged, under the HART Act, to consult the Minister of Health before issuing them to ECART, but Ministerial approval for the content of the guidelines, or their release, is not required. There is also no provision in the Act for the Minister to direct ACART on the content, or release, of any guidelines. However, ACART's Terms of Reference, and practice to date, has been for ACART to agree its work programme with the Minister.

[2] Now that the Act and guidelines have been in use for over 10 years an increasing number of stored embryos are passing the ten year limit for storing embryos.

Options

17. [redacted]

ACART also commented on the Secretariat staffing and their progress

18. Out of scope

19. [redacted]

Recommendations

The Ministry recommends that you:

EITHER

a)	**decline** any review of the guidelines for human reproductive research on ACART's work programme, **OR**	**Yes / No**
b)	**agree** that ACART may provide you with further details on its proposed review and consultation process, including how they would measure public support for research on viable embryos, and a range of options for your consideration, **OR**	**Yes / No**
c)	**agree** to a limited review of the guidelines, within their current scope, and focusing on where more detailed guidance could be valuable, **OR**	**Yes / No**
d)	**agree** to a full review of the guidelines, including broadening their scope (such as the possibility of expanding them to include research on viable embryos and social research).	**Yes / No**

Keriana Brooking
Deputy Director-General
Health System Improvement and Innovation

Minister's signature:

Date:

END.

9 October 2018

Hon Dr David Clark

Minister of Health

Parliament Buildings

WELLINGTON

Tēnā koe Minister Clark

On behalf of the Advisory Committee on Assisted Reproductive Technology (ACART) I would like to thank you for your interest in the committee's work and your agreement to meet the committee Chair on a regular basis.

The Chair you met in May, Gillian Ferguson, has resigned from ACART and as Acting Chair I would like to ensure you continue to enjoy a productive engagement with the committee. In particular, I would like to know if you agree with ACART's work programme. ACART's planned work on human reproductive research is a particularly important project and the committee would be grateful for your response to its advice to you of 11 May 2018. ACART would like to know if you agree that we should undertake the full review of the guidelines for human reproductive research.

Currently, the fertility clinics are constrained in how they can improve their practices and techniques because they cannot test them on donated embryos. The existing guidelines (that have never been reviewed) prevent any kind of prospective trials to test potential fertility treatment improvements, for example using patients' own embryos in their own fertility treatment.

ACART is aware of two recently rejected research proposals in which procedures currently used in fertility treatments were to be compared using prospective, randomised, controlled trials. They could not be done because they were prospective trials, and therefore considered to be research.

One study involved comparing embryo transfer on day 3 versus day 5 of embryo development. The other study involved comparing two different media in which embryos are cultured *in vitro* before transfer: a low lactate 'single-step' medium versus a regular medium. Both studies had to be declined because the current guidelines do not permit research on viable embryos. The guidelines only apply to 'non-viable' embryos, and are unworkable, as demonstrated by these examples. The fertility sector has long awaited a review of these guidelines so it can conduct research that improves outcomes of fertility services — both for intending parents and for the health of potential children.

ACART is making steady progress on its two projects to review the guidelines for posthumous reproduction and the guidelines for donations and surrogacy. The committee will provide you a

more detailed update in the near future. However, I note that our progress is slower than we had anticipated due to the reduction over the last 18 months in the staffing of the Secretariat (from 2.5 full time equivalent staff to approximately 0.7 FTE).

ACART members and the Secretariat have begun the process to select a new Chair and they will liaise with your office in the next few weeks to confirm the process and seek your agreement to the proposed Chair.

I would be grateful if your office would liaise with the ACART secretariat to arrange the regular six monthly meetings that you requested when we met on 2 May 2018.

Ngā mihi nui

Dr Kathleen Logan,

Acting Chair, Advisory Committee on Assisted Reproductive Technology

cc Hon Julie-Ann Genter. Associate Minister of Health
Hon Jenny Salesa. Associate Minister of Health
Hon James Shaw. Acting Associate Minister of Health
Dr Ashley Bloomfield. Director-General of Health
Dr Stewart Jessamine. Director; Protection, Regulation and Assurance; Ministry of Health

Dr Kathleen Logan
- k.logan@occ.org.nz
- ph: 04 495 7804

Recommendations:

ACART should undertake the full review of the guidelines for human reproductive research.	Agree / Disagree
Your office should liaise with the ACART secretariat to arrange the regular six monthly meetings.	Agree / Disagree

acart

Database number: 20180976
File number: AD-62-14-18

11 May 2018

Hon Dr David Clark
Minister of Health
Parliament Buildings
WELLINGTON

Dear Dr Clark,

Thank you for taking time to meet me on 2 May 2018 to discuss the functions of the Advisory Committee on Assisted Reproductive Technology (ACART), the related work done by the Ministry of Health, and the Government's priorities in this area.

You asked me to provide you an explanation of why ACART should review the guidelines for human reproductive research (the Guidelines[1]) and I have set out the explanation below.

Like numerous other countries, New Zealand has legislation that permits research using human embryos. However, New Zealand is unusual in that much research that would be of value is effectively precluded due to the restricted nature of the existing Guidelines.

Our work programme

One of the projects on our current work programme is the partial review of the Guidelines. The current Guidelines provide for the Ethics Committee on Assisted Reproductive Technology (ECART) to approve only research using gametes and non-viable embryos. The restricted nature of these guidelines effectively precludes any human reproductive research being undertaken in New Zealand.

In March 2017, Cabinet agreed to a limited review of the Guidelines, looking at what could be improved within the current scope without extending research to viable embryos that are surplus to human reproductive use. As discussed with you on 2 May, ACART believes the limits placed on the scope of the review mean that it would leave significant matters unresolved. In particular, the problematic distinction between viable and non-viable embryos would remain in place.

We are seeking your agreement

The scope of our Guidelines project needs to be broader and we are seeking your agreement to modify the scope. Specifically, we believe the project should be a full and unlimited review.

New Zealand is a world leader in epigenetics, yet quality research in human embryology is severely constrained; frustrating fertility researchers and limiting advances in reproductive health knowledge. New Zealand has a responsibility to develop its own research capability in response to our unique population fertility needs and growing demand, particularly for Māori,

[1] Full title: "Guidelines for Research on Gametes and Non-viable Embryos."

Pacifika and Eurasian health needs that may lead to the development of new or better treatment options for all New Zealanders.

There is strong support from consumers for revised Guidelines that enable use of surplus embryos for research purposes. Client feedback and independent research, both internationally and in New Zealand, indicate that when people have embryos surplus to their own reproductive needs, their preference is to donate the remaining embryos for research purposes. Currently, where surplus embryos are not required for future use in fertility treatment, they are destroyed with permission from the gamete donors.

Benefits of human reproductive research include economic gains

ACART considers that human reproductive research, including on surplus human embryos, will promote an evidence-based clinical and science environment with accompanying data, in keeping with the Government's strategy for health research.[2]

The New Zealand Health Research Strategy notes the economic and social benefits that would be derived from more cohesive health research. In particular, the strategy addresses the opportunities for innovation, industry partnerships and commercialising innovations. We note this market in the agricultural sphere has led to New Zealand being a world leader in animal genetics and animal IVF reproduction. It is notable the fertility treatment sector is an expanding industry worldwide, with on-going research needs.

Specific benefits that would be derived from a full review and allowing research on all surplus embryos are that it would:

a. lead to research findings that increase the success rate of fertility treatments in New Zealand and internationally

b. put surplus embryos to good use, if the owners wish to donate them to research (many people prefer to donate their surplus embryos to research rather than to other families and, legally, they must eventually be destroyed)[3]

c. enable New Zealand researchers to carry out a wider range of independent research, or participate in research that is done in several countries simultaneously. This would support those researchers in their careers, encourage them to stay in New Zealand, and enhance New Zealand's reputation as a nation that participates in valuable research, and

d. develop New Zealand-specific research, reflecting local priorities, processes and ethics, e.g. Māori and Pacific stem cell lines so that future treatments can better support these population groups.

The process we would follow

In the event that you agree to modify the scope of the project we would:

- consult the public on proposed revised guidelines for human reproductive research. We would ask the public whether the guidelines should be revised and if so whether the proposed revisions are suitable

[2] *New Zealand Health Research Strategy*. Published June 2017.

[3] Now that the Act and guidelines have been in use for over 10 years an increasing number of stored embryos are passing the ten year limit for storing embryos.

- incorporate feedback and provide advice to the Minister
- amend the guidelines as required, following public and Ministerial consultation
- publish the revised guidelines
- submit advice to the Minister.

The exact timing of our work would need to be confirmed as we also need to complete the two other substantial projects we have underway and carry out our statutory monitoring and reporting functions.

I can be contacted if there are any further questions:

- s 9(2)(a)
- [redacted]

I can also be contacted through the Secretariat that supports ACART:

- Martin_Kennedy@moh.govt.nz, phone 04 816 4459
- Hayley_Robertson@moh.govt.nz, phone 04 816 4353

Yours sincerely

Gillian Ferguson

Chair, Advisory Committee on Assisted Reproductive Technology

Database number: 20180449
File ref: AD62-14-2018

ADVISORY COMMITTEE ON ASSISTED REPRODUCTIVE TECHNOLOGY (ACART).

BACKGROUND BRIEFING TO THE MINISTER OF HEALTH.

A. INTRODUCTION

1. This briefing introduces the Advisory Committee on Assisted Reproductive Technology (ACART). ACART is an independent Ministerial committee, established under the Human Assisted Reproductive Technology Act 2004 (the HART Act). The Minister of Health appoints ACART members.

2. ACART is part of the regulatory framework for assisted reproduction services and human reproductive research in New Zealand. The Committee prepares and issues guidelines that set out the criteria for ethical approval of certain procedures (for example, embryo donation and the use of donated eggs with donated sperm) and for human reproductive research. ACART also provides advice to the Minister of Health. Its work programme is agreed with the Minister of Health.

3. This paper explains the regulatory setting for assisted reproduction in New Zealand, focusing on ACART's role, before presenting a summary of its statutory functions, key relationships and work programme. The Committee's Terms of Reference and current membership are presented as appendices, together with a brief background to assisted reproduction in New Zealand.

B. THE REGULATORY SETTING

a. The HART Act

4. The HART Act is the principal Act that regulates human assisted reproductive technology (ART) and human reproductive research in New Zealand. Important features of the HART Act include the following.

- Guiding Principles including to secure the benefits of assisted reproductive technologies by protecting and promoting the health and well-being of children conceived from assisted reproduction
- Prohibitions against certain actions
- Established procedures, which are fertility procedures that fertility clinics can carry out without needing approval from the ethics committee
- Assisted reproductive procedures, which are fertility procedures that can only be carried out with approval by the ethics committee, applying guidelines issued by ACART
- Registers to record information about gamete and embryo donors, and about people born from donations

- Processes and institutional arrangements that allow for a flexible system that is able to make some changes without Parliament's involvement. The HART Act delegates to ACART responsibility for establishing the requirements for using some procedures. ACART is required to consult the public and the Minister of Health before issuing new guidelines or making significant changes to guidelines.
- Enabling regulations to be made about both specific issues (eg, informed consent, importing and exporting gametes and embryos) and any other matters necessary for giving full effect to the HART Act.

Assisted reproductive activities that require ethical approval

5. ACART issues guidelines for activities requiring approval by the Ethics Committee on Assisted Reproductive Technology (ECART). The activities requiring ECART approval are generally seen to be more ethically complex than the "established procedures".

6. ACART has issued, or has responsibility for, guidelines for

   a) surrogacy involving assisted reproductive procedures

   b) embryo donation for reproductive purposes

   c) creation and use, for reproductive purposes, of an embryo created from donated eggs in conjunction with donated sperm

   d) donation of eggs or sperm between certain family members

   e) preimplantation genetic diagnosis with human leucocyte antigen tissue typing (selecting an embryo that is compatible with an existing seriously ill sibling, with a view to using donated cord blood or bone marrow from resulting child)

   f) storage, use and disposal of sperm from a deceased man (issued before the HART Act and still in force).

   g) extending the storage period of gametes and embryos beyond 10 years and

   h) research on gametes and non-viable embryos (issued before the HART Act and still in force).

b. The Human Assisted Reproductive Technology Order 2005 (Hart Order)

7. The HART Order sets out procedures that are declared to be "established procedures". Established procedures do not require ethical approval and therefore are not subject to ACART guidelines. The majority of procedures are established procedures and include in vitro fertilisation.

8. The HART Order also sets out some exceptions to the established procedures, where the use of specific procedures is subject to ACART guidelines and ECART approval.

c. The Fertility Services Standard

9. The Fertility Services Standard sets out the requirements for the safety and quality of fertility services in New Zealand. Providers are audited and certified against the Standard, which is administered by the Ministry of Health. ACART does not have any responsibility for the Standard, though is consulted by the Ministry of Health when it is reviewing the Standard.

d. Code of Health and Disability Services Consumers' Rights

10. Patients of fertility services providers are protected by the Code of Health and Disability Services Consumers' Rights (the Code).

11. We note that egg and sperm donors are not considered patients under the Code for the purposes of fertility treatment. Consequently, donors might, from time to time, wish to seek assistance under the Code but be precluded from doing so.

C. ACART'S STATUTORY FUNCTIONS

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

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

13. ACART must consult the public before issuing guidelines to ECART and before giving significant advice to ECART and/or the Minister of Health.

14. ACART does not have any functions associated with public funding of fertility treatment or auditing fertility services.

15. ACART operates under Terms of Reference. These include ACART's formal functions under the HART Act, the operation of meetings, and expectations of members. A copy of the Terms of Reference is attached as Appendix 1.

D. KEY RELATIONSHIPS

a. ACART's relationship with the Minister of Health

Agreement to a work programme

16. ACART's Terms of Reference state that it will agree its work programme with the Minister of Health. ACART seeks the Minister of Health's agreement to all significant projects, including where public consultation is likely to be required. ACART may request that the Minister meet the Chair to discuss the work programme.

17. While the current work programme was agreed with Associate Minister Dunne, in June 2017, we suggest the programme be discussed and agreed.

18. We have a substantial work programme and there are other matters not yet on the programme that need to be addressed. Given the need to work with the resources available we suggest that while new topics can be added to our programme, we would address each matter as resources permit.

Public consultations

19. ACART provides the Minister of Health with a copy of public consultation documents, for information, before publishing and beginning public consultation.

Issuing guidelines

20. ACART is required to consult the Minister of Health before issuing guidelines. The Minister of Health does not have the role of approving guidelines. To date, ACART has not issued any guidelines before completing consultation with the Minister of Health.

21. ACART must advise the Minister of Health when guidelines are issued.

Advice to the Minister

22. The HART Act states the matters on which ACART is required to advise the Minister of Health, within timeframes agreed with the Minister of Health (s.37 and s.38).

23. ACART also briefs the Minister of Health:

- on any other matters where the Minister requests advice or information
- on any matters that ACART considers may be of interest to the Minister or where the Minister's agreement is needed.

Regular reports

24. Under the HART Act, ACART is required to give the Minister a report, after each 12 month period ending 30 June, on its progress in carrying out its functions; and on the number and kinds of decisions given by ECART in that period.

b. ACART's relationship with the Ministry of Health

25. The Ministry of Health provides policy analysis and administrative support to ACART through Secretariat staff members. The Secretariat staff sit in the Protection, Regulation and Assurance business unit.

26. The Ministry has responsibility for the budget that supports ACART. In addition to member fees and meeting costs, ACART requires funding to fulfil its statutory obligations on matters such as public consultation.

27. ACART has an open relationship with the Ministry of Health. It gives the Ministry copies of all correspondence and reports to the Minister on a "no surprises" basis, and so that the Ministry is able to provide parallel advice to the Minister if requested.

28. The Ministry provides ACART with legal advice when requested, including on interpretations of the HART Act, and also provides communications support. The Ministry assists with any requests under the Official Information Act for ACART information.

29. Once ACART has provided advice to the Minister, the Ministry prepares parallel advice before the Minister responds to the recommendations. In some cases, the Minister might request that further policy work is undertaken.

30. At the time of writing the Ministry is supporting Cabinet to make an amendment to the HART Order (by Order in Council) to make the reimplantation of cryopreserved ovarian tissue an established procedure.

c. ACART's relationship with ECART

31. The HART Act requires ACART to liaise with ECART on general and specific matters relating to assisted reproductive procedures and human reproductive research. The Chairs, or members, of each committee attend the meetings of the other committee as observers. The Chairs meet as needed to discuss matters of mutual interest.

32. ACART issues guidelines to ECART, which ECART uses to consider, determine and monitor applications made by fertility clinics for certain assisted reproductive procedures, extending storage of gametes and embryos, and human reproductive research.

33. If ECART receives an application for an activity which is not covered in the guidelines, or in advice given to it by ACART, ECART must decline the application and refer the application to ACART. The HART Act does not prescribe any specific action that ACART must take in such a situation. In practice, ACART considers whether there are grounds to review the guidelines.

34. The distinct statutory roles of ACART and ECART require that the Committees operate independently of each other.

d. ACART's relationships with the fertility sector and other stakeholders

35. ACART has an important relationship with fertility services providers, particularly given the direct impact of ACART's guidelines on them. Their contribution is essential to ACART's work.

36. Outside formal public consultations and contacts, ACART's ongoing relationships include fertility services providers. Providers are consistently helpful in providing information needed for ACART's policy development. Providers have also given ACART members tours of their facilities as part of orientations. Training days for new ACART members typically include presentations by fertility counsellors and members of Fertility New Zealand (national consumer group).

37. ACART has developed relationships with New Zealand researchers who are working in areas relevant to ACART's policy development. For example, Professor Ken Daniels at Canterbury University (a former member of ACART) is an international expert on families formed by donor insemination. Sonja Goedeke at the Auckland University of Technology has recently completed doctoral work on embryo donation. Staff members

at Otago University have interests that include human reproduction technologies and science, bioethics, and law related to ART. These relationships support ACART to fulfil its function of monitoring research and clinical outcomes of ART.

E. ACART'S WORK PROGRAMME

a. Current projects

38. ACART has three major guideline review projects either under way or under development. The projects are the reviews of:

    a. the four "donation guidelines"

    b. the guidelines on human reproductive research

    c. the *Guidelines on the Storage, Use and Disposal of Sperm from a Deceased Man.*

Project 1: review the four guidelines that involve donations

39. ACART is reviewing four guidelines, all of which involve the donation of gametes or embryos, with a view to removing a potentially discriminatory feature and to make other improvements. The four guidelines are for:

- surrogacy involving assisted reproductive procedures
- embryo donation for reproductive purposes
- creation and use, for reproductive purposes, of an embryo created from donated eggs in conjunction with donated sperm
- donation of eggs or sperm between certain family members.

40. The potentially discriminatory feature is the "biological link" policy[1] which carries a risk of discrimination on grounds of disability, for example, where both people in a same sex or heterosexual couple are infertile and also require a surrogate to gestate a pregnancy.

41. We consulted the public from September to November 2017 and analysed the submissions. We are about to carry out a second round of targeted consultation and expect to send advice to you and issue the new guidelines to ECART in 2018.

Project 2: review the guidelines on human reproductive research

42. Under the HART Act, human reproductive research can only be undertaken with the approval of ECART. The current guidelines provide for ECART to approve research using gametes and non-viable embryos.

43. A former committee issued the guidelines in 2004 (the National Ethics Committee on Assisted Human Reproduction, NECAHR). The guidelines, and the HART Act, fail to define non-viable embryos or to define embryo viability, and the origin of the NECAHR criteria is unknown. No other jurisdiction uses a distinction between viable and non-viable embryos in its regulation of research. There are practical difficulties in distinguishing between viable and non-viable embryos, and the provision means that

[1] The biological link policy is the requirement that an intending parent and child be related either by sharing genetic material or by the mother having gestated the child.

the guidelines are effectively unworkable due to the uncertainty as to what is and is not permitted.

Problems with the limited scope of the review

44. s 9(2)(f)(iv) [redacted]

45. ACART believes that the inability to make clear distinctions on viable and non-viable embryos creates uncertainty for any ECART decisions and therefore poses serious regulatory risk by using unworkable guidelines

46. Both international and New Zealand data indicates that embryo donation for research purposes is the preferred option where embryos are surplus for use in ART procedures, rather than on-donation. Currently, embryos surplus to ART are either frozen or destroyed with permission from the gamete donors.

Project 3: review the Guidelines on the Storage, Use and Disposal of Sperm from a Deceased Man

47. The current guidelines apply only to the use of sperm following a man's death. They do not cover a number of situations in which people might wish to take advantage of reproductive technologies. These situations include using eggs from a comatose or deceased woman or the possibility of collection of gametes from a recently deceased or comatose person. Technological advances mean that some of these activities have become possible since the original guideline was developed.

48. We plan two rounds of public consultation in 2018. Stage one will seek responses on a possible expansion of the scope of the guidelines. Stage two would then seek responses on the proposed guideline.

49. This project is likely to result in recommendations that legislative changes be made.

b. Other matters we are progressing

50. Some matters we are working on have arisen from sources such as, but not limited to, enquiries from other parties. For example, we are liaising with the Department of Internal Affairs on the way in which donors are recorded (or not) on the "Births, Deaths and Marriages 400" form. We are investigating whether a change is needed to the forms and/or to the ways in which they are completed.

c. Matters we will brief you on

51. s 9(2)(f)(iv) [redacted]

52.

s 9(2)(f)(iv)

53. [redacted]

54. [redacted]

55. [redacted]

56. [redacted]

57. [redacted]

Gillian Ferguson
Chair
Advisory Committee on Assisted Reproductive Technology

Minister's signature

Date

APPENDIX 1

TERMS OF REFERENCE

Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research

The Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research ('the Advisory Committee on Assisted Reproductive Technology' or ACART) is established under section 32 of the Human Assisted Reproductive Technology (HART) Act 2004. These Terms of Reference outline the role and functions of ACART.

Functions of ACART

ACART has the following functions:

- to issue guidelines and give advice to the Ethics Committee on Assisted Reproductive Technology (ECART) on any matter relating to any kind of assisted reproductive procedure or human reproductive research and to keep such guidelines and advice under review
- to issue guidelines and give advice to ECART on the matters ECART must take into account in considering whether to give, change or cancel an approval for an extension to the applicable period for the storage of a human *in vitro* gamete or a human *in vitro* embryo
- to provide the Minister of Health with advice on aspects of, or issues arising out of, kinds of assisted reproductive procedure or human reproductive research and, without limitation, advice as to whether:
  - the HART Act or another enactment should be amended to prohibit or provide for any kind of assisted reproductive procedure or human reproductive research
  - any kind of procedure or treatment should be declared an established procedure, on the basis of the information, assessment, advice, and ethical analysis required to declare a procedure to be an established procedure under section 6 of the HART Act
  - any established procedure should be modified or should cease to be an established procedure
  - a moratorium should be imposed on any kind of assisted reproductive procedure or human reproductive research
  - regulations should be made under section 76 of the HART Act to regulate the performance of any kind of assisted reproductive procedure or the conduct of any kind of human reproductive research.
- to liaise with ECART on general and specific matters relating to assisted reproductive procedures or human reproductive research
- to consult with any persons who, in the opinion of ACART, are able to assist it to perform its functions
- any other function that the Minister of Health assigns to ACART by written notice.

For the purposes of performing the above functions, ACART must monitor:

- the application, and health outcomes, of assisted reproductive procedures and established procedures
- developments in human reproductive research.

ACART should also monitor the decisions of ECART to ensure that they fall within the guidelines as intended by ACART. If, after consideration of one of ECART's decisions, ACART considers that the decision falls outside of its guidelines, ACART should inform ECART of this.

Guiding principles

ACART shall be guided by the following principles:

- the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure
- the human health, safety, and dignity of present and future generations should be preserved and promoted
- while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application and the health and well-being of women must be protected in the use of these procedures
- no assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent
- donor offspring should be made aware of their genetic origins and be able to access information about those origins
- the needs, values, and beliefs of Māori should be considered and treated with respect
- the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

Guidelines

ACART may issue guidelines to ECART only after it has:

- on the basis of a discussion paper or an outline of the proposed guidelines, given interested parties and members of the public a reasonable opportunity to make submissions
- taken any such submissions into account, and
- consulted on the proposed guidelines with the Minister of Health.

When ACART issues guidelines to ECART, it must:

- give copies of the guidelines to the Minister, the Director-General of Health, to ECART, and to providers; and
- publish the guidelines on the internet and in any other publications (if any) that the Committee thinks appropriate; and
- give public notice of the issue of the guidelines by publishing in any publication that it considers appropriate for the purpose a notice that states:
    - the date and subject matter of the guidelines
    - the internet website on which they are published.

Specific advice

ACART must, within time frames agreed with the Minister, provide the Minister with information, advice, and if it thinks fit, recommendations on the following matters in relation to the use of gametes and human embryos in human reproductive research:

- cloned embryos
- donations of human embryos
- genetic modification of human gametes and human embryos
- human gametes derived from foetuses or deceased persons
- hybrid embryos
- requirements for informed consent
- the import into, or export from, New Zealand of *in vitro* human gametes or *in vitro* human embryos.

ACART must, within the time frames agreed with the Minister, provide the Minister with information, advice, and if it thinks fit, recommendations on the following matters in relation to human assisted reproductive technology:

- donations of human embryos
- *in vitro* embryo splitting
- gametes derived from deceased persons
- requirements for informed consent
- selection of embryos using preimplantation genetic diagnosis
- the import into, or export from, New Zealand of *in vitro* donated cells or *in vitro* donated gametes.

ACART may give advice on the above areas only after it has:

- on the basis of a discussion paper or an outline of the proposed advice, given interested parties and members of the public a reasonable opportunity to make submissions; and
- taken any such submissions into account.

Public meetings on proposed significant advice

If, in the opinion of ACART, a significant number of persons wish to make oral submissions on a proposal to give specific advice on any of the above matters, ACART must hold as many meetings as are required to enable those submissions to be made.

ACART must:

- notify the persons who wish to make oral submissions of the time and place of any meeting to be held; and
- publish a notice on the internet and in any other publication the committee thinks appropriate that states the time, place, and purpose of any such meeting and that the meeting will be held in public.

Consultation

Before ACART gives advice to the Minister or issues guidelines to ECART, it must consult on the proposed advice or guidelines with:

- any members of the public that the committee considers appropriate
- appropriate government departments and agencies
- any other person or group that the committee considers appropriate.

Composition and membership

The Minister may appoint any person to be a member of ACART and must, before doing so, consult any persons who, in the Minister's opinion, are able to provide advice on prospective appointees who have the required expertise and the ability to reflect relevant perspectives and concerns, including, without limitation, the perspectives and concerns of women.

Guiding objective

The primary guiding objective for appointing members to ACART is to ensure that ACART has the appropriate expertise, skills, knowledge and perspectives to provide advice and guidelines of the highest quality.

Member numbers

ACART must consist of not fewer than 8 and not more than 12 members appointed by the Minister of Health.

Lay/Non-lay membership

At least half of the members of ACART must be lay members.

For the purposes of these Terms of Reference, a layperson is a person who, at no time during the person's membership of ACART or in the 3 years before becoming a member of ACART:

- is a health practitioner within the meaning of the Health Practitioners Competence Assurance Act 2003; or
- is involved in health research; or

- is employed by or associated with, or has a pecuniary interest in, a fertility service provider.

Ex-officio attendance

The chairperson of ACART, or a member of ACART nominated by the chairperson of ACART for the meeting may attend each meeting of the Ethics Committee on Assisted Reproductive Technologies (ECART). The ACART member or Chair attending the Advisory Group meeting is not a member of the committee.

The chairperson of ECART, or a member of ECART nominated by the chairperson of ECART for the meeting may attend each meeting of ACART. ECART member or Chair attending the ACART meeting is not a member of the committee.

Member categories

ACART's membership must include:

- one or more members with expertise in assisted reproductive procedures
- one or more members with expertise in human reproductive research
- one or more members with expertise in ethics
- one or more Māori members with expertise in Māori customary values and practice and the ability to articulate issues from a Māori perspective
- one or more members with the ability to articulate issues from a consumer perspective
- one or more members with the ability to articulate issues from a disability perspective
- one or more members with the ability to articulate the interests of children who, at the time of his or her appointment, holds the office of Children's Commissioner or is a representative or employee of the person who holds that office
- one or more members with expertise in relevant areas of the law.

Whole committee requirements

Members should possess an attitude that is accepting of the values of different professions and community perspectives, and it is important that ACART comprise people from a range of backgrounds and ethnicities. All members of ACART are expected to have an understanding of how the health sector responds to Māori issues and their application to ethical review.

Despite being drawn from groups identified with particular interests or responsibilities in connection with health and community issues, members are not in any way the representatives of those groups. They are appointed in their own right, to participate in the work of ACART as equal individuals of sound judgement and relevant experience.

Terms and conditions of appointment

Members of ACART are appointed by the Minister of Health for a term of office of up to three years. The terms of office of members of ACART will be staggered to ensure continuity of membership. Members may be reappointed from time to time. No member may hold office for more than six consecutive years.

Persons who have served six consecutive years as members of the previous National Ethics Committee on Assisted Human Reproduction (NECAHR) shall not be immediately eligible for appointment to ACART.

A person may not be a member of ACART and ECART simultaneously.

Unless a person sooner vacates their office, every appointed member of ACART shall continue in office until their successor comes into office. Any member of ACART may at any time resign as a member by advising the Minister of Health in writing.

The Minister may, by written notice, terminate the appointment of a member or chairperson of the advisory committee.

The Minister may from time to time alter or reconstitute ACART, or discharge any member of ACART, or appoint new members to ACART for the purpose of decreasing or increasing the membership or filling any vacancies.

Chairperson and Deputy Chairperson

The Minister may appoint any person to be a chairperson of ACART and must, before doing so, consult any persons who, in the Minister's opinion, are able to provide advice on prospective appointees who have the required expertise and the ability to reflect relevant perspectives and concerns, including, without limitation, the perspectives and concerns of women.

ACART may appoint one of its members to be Deputy Chairperson.

The Chairperson will preside at every meeting of ACART at which he or she is present.

Duties and responsibilities of a member

This section sets out the Minister of Health's expectations regarding the duties and responsibilities of a person appointed as a member of ACART. This is intended to aid members of ACART by providing them with a common set of expectations for appropriate conduct and behaviour and serves to protect ACART and its members.

As an independent statutory body, ACART has an obligation to conduct its activities in an open and ethical manner. ACART has a duty to operate in an effective manner within the parameters of its functions as set out in its Terms of Reference and in accordance with the HART Act.

General

ACART members should have a commitment to work for the greater good of the Committee.

There is an expectation that members will make every effort to attend all ACART meetings and devote sufficient time to become familiar with the affairs of ACART and the wider environment within which it operates.

Members have a duty to act responsibly with regard to the effective and efficient administration of ACART and the use of ACART funds.

Conflicts of interest

ACART members must perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will protect ACART and its members and will ensure that it retains public confidence.

Members attend meetings and undertake committee activities as independent persons responsible to ACART as a whole. Members are not appointed as representatives of professional organisations and or particular community bodies. ACART should not, therefore, assume that a particular group's interests have been taken into account because a member is associated with a particular group.

Members should declare, and the committee regularly review their actual and potential conflicts of interest. ACART must exhibit transparency in avoiding or managing any real or perceived conflict of interest.

Confidentiality and information sharing

The public has a right to be informed about the issues being considered by ACART. The chairperson of ACART must ensure that the agenda and minutes are published on the internet as soon as possible after they are confirmed by the members of the committee. ACART should have procedures in place regarding the release of information and processing requests for information.

Individual members must observe the following duties in relation to ACART information.

These provisions ensure that ACART as a whole maintains control over the appropriate release of information concerning issues before it.

- Meetings of ACART, including agenda papers and draft minutes, are confidential. Members must ensure that the confidentiality of ACART business is maintained.
- Members are free to express their own view within the context of committee meetings or the general business of ACART.
- Members must publicly support a course of action decided by ACART. If unable to do so, members must not publicly comment on decisions.
- At no time should members individually divulge details of ACART matters or decisions of ACART to persons who are not ACART members. Disclosure of ACART business to anyone outside

ACART must be on the decision of ACART, or at the discretion of the Chairperson of ACART between meetings. In choosing to release or withhold information, the Committee must comply with the Official Information Act 1982 and the Privacy Act 1993.

- ACART members must ensure that ACART documents are kept secure to ensure that the confidentiality of committee work is maintained. Release of committee correspondence or papers can only be made with the approval of ACART.

Meetings of the Committee

Meetings shall be held at such times and places as ACART or the Chairperson of ACART decides.

A quorum is the minimum number constituting a majority.

Every question before any meeting shall generally be determined by consensus decision-making. Where a consensus cannot be reached a simple majority vote will apply. In such circumstances, the Chairperson shall have the casting vote.

Subject to the provisions set out above, ACART may regulate its own procedures.

Reporting requirements

ACART must, as soon as practicable after each 12-month period ending on 30 June, give the Minister of Health a report:

- on its progress in carrying out its functions; and
- on the number and kinds of decisions given by ECART in that period.

Fees and allowances

Members of ACART are entitled to be paid fees for attendance at meetings. The level of attendance fees are set in accordance with the State Services Commission's framework for fees for statutory bodies.

The Chairperson will receive $542.50 per day (plus half a day's preparation fee) and an allowance of two extra days per month to cover additional work undertaken by the Chairperson. The attendance fee for the Deputy Chairperson is set at $428 per day (plus half a day's preparation fee). The attendance fee for members is set at $342.50 per day (plus half a day's preparation fee). The Ministry of Health pays actual and reasonable travel and accommodation expenses of ACART members.

Servicing of ACART

ACART will agree a work programme with the Minister of Health. ACART will be serviced by permanent staff, sufficient to meet the Committee's statutory functions, who will be based in the Ministry of Health.

APPENDIX 2

ACART MEMBERSHIP

ACART normally has ten members. From December 2017 to April 2018 there will be 11 members to allow for a handover period between the out-going and in-coming members with expertise in human reproductive research.

The current members, their area of specialisation, and length of appointment are as follows.

1. Gillian Ferguson
   - consumer perspective
   - originally appointed in April 2016
   - appointed as **Chair** from 23 June 2017
   - current term ends June 2020.

2. Michael Legge (Deputy Chair)
   - human reproductive research and ethics expertise
   - originally appointed October 2011
   - current term ends April 2018.

3. Jonathan Darby
   - disability perspective
   - originally appointed in April 2013
   - current term ends April 2019.

4. Colin Gavaghan
   - expertise in law
   - appointed in June 2017
   - current term ends June 2020.

5. Kathleen Logan
   - expertise in the interests of children
   - originally appointed in April 2015
   - current term ends March 2018.

6. Sue McKenzie
   - general layperson
   - originally appointed in April 2013
   - current term ends in April 2019.

7. John McMillan
   - expertise in ethics
   - appointed in April 2016
   - current term ends April 2019.

8. Catherine Poutasi
   - general layperson
   - appointed in April 2016
   - current term was due to end in April 2019 but she resigned in February 2018 and we are seeking a replacement for her.

9. Karen Reader
   - human reproductive research expertise
   - appointed in December 2017
   - term ends 30 November 2020.

10. Barry Smith
    - expertise in Māori customary values and perspectives
    - originally appointed in April 2013
    - current term ends April 2019.

11. Sarah Wakeman
    - expertise in assisted reproductive procedures
    - appointed in December 2016
    - current term ends in December 2019.

APPENDIX 3

PROJECTS WE HAVE COMPLETED SINCE DECEMBER 2014

Project	Reason	Timeline
Advice on importing and exporting gametes and embryos for human reproductive research and assisted human reproduction.	Required by s.37(1)(g) and s.38(f) of the HART Act.	Advice provided 17 December 2014.
Advice to the Minister of Health on requirements for informed consent in regard to human assisted reproduction.	Required by s.38(d) of the HART Act.	Advice provided 2 September 2016.
Development of advice to the Minister of Health that the use of cryopreserved ovarian tissue should be declared an established procedure in the Human Assisted Reproductive Technology Order 2005.	ACART has considered a recent technical report and concluded that the procedure should be enabled for the use of the woman for whom it was stored, and that the procedure should not require ECART review.	Advice provided week of 6 February 2017.

APPENDIX 4

A BACKGROUND TO ASSISTED REPRODUCTIVE TECHNOLOGY IN NEW ZEALAND

1. The introduction, in the early 1970s, of freezing semen enabled sperm to be stored for future use. The first *in vitro* fertilisation (IVF) clinic was established at National Women's Hospital in 1983. The first New Zealand IVF baby was born the following year, six years after the first child was born from IVF, in the United Kingdom.

2. New Zealand did not have specific ART legislation until 2004. The former National Ethics Committee on Assisted Human Reproduction (NECAHR), established in 1993, formulated guidelines for the use of some procedures that posed particular ethical challenges (for example, surrogacy and embryo donation), and for human reproductive research. NECAHR also decided case by case applications for those procedures.

THE HART ACT 2004

3. The HART Act in many ways picked up and codified established practices by New Zealand fertility services providers.

    - Providers had incorporated counselling into their services, on the basis that counselling provided an opportunity for donors and intending parents to consider the implications of procedures.
    - From the late 1980s, providers began a policy of openness by requiring all sperm donors to be identifiable. Providers were also counselling intending parents who were using donated gametes about the importance of children knowing about their origins. This approach reflected changes in adoption legislation and what had been learnt from the era of closed adoption: that it is important for people to have the option of accessing identifying information about their genetic origins. The practice was also consistent with Māori values in respect of whānau/families eg, whakapapa and whanaungatanga.
    - New Zealand had an established culture of altruistic donation of human tissue, including sperm donation.

4. The HART Act originated as a Member's Bill that subsequently became a Government Bill. The original Bill was largely modelled on the United Kingdom legislation, although the HART Act has a distinct framework that is particular to New Zealand.

5. The HART Act incorporates similar values to ART legislation in the United Kingdom and Australian states, including:

    - prohibition on commercial trade in gametes and embryos
    - prohibition on commercial surrogacy
    - access for donor offspring to identifying information about donors.

6. A key difference between the HART Act and legislation in Australia and the United Kingdom is that the HART Act established a framework that does not require the primary legislation to be amended to change the rules about the use of some procedures. The HART Act gave ACART the statutory role of issuing guidelines on particular procedures that are ethically complex and require approval by the Ethics Committee on Assisted Reproductive Technology (ECART).

7. Another associated paper in this Briefing (Associated paper 4) provides details of the ART regulatory framework.

FERTILITY SERVICES IN NEW ZEALAND

Providers

8. The dominant fertility services provider is a private provider, Fertility Associates, which has clinics in Auckland, Hamilton, Wellington and Christchurch plus outreach to other regions. Fertility Associates has a relationship with a fertility clinic in San Diego for the purposes of supporting patients who choose to access fertility treatment overseas. Fertility Associates has recently established a clinic in Malaysia.

9. Other private providers are Repromed (Auckland) and a new entrant, Genea, which is an international company. Genea has affiliated with the Oxford Women's Health Clinic in Christchurch. There are two district health board providers: Fertility Plus (Auckland) and Otago Fertility Services (Dunedin) now run by Fertility Associates.

Funding

10. ACART does not have any policy or operational role in respect of funding for fertility treatment. District health boards contract with providers for publicly funded fertility services. Providers have both publicly and privately funded patients. Providers use criteria established by the Ministry of Health to determine patients' priority for publicly funded services.

Stakeholders

11. Fertility New Zealand is the national consumer group, comprising people who have had or are undergoing fertility treatment. Fertility New Zealand's activities include local support groups, a national Fertility Week, and advocacy on behalf of members. Fertility New Zealand regularly makes submissions to ACART about proposals.

12. There are also some web based groups and forums eg, linking potential egg donors and surrogates with intending parents, and sharing information about overseas fertility treatment. Some of these forums are only accessible by members.

13. A range of individuals and organisations regularly respond to ACART public consultations through written submissions and/or meetings. These include ECART, the Human Rights Commission, the Health and Disability Commission, the New Zealand Law Society, the Nathaniel Centre, the Interchurch Bioethics Council, Right to Life, medical professionals, Māori with an interest in family/whānau wellbeing, and academics in various disciplines such as bioethics, human reproductive research, sociology, and law.

14. The mix of stakeholders varies according to the issue being considered. For instance, members of the gay/lesbian/transgender/intersex community provided feedback to a past consultation on proposed changes to surrogacy guidelines.

15. Donor offspring — that is, those born as a result of assisted reproduction using donated gametes or embryos — are stakeholders who are not currently visible in public input to policy development. It is possible that their views about ART policy will enter public debate when a significant cohort of donor offspring reaches adulthood over the next two decades.

USE OF ASSISTED REPRODUCTION BY NEW ZEALANDERS

Use of fertility treatment in New Zealand

16. Since 2004, fertility services providers have contributed comprehensive annual data to the Australia New Zealand Assisted Reproduction Database (ANZARD), maintained at the University of New South Wales.[2] The ANZARD data is used to produce an internationally well regarded annual report *Assisted reproductive technology in Australia and New Zealand.* At the time of writing the most recent report is for 2014.

17. For most topics in the report, the analysis combines Australian and New Zealand data. In the past five years, ACART has been contracting for and publishing a New Zealand-specific report *Assisted reproductive technology in New Zealand* that includes selected items from the fuller Australasian reports. The most recent report is for 2014, and will be published on ACART's website within the next few months.

18. An analysis of New Zealand-specific trends will be possible for data from 2015 onwards (there is a 2 year lag between the reporting period and the publication date due to the 9 month gestation period plus data collation, analysis and report writing).

19. ACART's Annual Reports must include a report of the number and types of decisions made by ECART. ECART also produces an Annual Report which gives details of the type of applications, decisions made and outcomes.

20. Fertility services providers that have contracts with District Health Boards must report on the services provided as part of the contract.

21. Between 1 July 2015 and 30 June 2016, ECART considered 48 applications for assisted reproductive procedures. The cases that must be approved by ECART are a small proportion of all assisted reproductive procedures. Most procedures — eg, IVF using a couple's own gametes — do not require ECART approval.

Data about human reproductive research in New Zealand

22. All human reproductive research must be approved by ECART. The Annual Reports of ACART and ECART both include information about applications to undertake human reproductive research and ECART's decisions. In the period 1 July 2013 to 30 June 2014 ECART received two applications to undertake human reproductive research.

Use of assisted reproduction in New Zealand outside a fertility services provider

23. No data is available about the use and outcomes of donor insemination and surrogacy in informal arrangements outside fertility services providers. Any comment about its scale is therefore speculative. However, it is clear that insemination outside the formal system is practised by, for example, single women and lesbian couples. Informal

[2] ANZARD supersedes an earlier Australasian database which was established in 1979.

arrangements are also made for "traditional surrogacy"; that is, surrogacy in which the egg of the surrogate is used.

Use of assisted reproductive technology overseas by New Zealanders

24. There is a global market for fertility treatment, with some countries becoming destinations because procedures are more readily available or at a lower cost there than they are in patients' home countries. New Zealanders are taking advantage of opportunities in other countries, with easy access to information about procedures available elsewhere and the associated costs and requirements. Jurisdictions differ significantly in the extent to which ART is regulated, what is allowed and prohibited, and clinical practice.

25. A key driver for New Zealanders to go overseas is the shortage of donated eggs in this country. New Zealand prohibits commercial trade in gametes and embryos, whereas donated gametes are readily available in countries that do not prohibit valuable consideration for gametes, or which allow donors to receive substantial expenses. For instance, California and South Africa are popular destinations to obtain and use donated eggs.

26. The use of donated eggs obtained overseas appears to be a substantial proportion of all cases where New Zealanders use donated eggs. While no data are collected about numbers of New Zealanders going overseas to source donated gametes, anecdotal information suggests that around a third of all donated eggs used by New Zealanders may be obtained overseas. Fertility Associates estimates that it knows of up to 100 couples a year going overseas to access donated eggs. In comparison, in New Zealand in 2011 there were 203 cycles using locally sourced donated eggs.

APPENDIX 5

GLOSSARY

Advisory Committee on Assisted Reproductive Technology (ACART)	The advisory committee established under New Zealand's HART Act. Members are appointed by the Minister of Health. For more information, see ACART's website at: acart.health.govt.nz
Assisted reproductive procedure	Under the HART Act, a procedure performed for the purpose of assisting human reproduction that involves: • the creation of an in-vitro human embryo, or • the storage, manipulation or use of an in-vitro human gamete or an in-vitro human embryo, or • the use of cells derived from an in-vitro human embryo, or • the implantation into a human being of human gametes or human embryos.
Clinic-assisted surrogacy	A procedure facilitated by a fertility clinic where a woman gestates an embryo for an intending parent.
Donated embryo	An *in-vitro* human embryo that is donated for reproductive purposes.
Donor	A person whose gametes or embryo are given to another person for use in assisted reproduction. See section 5 of the HART Act. (Note that the legal definition under the HART Act means that a person who gives a gamete to his or her partner is not considered a donor.)
Donor offspring	Children born from assisted reproduction in which a donor has been involved.
Established procedure	Procedures declared in the Human Assisted Reproductive Order 2005 (HART Order) that do not require ECART review and approval. The Minister of Health is responsible for the HART Order.
Ethics Committee on Assisted Reproductive Technology (ECART)	The Ethics Committee established under New Zealand's HART Act. ECART reviews and decides case-by-case applications to undertake assisted reproductive procedures, human reproductive research and to extend the statutory storage period of gametes and embryos. ECART members are appointed by the Minister of Health. For more information, see ECART's website at: ecart.health.govt.nz
Fertility services provider	A fertility clinic.
Fertility Services Standard	A standard issued under the Health and Disability Services (Safety) Act 2001 that sets out the safety and quality measures that all New Zealand fertility services providers must meet. This standard came into force in 2009 and is available on ACART's website.
Gamete	An egg or sperm, whether mature or not, or 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.
Genetic link	A link created when the embryo used is created by the sperm and/or eggs of the intending parents.
Gestational link	A link created when the embryo used is gestated by a woman who is an intending parent.
Gestational surrogacy	A surrogacy where an embryo is transferred into the uterus of the surrogate and has no genetic link to the surrogate.
HART Act (2004)	New Zealand's human assisted reproductive technology legislation, under which ACART and ECART were established. The Minister of Justice is responsible for the HART Act.

Informed consent	A person's voluntary agreement, based on adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure.
In-vitro fertilisation (IVF)	The uniting of egg and sperm outside the body (in the laboratory).
Surrogate	A woman who becomes pregnant, carries and delivers a child on behalf of another person or couple (intended parent(s)).
Te Ao Māori	A Māori world view or the Māori dimension of understanding.
Third-party assistance	Assisted reproductive procedures that require a party other than the intended parents to contribute to family formation and where a fertility services provider is involved.
Tikanga Māori	The customary system of Māori values and practices that have developed over time.
Traditional surrogacy	Surrogacy where the eggs of the surrogate mother are used in conception (by in-vitro fertilisation or insemination).
Whakapapa	Genealogy, ancestral history, descent.
Whānau	Family group. In the modern context, the term is sometimes used to include friends who may not have any kinship ties to other members.
Whanaungatanga	A relationship, kinship, sense of family connection, through shared experiences of working together, which provides a sense of belonging.
Whāngai	Customary Māori practice where a child is raised by someone other their birth parents, usually a relative.

Review of ACART's guidelines for human reproductive research

Purpose

The Advisory Committee on Assisted Reproductive Technology (ACART) proposes reviewing its guidelines for human reproductive research, with a focus on expanding the guidelines to encompass research on viable embryos that are surplus to requirements for fertility treatment.

This briefing explains the status of human reproductive research in New Zealand, what the current guidelines allow for, and reasons for and against reviewing them.

Key points

- The Human Assisted Reproductive Technology (HART) Act 2004 directly prohibits or restricts a number of activities, and allows for others to proceed only with the approval of the Ethics Committee on Assisted Reproductive Technology (ECART). There is *no* blanket prohibition in New Zealand on research on embryos.
- ACART has independent powers to establish guidelines to determine when human assisted reproductive procedures that require approval are able to be approved by ECART. The constraints and expectations of assisted reproductive technology research are set down in ACART's *Guidelines for Research on Gametes and Non-Viable Embryos* (the guidelines). These guidelines date from 2005 and provide for research on eggs, sperm and non-viable embryos, but do not allow research on donated surplus viable embryos.
- In 2006/07 ACART consulted on aspects of human reproductive research and advised the then Minister of Health that research using donated surplus viable embryos should be allowed, and the guidelines revised accordingly. Despite a number of approaches from ACART since 2007, work to review the research guidelines has not proceeded because Ministers have never agreed to include the review on ACART's work programme.
- In ACART's letter to you of 11 May 2018 they have sought permission to include a review of the guidelines for research on their work programme. They consider that the guidelines constrain valuable research and should provide more detailed guidance than they do currently. ACART also believe the guidelines should be explicit about some matters not already included: research on viable embryos, and, possibly, social research (which focuses on the long term outcomes for people born of assisted reproductive technology and their families).
- [redacted] s 9(2)(f)(iv)
- Relatively little research into human reproductive technology is carried out in New Zealand. Many countries that are comparable to New Zealand allow research on surplus embryos, including viable embryos, although a small number do not allow any research on embryos at all.

- s 9(2)(f)(iv)
- [redacted]
- [redacted]

Research on embryos: the current situation in New Zealand

1. In New Zealand, human reproductive research is intentionally constrained through the HART Act 2004. The HART Act establishes roles for the Government (through the Minister of Health), and independent expert groups in considering and making decisions on technical and possibly controversial issues in assisted reproduction. This separation of roles provides the appointed technical experts with substantial flexibility and independence in considering the acceptability of procedures for assisted human reproduction.
2. There is no blanket prohibition on all research on embryos, including research using surplus viable embryos. However, some specific forms of research *are* prohibited, for example, implanting a cloned embryo into a human. The HART Act directly prohibits or restricts a number of actions. These prohibited actions may only be altered by Parliament amending the HART Act.
3. The HART Act also establishes processes (such as issuing guidelines and advice) for those activities that are not prohibited, but which require approval by the ethics committee. No human reproductive research can be conducted without the approval of the ethics committee, ECART. ECART may not approve an application for research unless that kind of research is covered by, and is in accordance with, guidelines issued by the advisory committee.
4. ACART's current *Guidelines for Research on Gametes and Non-Viable Embryos* provide for research using eggs, sperm and non-viable embryos but are silent on other categories of research. The guidelines do not, therefore, currently allow researchers to carry out research on surplus viable embryos. A copy of the guidelines is attached as *Appendix 1*.

ACART's obligations regarding human reproductive research

5. ACART is an independent statutory committee, established and appointed by the Minister of Health. In the area of human reproductive research, ACART's functions include:
    - issuing guidelines and giving advice to ECART on any matter relating to any kind of human reproductive research

- keeping guidelines and advice under review
- providing the Minister of Health with advice on aspects of, or issues arising out of, human reproductive research. This includes advice as to whether legislation should be amended or created.

6. ACART is also able to consult with anyone who, in its opinion, is able to assist it to perform its functions.

History of this matter

7. The *Guidelines for Research on Gametes and Non-Viable Embryos* predate both the HART Act and the establishment of ACART, and were taken from a 2004 publication by the Australian National Health and Medical Research Council. ACART published the guidelines in 2005 by the then National Ethics Committee on Assisted Human Reproduction, and they were officially adopted by ACART after its establishment, and issued to ECART.

8. The guidelines have not been reviewed or revised since their publication, although, in 2006/07, ACART consulted on aspects of human reproductive research. At the conclusion of that consultation process, ACART advised the then Minister of Health that in addition to continuing to allow research on gametes and non-viable embryos, researchers should also be allowed to use donated surplus viable embryos in research. Any such research would be subject to ethical review by ECART under guidelines issued by ACART.

9. [redacted] s 9(2)(f)(iv)

10. Under ACART's terms of reference the Minister and ACART must agree the Committee's work programme. To date, despite a number of approaches from ACART since 2007, Ministerial approval to include a review of the guidelines on the Committee's work programme has not been granted. ACART is frustrated at its inability to progress this issue, and has never been advised of earlier Ministerial attempts to clarify a government position. A timeline of events since 2005 is attached as Appendix 2.

11. On 11 May 2018, the then Chair of ACART, Gillian Ferguson, wrote to you explaining ACART's proposed review and asking you to agree to the Committee's request to add research on 'pre-implantation' (viable) embryos to its current work programme.

Why ACART wants to review the research guidelines

12. Besides being legally obliged to keep the research guidelines under review, ACART considers that the guidelines are too high level to provide adequate guidance to the sector, and should also include direction on areas not currently or explicitly included.

Providing more detailed guidance

13. ACART's approach to date has had a strong focus on revising the guidelines to explicitly include research on surplus viable embryos and social science research. They state that reasons to review the guidelines include to:

    a. ensure they more fully reflect the HART legislation (the guidelines were developed before the HART Act)

b. provide better guidance about the existing provisions in the guidelines, including on the nature and limits of acceptable research (for example explaining when an embryo is considered to be viable or non-viable) and

c. increase the emphasis in the guidelines on: reviewing the scientific value of the research; issues of informed consent; or New Zealand-specific cultural considerations that researchers should be taking into account.

14. While the research guidelines are very high level, this has possibly contributed to them maintaining a degree of currency over the past 10 years. Depending on their content, detailed guidelines may need to be updated more frequently.

15. ACART is likely to consider that adding more detailed guidance will:

a. make it easier for researchers to write their applications because they will know what information they will need to provide

b. help ECART assess applications because they will have clear guidance on the matters they must consider when assessing applications

c. reduce the risk of disputes arising about applications.

16. As there are very few applications made to ECART for ethical approval under the guidelines, it is difficult to assess the extent to which there are problems with them that need to be addressed. ECART has not indicated that it has difficulty evaluating applications, but there has been one dispute relating to an application that was determined to include research on viable embryos, and subsequently ECART declined another application that would have involved embryos being 'used' in research.

17. The definition of 'use' of embryos is one of the matters that could be addressed in a review of the guidelines.

Including areas not currently in the guidelines

18. ACART is of the view that the current guidelines are too narrow and that they constrain valuable research. At this stage, there are two areas that are not currently included in the guidelines that ACART would like to consider: research on surplus viable embryos and, possibly, social research. Issues around research on viable embryos are considered in more depth in the next section of this report.

19. s 9(2)(f)(iv) [redacted]

20. s 9(2)(f)(iv), s 9(2)(h) [redacted]

Embryo research

The nature and purpose of research on embryos

21. The benefits of embryo research include being better able to:
    a. treat injuries and diseases, by using stem cells
    b. understand the effects of embryonic development, including on health in later life, and potentially reverse developmental abnormalities
    c. test medicines and
    d. understand infertility and improve fertility treatments.
22. Any revised research guidelines would need to align with the HART Act, which prohibits or restricts some specific research on embryos, such as research on artificially formed embryos outside of the body after 14 days of development, and research on embryos stored for more than 10 years. Any researcher wanting to carry out research on embryos would need to abide by the guidelines and apply to ECART for ethical approval.

Why do research on viable embryos?

23. Non-viable embryos are readily available, as over 50% of created embryos display arrested development, and will never develop. Viable embryos would be obtained from people who have embryos surplus from fertility treatment, with their consent.
24. Some research can use either viable or non-viable embryos. For example, non-viable embryos are a reasonable source of embryonic stem cells, although viable embryos are a better source. Other research can only be done with viable embryos, as non-viable embryos will not develop. This would include watching embryonic development in different situations e.g. in different cultures, and if different edits were made to genes.

Potential benefits of research on viable embryos

25. There are some potential benefits of allowing New Zealand research on viable embryos. It could:
    a. lead to research findings that increase the success rate of fertility treatments in New Zealand, and internationally
    b. put surplus viable embryos to good use, if the owners wish to donate them to research (a number of owners have expressed a preference to donate surplus embryos to research. It is uncommon for surplus embryos to be donated to other families and, legally, they must eventually be destroyed.)[1]
    c. enable New Zealand researchers to carry out a wider range of independent research, or participate in research that is done in several countries simultaneously. This would support those researchers in their careers, encourage them to stay in New Zealand, and enhance New Zealand's reputation as a nation that participates in valuable research
    d. develop Maori and Pacific stem cell lines so that research can be better attuned to these populations.

Potential concerns about research on viable embryos

26. The use of embryos for research is the subject of intense debate. Unlike a non-viable embryo, a surplus viable embryo could potentially have become a child had someone been available to carry

[1] Now that the Act and guidelines have been in use for over 10 years an increasing number of stored embryos are passing the ten year limit for storing embryos.

it. People have deeply held views and ethical perspectives about the status of embryos, and whether their use in research is morally right or respectful.

27. The parliamentary debate preceding the third reading of the HART Bill in 2004 revealed that Members of Parliament held a range of views about research on human embryos. A number of parties split their vote on the Bill, enabling Members to vote according to their conscience.

28. When ACART consulted the public about these guidelines in 2006/07 it found two clear schools of thought, one opposed to embryo research and the other in favour. Most of those who opposed research using embryos were also opposed to all use of in vitro fertilisation, on the same basis: that it results in the creation of surplus embryos, which must later be destroyed.

Likely domestic interest in embryo research

29. Some New Zealand researchers would like to be able to undertake research using surplus viable embryos. However, to date, they have expressed little interest in applying for ethical approval for research on any embryos. This could be attributed to the limits of the existing guidelines, although we note that embryo research is also a highly specialised area.

30. ECART typically receives between 0 and 2 applications per year to do any kind of assisted reproductive research. From 2012 to 2015 ECART considered 4 research applications, none of which involved embryo research One application in 2013 was rejected, as ECART concluded that it would involve research on viable embryos, and another in 2018 for the same reason.

31. Even if revising the guidelines, and extending research to viable embryos, doubled or trebled the number of research applications, the overall number of applications would remain very small.

International comparisons

32. Many countries that are comparable to New Zealand allow research on surplus embryos including viable embryos. New Zealand is somewhat unusual in distinguishing between viable and non-viable embryos when allowing research. However, in the case of fertility treatment (not research) Australia currently makes a distinction between embryos that are suitable for transplantation into a woman's uterus and those that are not suitable.

Surplus embryos can be used in research	Surplus embryos cannot be used in research
Australia, Belgium, Canada, Czech Republic, Denmark, Finland, France, Greece, Hungary, Netherlands, Russia, Singapore, Sweden, United Kingdom, United States (all but 5 states)	Austria, Germany, Ireland, Italy, Norway, Poland, Portugal

33. Few countries permit embryos to be created for use in research and ACART is not considering making such a proposal. New Zealand also has a statutory prohibition on implanting genetically modified embryos. Again, this is not a matter ACART is considering investigating.

ACART's consultation process

34. Should you agree to ACART revising the research guidelines, it is likely to consult on those areas identified earlier:

- making the existing guidelines current, more detailed and useful
- adding guidance on research on surplus viable embryos and
- the merits of adding guidance on social research on assisted reproductive technology.

35. Given the likely interest in this subject, a multi-stage consultation process may be proposed. The process would probably include:

    a. preparation of a consultation document that sets out the regulatory context and the perceived inadequacies of the existing guidelines, proposed changes and ACART's analysis of those proposals. ACART would be likely to present the limits that could apply to any research on viable embryos, and set out the legislative and ethical reasons for those limits

    b. public and sector consultation on proposed revised guidelines for a minimum of six weeks, including both written submissions and meetings with interested parties

    c. possible additional consultation on a new draft guideline (alternatively, a draft proposed guideline could be included in the initial consultation document) and

    d. consultation with the Minister of Health on the final guidelines, before they are issued to ECART

36. Although ACART s not required to do so, it could also engage in targeted pre-consultation discussions around the proposed scope and process, such as with the Minister of Health and Ministry of Health.

37. Reviewing and revising the guidelines would constitute a significant project for ACART, likely to take at least 12 to 18 months. Other important work may need to be delayed in order to undertake the review. This could include work addressing known risks or emerging issues, or of more practical benefit to people wanting to have children.

38. We expect that researchers would, typically, favour research on viable embryos. There would be vocal opposition to allowing research on viab e embryos from some quarters, such as right to life groups. There is likely to be a mixed reaction from the general public.

39. There are likely to be fewer objections to amending the current guidelines if those amendments do not include adding provisions to the guidelines about research on viable embryos. Having said this, it is likely that parties who are opposed to assisted reproductive technology and research of any sort would take the opportunity to express their concerns about the guidelines.

Role of the Government in determining a position on research on viable embryos

40. Under the HART Act, the *Guidelines for Research on Gametes and Non-Viable Embryos* are the responsibility of, and issued by, ACART. They do not necessarily express or represent the Government's position.

41. Should a review of the guidelines be undertaken, ACART would be obliged, under the HART Act, to consult the Minister of Health on the proposed guidelines before issuing them to ECART. However, the legislative framework gives the responsibility and decision making power for the guidelines to ACART. Ministerial approval for the content of the guidelines, or their release, is not required. There is also no provision in the Act for the Minister to direct ACART on the content, or release, of any guidelines. A direction by the Minister to ACART relating to the content of the guidelines would likely be ultra vires.

42. This means that ACART may determine what kind of research may be approved by ECART, as long as it is allowed by the HART Act: which does not prohibit research using surplus viable embryos.

43. Ministers have the option of declining to grant approval to review the *Guidelines for Research on Gametes and Non-Viable Embryos*. This is the approach taken by previous Ministers. By doing so, the content of the guidelines remains fixed, and they continue to be silent on the issue of research on viable embryos.

44. The HART Act also includes the ability to impose moratoria, prohibited actions and regulations.

45. s 9(2)(f)(iv) [redacted]

46. [redacted]

47. [redacted]

Next steps: options available to progress this issue

48. s 9(2)(f)(iv) [redacted]

49. [redacted]

50. [redacted]

[2] s 9(2)(f)(iv) [redacted]

s 9(2)(f)(iv)

51.

52.

53.

54.

END.

Appendix One: Guidelines for Research on Gametes and Non-viable Embryos

MINISTRY OF HEALTH
MANATŪ HAUORA

Security classification: In-Confidence

05 FEB 2019

COPY

Health Report: Compensation for egg and sperm donors

Date:	31 January 2019	Report No:	20182242
		File Number:	AD62-14-19

Action Sought

	Action Sought by Minister's Office	Deadline
Minister Clark	Agree	23 February 2019
Minister Genter	Note	

Contact for Telephone Discussion (if required)

Name	Position	Telephone	Contact Order
Martin Kennedy	Senior Policy Analyst, Ethics, Health System Improvement and Innovation	04 816 4353	1st Contact
Rob McHawk	Acting Manager, Ethics, Health System Improvement and Innovation	04 819 6821	2nd Contact

Actions for the Minister's Office Staff

Return the signed report to Ministry of Health

Due date: 23 February 2019. To enable planning of the work programmes of both ACART and the Ethics team.

Note any feedback on the quality of the report

MINISTRY OF HEALTH
MANATŪ HAUORA

Health Report number: 20182242

Security classification: In-Confidence

File number: AD62-14-19
Action required by: 23 February 2019

Compensation for egg and sperm donors

To: Hon Dr David Clark, Minister of Health
Copy to: Hon Julie Anne Genter, Associate Minister of Health

Purpose

You have asked for advice about whether human egg and sperm donors should be compensated. You requested this advice after meeting the Chair of the Advisory Committee on Assisted Reproductive Technology (ACART), and the manager of the Ethics team at the Ministry of Health (the Ministry).

This briefing outlines the main factors to consider when evaluating if and how donors could be compensated and asks whether you wish the Ministry to undertake policy work for these options.

Key points

- In 2015, ACART recommended a change to the current law to enable donors to be compensated for reasonable expenses incurred in the process of donation. (ACART's advice[1] is attached as **Appendix 1**.)
- The Ministry's initial position is that it is not conclusive that reimbursing expenses would increase donation rates in New Zealand.
- To allow compensation for donors would require further policy work and legislative change to the Human Assisted Reproductive Technology Act 2004 (HART Act).
- ACART also recommended a number of promotional initiatives to increase donations within the existing legislative framework. The Ministry supports the promotion of reproductive health literacy and is already undertaking action in this area (see paragraph 37). The Ministry could provide further advice on the methods and costs associated with possible non-legislative options.
- ACART also recommended developing new regulations to set out requirements for importing and exporting of gametes and embryos. The rules for importing gametes and embryos are not well understood by the fertility sector and consumers, with many believing it is prohibited, which is not the case. It may be beneficial to clarify the rules on import and export of gametes and embryos through regulation, standards or other guidelines.

[1] The advice was submitted to the then Minister of Health on 17 December 2014 while the version on ACART's website was published on 30 March 2015 with minor redactions to protect legal privilege.

Contacts:	Rob McHawk, Acting Manager, Ethics, Health System Improvement and Innovation	s 9(2)(a)
	Martin Kennedy, Senior Policy Analyst, Ethics, Health System Improvement and Innovation	04 816 4459

Health Report number: 20182242

Compensation for egg and sperm donors

Recommendations

The Ministry recommends that you:

a) **note** that reimbursing expenses for gamete donors would not fully solve the donation shortage in New Zealand

b) **note** that the availability of donations might be increased by clarifying to clinics that import is permitted

c) **note** that increasing fertility would best be achieved through a multi policy approach

d) **note** that the Ministry intends to:

- ensure clinics are clear about the legal position on the import and export of gametes and embryos
- encourage clinics to discuss the option of egg and sperm sharing with all fertility patients

e) [redacted] s 9(2)(f)(iv)

Yes / No

Yes / No

Yes / No

Keriana Brooking
Deputy Director-General
Health System Improvement and Innovation

Minister's signature:
Date:

Health Report number: 20182242

Compensation for egg and sperm donors

Background

1. In New Zealand the supply of human sperm and eggs for use in fertility treatment does not meet the demand.
2. The shortfall leads to some people seeking alternatives including treatment overseas or possibly the use of surrogates. Treatment overseas and surrogacy both pose risks to all the parties involved, including the offspring. For some people, overseas treatment or surrogacy are not options and these people are often unable to have babies by any means.
3. Increasing access to fertility treatment and the availability of donor sperm and eggs are two factors that affect people's ability to have children. A range of other factors may also determine whether people will be able to have children, including the age at which they try to have them and general health.
4. s 9(2)(f)(iv) [redacted]

ACART recommended amending the regulatory setting

5. ACART's 2015 report argued that the regulatory setting for fertility treatment (particularly the regulation around gamete donation) is part of the cause of the shortage. ACART also argued that by amending the regulatory setting the Government could increase the supply of gametes for use in New Zealand. Doing so would reduce the number of people seeking treatment overseas or surrogacy and, most importantly, enable people to have families in New Zealand.
6. ACART's advice recommended a number of other actions including educational efforts to improve the general public's understanding of fertility. In 2016, the Ministry responded to ACART's advice with advice to the then government.
7. You have asked for advice on whether human egg and sperm donors should be compensated. The s 9(2)(f)(iv), s 9(2)(h) [redacted]
8. In the interim, several stakeholders within the sector have contacted the Ministry regarding the lack of progress in considering payment of compensation to egg and sperm donors. The previous government also received correspondence requesting clarification around import and export requirements, and the legalities of compensation under the Human Assisted Reproductive Technology Act 2004.

ACART's specific recommendations about compensating gamete donors

9. ACART identified two key risks in relation to the shortage of available gametes.
   a. There are clinical risks for women and children when treatment is sought overseas as some practices not regarded as good practice in New Zealand are used. For example, the transfer of more than one embryo into a woman.
   b. Risks to donor offspring born from trans-border reproduction having anonymous donors and not knowing their whakapapa/genetic heritage.

10. ACART's recommendations about compensating gamete donors were:
    a. section 13 of the HART Act should be amended to enable donors to be compensated for reasonable expenses incurred in the process of donation
    b. regulations should also be made about the scope of reasonable expenses that are available for donors
    c. for consistency, the scope of reasonable expenses available for surrogates should also be considered.

Other factors are at play

11. The Ministry agrees with ACART that some people seek treatment overseas because of the shortage of donors in New Zealand, but recognises there may be other factors that influence people's decision to have treatment overseas such as:
    a. a greater availability of practices that are prohibited in New Zealand, such as sex selection
    a. availability of anonymous donations
    b. faster or cheaper treatment
    c. individual choice and personal preference.

The size of the shortage

12. The number of individuals affected by low rates of gamete and embryo donation in New Zealand is unclear but appears to be low.
13. In 2014, ACART estimated (based on anecdotal feedback) that around 100 patients per year travel overseas for fertility treatment. In contrast, around 5000 individuals access fertility treatments in New Zealand each year.
14. Fertility Associates, the largest provider in New Zealand has advised the Ministry that they help around 50 couples a year who travel overseas for treatment. This help consists of doing tests, sometimes including blood tests and scans on behalf of their overseas clinic to shorten the time that people seeking treatment need to spend away from New Zealand.
15. ACART recommends that gamete donors in New Zealand should be compensated for reasonable expenses incurred in the process of donation, and that regulations are needed to define the scope of such expenses. ACART and the sector believe that paying compensation would increase donation rates and decrease the number of individuals travelling overseas for treatment.
16. There is a lack of evidence to definitively state that allowing compensation for gamete donations would increase donation rates or decrease the number of New Zealanders travelling overseas to access fertility treatment. Donations can also be affected by the potential burden to donors and potential recipients might be uncomfortable asking people to donate due to the expenses and/or inconvenience. However, the Ministry agrees that the regulatory setting, including the ban on compensation, to some extent limits the supply of gametes in New Zealand [redacted] s 9(2)(f)(iv)

Options to address the shortage

17. In the next section we outline options for addressing infertility that include both regulatory options and options to increase public knowledge and education.
18. We understand that one of the primary motivating factors for sperm donation is altruism. However, in countries where compensation for donors is allowed, many donors have indicated that they would cease donation in the event that compensation was discontinued.
19. Altruism may be a motivation but the lack of compensation may present a barrier for potential donors.

20. The options outlined below are aimed at addressing both the broader issue of infertility as well as s 9(2)(f)(iv) These options are not mutually exclusive and can be done in tandem or sequentially if you wish.

A.

21. s 9(2)(f)(iv)

22. ACART stated that gamete donors should be able to receive compensation at a level which fairly compensates for the expenses incurred and the significance of the gift. This is particularly justified for egg donation, which is intrusive, uncomfortable and risky for donors. The donation procedure involves a series of hormone injections, and retrieval of eggs under anaesthetic.

23. The method (or extent) of the compensation would depend, to some extent, on the inconvenience, time off work, pain and risk.

24. s 9(2)(f)(iv)

25. Our initial investigation of how other countries manage compensation for donors indicates that fewer than ten countries allow compensation for donors and most of those allow only expenses to be claimed. The United States of America is different in that in some cases donors can be handsomely compensated.

26. These matters, in particular costs and effectiveness would be addressed in any scoping work if you direct the Ministry to carry out such work (see recommendation e).

The HART Act currently prohibits compensation for gamete donors

27. There is a regulatory barrier to this option. Section 13(1) of the HART Act states that "No person may give or receive, or agree to give or receive, valuable consideration for the supply of a human embryo or human gamete."

28. The Ministry has interpreted this to mean that no payment of any sort can be offered or accepted for the donation of human embryos or gametes.

29. s 9(2)(f)(iv)

30. s 9(2)(h)

The HART Act permits reasonable compensation for other assisted reproductive procedures

31. The HART Act allows for surrogates to have certain specified necessary and reasonable services paid for them by another person (medical, legal and counselling services) so that they are no better or worse off for assisting couples who need a surrogate.

32. s 9(2)(f)(iv)

33. Out of scope

34. s 9(2)(f)(iv)

35. Out of scope

B. Non-legislative options for increasing gamete availability

36. The options presented by the Ministry below include policies that could help to a) reduce infertility, b) increase the supply of donor gametes and c) improve the collection of data on donations and demand for donated gametes and embryos. These options can be explored independently of a decision to amend, or not to amend, legislation around the compensation of gamete donors.

Option one: Targeted advertising and education

37. In their 2014 advice, ACART recommended that the Ministry consider public health initiatives to advise people how age and other factors affect fertility and to raise awareness about gamete donation.

38. The Ministry is aware that people can be poorly informed about the factors affecting fertility. The Ministry funds 33 Family Planning clinics in New Zealand and supports fertility education efforts by fertility services providers.

39. We also note that some fertility clinics and advocacy groups such as Fertility New Zealand run advertising and awareness campaigns. For example, Fertility New Zealand runs "Fertility Awareness Week" every year. However, this does not appear to substantially increase egg and sperm donations. As we note in paragraph 4 above we would need more information about the effectiveness of advertising campaigns and the target audience to determine whether spending on such activity is a good use of resources.

40. There is no regulatory barrier to exploring other ways to inform people about the unmet demand for gametes. Proactively addressing fertility literacy in New Zealand would be the most effective method long term.

41. Advertising and educational campaigns would require an operating budget. If you wish to explore options in this area, the Ministry could tender further advice on the methods and costs associated with possible options.

Option two: Encourage egg and sperm sharing

42. Egg sharing (the gifting of 'surplus' eggs by a woman undergoing fertility treatment to another person who needs eggs) is not prohibited under the HART Act or any regulations. The most widely accepted argument for permitting egg sharing is the lack of additional risk for the donors as they would be going through a cycle of treatment anyway.

43. s 9(2)(f)(iv) [redacted]

44. Encouraging egg and sperm sharing is an option that would work well alongside Option one above. Guidance would need to focus on best practice for ensuring consent is informed. Guidance would also need to discuss methods for ensuring equity of access to avoid private patients accessing all available gametes due to waiting times in the public system.

Option three: Clarify the legality of importing and exporting gametes and embryos

45. s 9(2)(f)(iv) [redacted]

46. ACART's 2014 advice noted that the fertility sector is unclear about the current regulations for importing and exporting gametes and embryos. Providers and consumers generally interpret the principles of the HART Act to mean that gametes and embryos cannot be imported into New Zealand, and should not be used unless they meet New Zealand standards in all respects. Some providers have told patients going overseas for treatment that they will not be able to import or use any gametes or embryos in New Zealand if payment of any kind was exchanged.

47. s 9(2)(h) [redacted]

48. s 9(2)(f)(iv) [redacted]

49.

END.

21 Feb 2019

Thu 21. Minister Clark — KC. Emma P. CofG Maddock

Reach enq:
- equity Q. – will [illegible] help equity?
- no decision today
- [illegible] from only to only — no [illegible] issue
- DOT except [illegible] right consequence
- rates [illegible] in NZ
- Maori + Pacific in Oz
- Do Oz have data on Maori + Pacific

HART Report – DIA
- anonymity of donors or republish donor want child to know

CPI – need [illegible] for [illegible] first
- agreed, add to ~~[illegible]~~ work programme

Review HART Act
- review – TPD priority
- what is next?
- doesn't want it to go from MoJ → MoH

Review of staff, MoH ...

~~- ~~ appointments ... membership.
- Must agrees.
- scott ↓ ∴ slow progress.
- Must discuss ... Ashley.~~