

Ethics Committee on Assisted Reproductive Technology Application Form for Ethics Approval of Donation of Gametes between Certain Family Members

Please note:

- All sections of the application are to be word processed - the text boxes for answers will expand as you type.
- All headings are to be included in your application. If you consider a section or part of a section does not apply to your application, please explain why.
- The final report date of each section (medical, legal, and counselling) must not be more than six months prior to the date of application submission to ECART.
- Additional relevant information that the headings do not allow for may be appended.
- Do not include personal identifying information about the involved parties. Please refer to the recipient woman as RW, the recipient's partner as RP, and the donor as ED (if egg donor) or SD (if sperm donor), and their partner as DP.

Completed applications are to be sent to:

Secretariat
Ethics Committee on Assisted Reproductive Technology
PO Box 5013
WELLINGTON

Information for Applicants

ECART advises applicants to read the *Guidelines on Donation of Gametes between Certain Family Members* which are located at: www.ecart.health.govt.nz

Ethics Committee on Assisted Reproductive Technology Application Form for Ethics Approval of Donation of Gametes between Certain Family Members

SECTION 1: Declaration by Person Responsible

Executive summary and authorisation by “the nominated person” as defined by sections 18(1) (d) and 20(1) of the HART Act 2004. This would generally be the director of the medical practice.

- 1.1 Name:
Designation:
Clinic:
Address:
E-mail:

1.2 Clinic Reference Number/s:

- 1.3 Executive summary of application to include:
- A descriptive summary of the application; and
 - Important ethical, medical, legal, cultural and psycho-social issues; and
 - Risks that are specific to those involved in this application.

(Note: Limited to 250 words)

1.4 I enclose all the following information with this application:

CHECKLIST – Mark with an ‘X’	→
• Section 1: Declaration by Person Responsible	<input type="checkbox"/>
• Section 2A: Report by medical specialist for RW and RP	<input type="checkbox"/>
• Section 2B: Report by medical specialist for ED/SD and DP	<input type="checkbox"/>
• Section 3A: Report by counsellor for RW and RP	<input type="checkbox"/>
• Question 3A.9: Letter/s from RW and/or RP	<input type="checkbox"/>
• Section 3B: Report by counsellor for ED/SD and DP	<input type="checkbox"/>
• Question 3B.9: Letter/s from ED/SD and/or DP	<input type="checkbox"/>
• Section 3C: Joint counselling report for RW and RP and ED/SD and DP	<input type="checkbox"/>
• Section 4: Statement from Key Person under 3A.8 and/or 3B.8	<input type="checkbox"/>
• Other	<input type="checkbox"/>

Please read and sign this declaration:

I have checked all the information supplied in this application and it is, to the best of my knowledge and belief, accurate.

I agree that these patients will be treated in accordance with the Code of Practice for Assisted Reproductive Technology Units or, when it comes into effect, the current New Zealand Standard *Fertility Services*.

I acknowledge that counselling will be available to all parties before and after pregnancy is achieved.

I am making available to RW and RP the relevant sections of the application (1, 2A, 3A, and 3C) and if they advise of significant alterations or additions, I will inform ECART prior to ethical review.

I am making available to ED and/or SD the relevant sections of the application (1, 2B, 3B, and 3C) and if they advise of significant alterations or additions, I will inform ECART prior to ethical review.

I agree to provide to ECART on an at least annual basis, the outcome of this application (if approved) until the treatment covered by this application is complete or discontinued, and to advise ECART immediately of any serious adverse outcomes.

Signature of nominated person:

Date:

The information requested in this application is for the purposes of the Ethics Committee on Assisted Reproductive Technology, which is considering your application for ethics approval. The Committee will endeavour to maintain confidentiality of this information in accordance with the Privacy Act 1993. This may result in disclosure of information for a purpose or a directly related purpose with which this application is concerned but is limited in terms of the Official Information Act 1984.

Ethics Committee on Assisted Reproductive Technology Application Form for Donation of Gametes between Certain Family Members

SECTION 2A: Report by medical specialist for RW and RP

Please note:

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- The final report date of each section (medical, legal, and counselling) must not be more than six months prior to the date of application submission to ECART.
- Additional relevant information that the headings do not allow for may be appended.
- Do not include personal identifying information about the involved parties. Please refer to the recipient woman as RW, the recipient's partner as RP, the donor as ED (if egg donor) or SD (if sperm donor), and the donor's partner as DP.

2A.1 Specialist Name:

Address:

E-mail:

2A.2 Give the location and dates of meetings with the recipient/s.

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2A.3 Give the location and dates of meetings with other medical specialists if applicable.

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2A.4 Provide background information on the recipient/s.

	RW	RP
Age		
Ethnicity (including iwi affiliations)		
Nationality		
Number and age of children		

2A.5 Are the RW and RP both living permanently in New Zealand?

Yes No

If the parties are not living permanently in New Zealand, please explain why treatment is being sought in New Zealand:

(Note: ECART must take into account whether the residency of the parties safeguards the wellbeing of all parties and especially any resulting child.)

2A.6 Provide the medical history for the RW, including obstetric and neonatal history (together with her ability to carry a pregnancy) and, where applicable, the medical condition and/or treatments that have resulted in gamete donation being the preferred management option.

(Note: The *Guidelines* require that the recipient or the recipient's partner has a medical condition affecting his or her reproductive ability, or a medical diagnosis of unexplained infertility, that makes gamete donation appropriate.)

2A.7 Provide the medical history for the RP, and, where applicable, include the medical condition and/or treatments that have resulted in gamete donation being the preferred management option.

(Note: The *Guidelines* require that the recipient or the recipient's partner has a medical condition affecting his or her reproductive ability, or a medical diagnosis of unexplained infertility, that makes gamete donation appropriate.)

2A.9 Please summarise whose gametes will be used in the fertilisation treatment.

2A.10 Describe any significant medical risks to the RW and/or RP associated with gamete donation treatment, and the measures recommended to minimise these risks. Please detail this information or attach a letter.

2A.11 Outline what you consider to be any psycho-social issues involved with the RW and RP relating to the preferred treatment. Explain how these psycho-social issues have been addressed.

2A.12 Under principles (f) and (g) of the HART Act, comment on how you believe the different ethical, spiritual, and cultural perspectives in society, including the needs, values, and beliefs of Maori, will be considered and treated.

2A.13 Provide any other comment and information about the RW and RP that you consider relevant to this application.

Declaration

The information supplied in this section is, to the best of my knowledge and belief, accurate.

Signature of Medical Specialist for recipient/s: _____

Date: _____

Ethics Committee on Assisted Reproductive Technology Application Form for Donation of Gametes between Certain Family Members

SECTION 2B: Report completed by medical specialist for ED/SD and DP

Please note:

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- The final report date of each section (medical, legal, and counselling) must not be more than six months prior to the date of application submission to ECART.
- Additional relevant information that the headings do not allow for may be appended.
- Do not include personal identifying information about the involved parties. Please refer to the recipient woman as RW, the recipient's partner as RP, and the donor as ED (if egg donor) or SD (if sperm donor), and the donor's partner as DP.

2B.1 Specialist Name:

Address:

E-mail:

2B.2 Give the location and dates of meetings with the ED/SD (and DP if applicable).

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2B.3 Give the location and dates of meetings with other medical specialists if applicable.

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2B.4 Provide background information on the ED/SD (and DP if applicable).

	ED/SD	DP
Age		
Ethnicity (including iwi affiliations)		
Nationality		
Number and age of children		

2B.5 Is the ED/SD living permanently in New Zealand?

Yes No

If the ED/SD is not living permanently in New Zealand, please explain why treatment is being sought in New Zealand:

(Note: ECART must take into account whether the residency of the parties safeguards the wellbeing of all parties and especially any resulting child.)

2B.6 Taking into consideration principle (c) of the HART Act, please provide the medical history for the ED/SD, including details of any medical condition and/or treatments that may affect the risks associated with gamete donation treatment.

2B.7 Provide the relevant medical history for the partner of the ED/SD.

2B.8 Has the ED/SD completed his or her family?

Yes No

If no, please comment.

2B.9 Outline what you consider to be any psycho-social issues involved with the ED/SD and DP relating to the preferred treatment. Explain how these psycho-social issues have been addressed.

2B.10 Under principles (f) and (g) of the HART Act, comment on how the different ethical, spiritual, and cultural perspectives in society, including the needs, values, and beliefs of Maori, will be considered and treated.

2B.11 Provide any other comment and information about the ED/SD that you consider relevant to this application.

Declaration

The information supplied in this section is, to the best of my knowledge and belief, accurate.

Signature of Medical Specialist for the donor: _____

Date: _____

Ethics Committee on Assisted Reproductive Technology Application Form for Donation of Gametes between Certain Family Members

SECTION 3A: Report completed by counsellor for RW and RP

Note: This section is to be filled in by RW and RP's counsellor

Please note:

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- The final report date of each section (medical, legal, and counselling) must not be more than six months prior to the date of application submission to ECART.
- Additional relevant information that the headings do not allow for may be appended.
- Do not include personal identifying information about the involved parties. Please refer to the recipient woman as RW, the recipient's partner as RP, and the donor as ED (if egg donor) or SD (if sperm donor), and the donor's partner as DP.

3A.1 Name of counsellor:

Address:

E-mail:

Telephone:

3A.2 Give the location/s and date/s of counselling, and who was present at the session.

3A.3 ECART prefers for counselling to be undertaken in face to face meetings. Please explain the circumstances where this has not always occurred.

3A.4 Please comment on the interval between counselling sessions in relation to the opportunity for adequate time to consider all the issues.

3A.5 With particular reference to the implications for the potential child, the ED/SD and the recipient/s (under principles (a) (b) and (c) of the HART Act), provide details of the counselling session with the recipient/s using the following headings:

(a) the social history of the RW including significant life experiences.

(b) the social history of the RP including significant life experiences.

(c) the relationship between the recipient/s and the ED/SD, including the length of time they have known each other, and with particular concern for any resulting child's wellbeing, ongoing contact with the ED/SD, and future access to information about their genetic origins.

(d) the needs and rights of any children resulting from the donation, in particular their needs and rights to information under sections 49 and 50 of the HART Act and possible contact with the ED/SD in the future.

(e) implications of accepting donated gametes from a family member, with particular reference to whether the potential impact of the genetic, social, cultural and intergenerational aspects of the arrangement safeguards the well-being of the resulting child, the ED/SD, and the recipient/s.

(f) the attitude of the recipient/s to openness about the donation, especially with any resulting child, including the importance of telling any resulting child about the nature of their conception under s46(3)(g) of the HART Act.

- (g) the understanding that the recipient/s are the legal parents of any resulting child.

- (h) the understanding that the ED/SD has the right to withdraw consent prior to insemination.

- (i) the provision for the inclusion of any existing children in counselling. Provide details of counselling undertaken or where this has not occurred, please comment on the reasons why.

- (j) the provision of whanau/extended family involvement in counselling.

- (k) particular life experiences (for example, psychiatric problems, substance/physical/sexual abuse, criminal history) which may predispose any of the persons to risk when moving into a new situation, or which may pose a risk to any resulting child.

- (l) any involvement of the ED/SD in any resulting child's upbringing.

- (m) the possibility of a change in the relationship and a process for the consequent resolution of disputes prior or subsequent to the completion of the donation.

3A.6 In your professional opinion, please outline what you consider to be the specific ethical and psycho-social issues involved for the RW and RP (and if appropriate their family group), including any potential conflicts of interest and risks to all persons involved including any resulting child. Explain how these ethical and psycho-social issues have been addressed.

3A.7 How have you ensured the counselling has been culturally appropriate?

3A.8 Where a party/ies is Maori, please advise how whakapapa, and the needs, values and beliefs of Maori, have been considered and managed.

(Note: A statement from a key person (e.g. Whanau member, kaumatua, Maori counsellor) may be attached as Section 4.)

3A.9 Provide comment and any other information about RW and RP you consider is relevant to this application. A letter from RW and/or RP may be attached.

Declaration

The information supplied in this section is, to the best of my knowledge and belief, accurate.

Signature of counsellor for recipient/s: _____

Date: _____

Ethics Committee on Assisted Reproductive Technology Application Form for Donation of Gametes between Certain Family Members

SECTION 3B: Report completed by counsellor for ED/SD and DP

Note: This section is to be filled in by ED/SD and DP's counsellor

Please note:

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- Do not include personal identifying information about the involved parties. Please refer to the recipient woman as RW, the recipient's partner as RP, and the donor as ED (if egg donor) or SD (if sperm donor), and the donor's partner as DP.

3B.1 Name of counsellor:

Address:

E-mail:

Telephone:

3B.2 Give the location/s and date/s of counselling, and who was present at the session.

3B.3 ECART prefers for counselling to be undertaken in face to face meetings. Please explain the circumstances where this has not always occurred.

3B.4 Please comment on the interval between counselling sessions in relation to the opportunity for adequate time to consider all the issues.

3B.5 With particular reference to the implications for any resulting child, the ED/SD and the recipient/s (under principles (a) (b) and (c) of the HART Act), provide details of the counselling session with the ED/SD's family group, using the following headings:

(a) the social history of the ED/SD including significant life experiences.

(a) the relationship between the recipient/s and the ED/SD, including the length of time they have known each other, and with particular concern for any resulting child's wellbeing, ongoing contact with the ED/SD, and future access to information about their genetic origins.

(b) the reasons for donating gametes.

(c) the ED/SD's feelings concerning the donation now and in the future.

(d) the provision for the inclusion of any existing children in counselling. Provide details of counselling undertaken or where this has not occurred, please comment on the reasons why.

(e) the provision of whanau/extended family involvement in counselling.

(f) particular life experiences (for example, psychiatric problems, substance/physical/sexual abuse, criminal history) which may predispose any of the persons to risk when moving into a new situation, or which may pose a risk to any resulting child.

(g) the needs and rights of any children resulting from the donation, in particular their needs and rights to information under sections 49 and 50 of the HART Act and possible contact with the ED/SD in the future.

(h) the attitude of the ED/SD to openness about the donation, especially with any resulting child, including the importance of telling offspring about the nature of their conception under s46(3)(g) of the HART Act.

(i) the understanding that the recipient/s are the legal parents of any resulting child.

(j) the understanding that the ED/SD has the right to withdraw consent prior to insemination.

(k) the implications of donating gametes to a family member, with particular reference to whether the potential impact of the genetic, social, cultural and intergenerational aspects of the arrangement safeguards the well-being of any resulting child, the ED/SD, and the recipient/s.

(l) any involvement of the ED/SD in any resulting child's upbringing.

(m) the possibility of a change in the relationship and a process for the consequent resolution of disputes, prior or subsequent to the completion of the donation.

3B.6 In your professional opinion, please outline what you consider to be the specific ethical and psycho-social issues involved for the ED/SD (and if appropriate their family group), including any potential conflicts of interest and risks to all persons involved including any resulting child. Explain how these ethical and psycho-social issues have been addressed.

3B.7 How have you ensured the counselling has been culturally appropriate?

3B.8 Where a party/ies is Maori, please advise how whakapapa, and the needs values and beliefs of Maori, have been considered and managed.

(Note: A statement from a key person (e.g. Whanau member, kaumatua, Maori counsellor) may be attached as Section 4.)

3B.9 Provide any other comment and information about ED/SD you consider relevant to this application. A letter from the ED/SD and/or DP may be attached.

Declaration

The information supplied in this section is, to the best of my knowledge and belief, accurate.

Signature of counsellor for donor: _____

Date: _____

Ethics Committee on Assisted Reproductive Technology Application Form for Donation of Gametes between Certain Family Members

SECTION 3C: Joint counselling report for RW and RP and ED/SD and DP

Note: The joint counselling session is to be undertaken with the counsellors for each party present.

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- Do not include personal identifying information about the involved parties. Please refer to the recipient woman as RW, the recipient's partner as RP, and the donor as ED (if egg donor) or SD (if sperm donor), and the donor's partner as DP.

3C.1 Give the location and date of counselling, and who was present at the session.

3C.2 ECART prefers for counselling to be undertaken in face to face meetings. Please explain the circumstances where this has not always occurred.

3C.3 Please comment on the interval between the individual and joint counselling sessions in relation to the opportunity for adequate time to consider all the issues.

3C.4 With particular reference to the implications for any resulting child, the ED/SD and the recipient/s (under principles (a) (b) and (c) of the HART Act), provide details of the counselling session, using the following headings:

- (a) the issues and implications of the donation for all parties involved, including any resulting child.

- (b) possible external attitudes towards the donation.

- (c) the needs and rights of any children resulting from the donation, in particular their needs and rights to information under sections 49 and 50 of the HART Act and possible contact with the ED/SD in the future.

- (d) the rights given under Part 3 of the HART Act to ED/SD and donor offspring, the guardians of donor offspring, and other people to obtain information about ED/SD and donor offspring.

- (e) the counsellors' observations of the relationship between the recipient/s and ED/SD, including power relationships/evidence of coercion.

- (f) the recipient/s' and ED/SD's understanding of each other's needs and their interactions with each other, with particular reference, under principle (d) of the HART Act, to the need for informed consent to participate in the donation.

- (g) a process for the resolution of any disputes that may arise.

- (h) any issues that have arisen in individual counselling sessions, including agreed resolutions or areas of disagreement that have not been resolved.

Declaration

The information supplied in this section is, to the best of my knowledge and belief, accurate.

Signature of counsellor for recipient/s: _____

Date: _____

Signature of counsellor for donor: _____

Date: _____

**Ethics Committee on Assisted Reproductive Technology
Application Form for Ethics Approval of Surrogacy Arrangements
involving Providers of Fertility Services**

Section 4: Statement from Key Person under 3A.8 and/or 3B.8

Please note:

- This section is to be word processed - the text boxes for answers will expand as you type.
- Do not include personal identifying information. Please refer to the recipient woman as RW, the recipient's partner as RP, the donor as ED (if egg donor) or SD (if sperm donor), and the donor's partner as DP.

4.1 Statement from the key person on how whakapapa, and the needs, values and beliefs of Maori, have been considered and managed.