

**Advisory Committee on
Assisted Reproductive Technology**

**Proposed guidelines on pre-implantation
genetic testing for monogenic disorders
(PGT-M) for cases involving clinical
specialist disagreement about diagnosis
of familial single-gene disorders**

Consultation document

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Background

The Advisory Committee on Assisted Reproductive Technology (ACART) is an independent Ministerial committee established under the Human Assisted Reproductive Technology (HART) Act 2004. ACART has several statutory functions, including to provide the Minister with advice on matters relating to assisted reproduction, and to issue guidelines to the Ethics Committee on Assisted Reproductive Technology (ECART).

ECART considers applications on a case-by-case basis, using guidelines developed by ACART. If there are no guidelines that cover a kind of activity for which ECART approval is required, ECART must decline the application and refer it to ACART.

Pre-implantation genetic testing

Pre-implantation genetic testing (PGT) is a way of checking embryos created through in vitro fertilisation (IVF) for certain genetic or chromosome conditions (e.g. cystic fibrosis and Down syndrome) before embryos are transferred.

PGT is a commonly used procedure in New Zealand. For example, PGT was performed in 954 Assisted Reproductive Technology cycles in 2022, representing 12.8% of all cycles¹.

Current regulation of pre-implantation genetic testing

PGT is currently regulated under the HART Act and associated secondary legislation (the HART Order). Several types of PGT are defined as 'established procedures' in the HART Order, meaning they can occur without ethics approval in certain circumstances².

Other types of PGT require ethics approval from ECART in accordance with guidelines issued by ACART before they can occur. Currently, the only ACART guidelines that cover PGT are the *Guidelines on Preimplantation Genetic Diagnosis with Human Leucocyte Antigen Tissue Typing* (these guidelines are not relevant to the matters considered in this consultation document).

¹ *Assisted Reproductive Technology in New Zealand 2022* report, page 23 (ANZARD-2022-final.pdf).

² See in particular:

- the HART Order Schedule under the heading 'Pre-implantation genetic diagnosis' (description of Established procedures); and
- clause 6 of the HART Order Schedule (provisions applicable to procedures generally).

Draft guidelines for consultation

ACART has developed a targeted set of guidelines on PGT (included at **Appendix 1**) for consultation in response to a specific case referred to it by ECART. In this case, genetic experts disagreed on whether there was sufficient evidence to support the diagnosis of a familial single-gene disorder as provided for in clause 6(a) of the HART Order Schedule.

While ECART's referral concerned only one case, ACART anticipates there could be a small number of similar cases in the future. Given modern advancements in genetic testing, ACART believes it is timely to consider this issue to ensure there are robust and ethical processes in place to support decision-making in such circumstances.

The draft guidelines have a narrow scope and would only apply in circumstances where two or more 'experts' (clinical geneticists and/or genetic pathologists) disagree on the pathogenicity of the genetic variant(s) for which PGT is sought (that is, whether the genetic variant(s) cause the condition).

In addition to developing these guidelines, ACART is undertaking a wider review of the regulatory settings for ART in New Zealand, including PGT. ACART will continue to engage with key stakeholders and the public as it progresses its wider review, however submitters are welcome to provide their views on PGT more broadly through this consultation. To support this, we have included some general questions at the end of the consultation questions below.



Sharing your views

Your feedback will help ACART ensure its proposed guidelines are robust and workable. ACART welcomes your views on its draft guidelines as well as PGT generally.

Please send any feedback, including responses to the questions listed in this document, to: ACART@health.govt.nz.

The closing date for feedback is 26 October 2026. Please contact the ACART Secretariat if you require more time to provide your feedback (ACART@health.govt.nz).

Publication of feedback

ACART may publish individual submissions or a summary of submissions on its website. Please let us know if you do not want your submission published.

Official Information Act requests

In line with guidance from the Ombudsman, standard procedure of Manatū Hauora / the Ministry of Health (the Ministry) is to not release the name and contact details of any submitter who has given feedback in their private capacity (ie, not in a professional capacity or on behalf of an organisation) and who has requested that their personal information not be published by ticking the relevant boxes on the feedback form (or by making such a request in writing).

Where a person has given feedback on behalf of an organisation, the Ministry will release the name and contact details of the submitter and the organisation unless there are other reasons for withholding the information under the Official Information Act 1982. If you consider that we should withhold your or your organisation's name and/or contact details under the Official Information Act 1982, please make this clear on your feedback form, or other method of submitting, noting your reasons.

For more guidance on information released under the Official Information Act 1982, visit the Ombudsman's website at: ombudsman.parliament.nz/resources-and-publications.

Consultation questions

The following questions pertain to **ACART's draft guidelines** (included at **Appendix 1**):

1. *The draft guidelines include a definition of pathogenicity (see footnote 2 of the draft guidelines, below). **For the purposes of these guidelines, is this definition accurate?***
2. *The draft guidelines define 'experts' as those currently practising as either clinical geneticists and/or genetic pathologists³.*
 - a. ***Do you agree that this is an appropriate definition?***
 - b. ***Should any other experts be included in the definition?***
3. *ACART estimates that only a handful of cases each year would be in scope of these guidelines. **If you are an "expert" as defined by these draft guidelines:***
 - a. ***Is there any information you can share with ACART from your own clinical experience about how many cases are likely to be within scope of the guidelines?***
 - b. ***Would you expect the number of cases to increase if the guidelines were introduced?***
4. ***Is there anything else the ethics committee (ECART) should be satisfied of when considering an application under these guidelines?***
5. *ACART anticipates that in practice, applications would be submitted to ECART on behalf of the applicant (patient) by an 'expert' (i.e. a clinical geneticist and/or a genetic pathologist). **Do you have any comments about how this approach would work in practice?***
6. ***Is there anything else you would like to comment on regarding the draft guidelines or their implementation?***

The following questions pertain to **PGT more broadly**:

1. ***Are there any examples of PGT that cannot currently occur in New Zealand, but you think should be able to?***
2. ***As technology develops, how should decisions be made about expanding or limiting the use of PGT in New Zealand?***

³ This reflects the specialist competence required to interpret uncertain genomic evidence safely and consistently, as variant pathogenicity assessment is a complex clinical-genomic judgement requiring advanced genetics training, current knowledge of evolving evidence, and careful consideration of patient-safety implications.

Appendix 1: Draft guidelines

Guidelines on pre-implantation genetic testing for monogenic disorders (PGT-M) for cases involving clinical specialist disagreement about diagnosis of familial single-gene disorders

Preamble

1. The Human Assisted Reproductive Technology Order 2005 (the Order) describes pre-implantation genetic diagnosis (PGD) as:

A procedure for genetically testing embryos for specific genetic conditions or chromosomal abnormalities prior to embryo transfer and that includes any of the following undertaken for, or in connection with, that procedure:

- a) biopsy of embryos to remove 1 or more cells;
 - b) transportation of the cells to an approved laboratory;
 - c) analysis of the genetic or chromosomal constitution of cells obtained by biopsy;
 - d) selection of embryos for transfer on the basis of the results from analysis.
2. Schedule clause 6 of the Order defines when the use of PGD is an established procedure. Of relevance to these guidelines is schedule clause 6(a):
 - a) diagnosis of familial single-gene disorders where—
 - i) the disorder has been identified in the family or whānau; and
 - ii) there is a 25% or greater risk of an affected pregnancy; and
 - iii) there is evidence that the future individual may be seriously impaired as a result of the disorder.
 3. Under the Human Assisted Reproductive Technology Act 2004 (the Act), the advisory committee (ACART) can issue guidelines to the ethics committee (ECART) on any matter relating to any kind of assisted reproductive procedure. Such guidelines are secondary legislation.
 4. If there are no guidelines that cover a kind of activity for which ethics committee approval is sought, the ethics committee must decline the application and refer it to the advisory committee. Currently, the only guidelines that cover pre-implantation genetic testing are the *Guidelines on Preimplantation Genetic Diagnosis with Human Leucocyte Antigen Tissue Typing*.¹

¹ Issued to the ethics committee on 18 August 2014.

Scope

5. These guidelines cover applications from applicants (patients) for approval of pre-implantation genetic testing for monogenic disorders (PGT-M) that involve two or more experts who do not agree on the diagnosis of a familial single-gene disorder, as provided for in schedule clause 6(a) of the Order.
6. Specifically, the experts must disagree on the pathogenicity² of the genetic variant(s) for which approval of PGT-M is being sought.
7. For the purposes of these guidelines, 'experts' must currently be practising as either:
 - a) Clinical geneticists, and/or
 - b) Genetic pathologists.
8. Any case considered by the ethics committee under these guidelines must have first been discussed at a *Health New Zealand Genomics Multidisciplinary Meeting (MDM)* or an equivalent body. The relevant minutes from the meeting should be made available to the ethics committee.

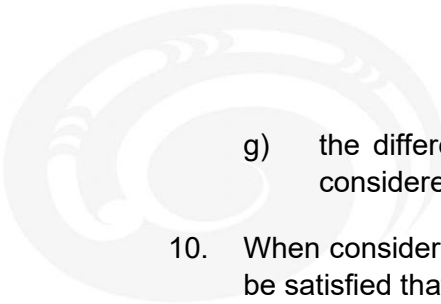
Guidelines

9. When considering an application under these guidelines, the ethics committee must be guided by the principles described in section 4 of the Act:

All persons exercising powers or performing functions under this Act must be guided by each of the following principles that is relevant to the particular power or function:

- a) 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:
- b) the human health, safety, and dignity of present and future generations should be preserved and promoted:
- c) 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:
- d) 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:
- e) donor offspring should be made aware of their genetic origins and be able to access information about those origins:
- f) the needs, values, and beliefs of Māori should be considered and treated with respect:

² In this context, pathogenicity refers to the likelihood of a genetic variant causing a condition or disease.

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- g) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.
10. When considering an application under these guidelines, the ethics committee must be satisfied that:
- a) Two or more experts do not agree on the pathogenicity of the genetic variant(s) for which approval of PGT-M is being sought, and
 - b) The application outlines the opinions of the experts involved, including their reasoning, and
 - c) The applicant(s) have received medical advice on, in accordance with NZS 8134:2021 *Ngā paerewa Health and disability services standard*, and understand:
 - i) What is pre-implantation genetic testing, how it would be used in their case, and the different possible outcomes from its use,³ and
 - ii) The relevant experts do not agree on the pathogenicity of the genetic variant(s) in their case, and the reasons for this disagreement, and
 - iii) Their case has been discussed at a *Health New Zealand Genomics Multidisciplinary Meeting (MDM)* or an equivalent body, and
 - iv) The alternative options available to the applicant(s), including prenatal testing, conception with a gamete donor, adoption, and delaying or not expanding family, and
 - v) The risks and benefits of the alternative options available to the applicant(s), and
 - vi) Should pre-implantation genetic testing be used in their case, what options for prenatal testing are available to the applicant(s), and
 - d) The application includes a description of the medical advice received by the applicant(s), and
 - e) The applicant(s) have received genetic counselling, in accordance with NZS 8134:2021 *Ngā paerewa Health and disability services standard*, that:
 - i) Addressed the implications of the different possible outcomes from the use of pre-implantation genetic testing, and
 - ii) Has been culturally appropriate, and
 - iii) Provided for whānau/extended family involvement, and
 - iv) Accounted for any other relevant factors, and
 - f) The application includes a description of the genetic counselling received by the applicant(s), and
 - g) The applicant(s), taking into consideration the medical advice and genetic counselling they have received, consent to pre-implantation genetic testing being used in their case.

³ Including the possibility of the future individual having the disorder regardless of whether pre-implantation genetic testing is used.