**Applications for approval of sex selection**

**Guidance note**

**July 2021**

*This Guidance Note has been prepared to assist applicants and assisted reproductive*

*treatment (ART) clinics in the preparation of applications to the Patient Review Panel for the*

*approval of sex selection under the* Assisted Reproductive Treatment Act 2008 (Victoria)*.*

*This Guidance Note does not constitute legal advice, nor does it pre-judge any decision that the Patient Review Panel might make in relation to any particular application.*

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| **NOTE:****In response to the COVID-19 pandemic, from 24 March 2020 until further notice:*** **all applications to the Patient Review Panel must be made via email:****prp@dhhs.vic.gov.au**
* **all inquiries should be made via email:****prp@dhhs.vic.gov.au**
* **hearings will continue and will be held via videoconference**
* **applicants will be advised of the process for videoconference hearings once a date for the hearing of their application has been fixed**
* **applicants should provide copies of their applications to their assisted reproductive treatment (ART) clinics**
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***Glossary/Definitions***

The Victorian *Assisted Reproductive Treatment Act 2008* (the ART Act) provides definitions for a number of terms that will be used within this Guidance Note.

* **assisted reproductive treatment (ART)** means medical treatment or a procedure that procures, or attempts to procure, pregnancy in a woman by means other than sexual intercourse or artificial insemination, and includes—
	+ in-vitro fertilisation; and
	+ gamete intrafallopian transfer; and
	+ any related treatment or procedure prescribed by the regulations;
* **child** means a person who is less than 18 years of age;
* **doctor** means a person registered under the Health Practitioner Regulation National Law to practise in the medical profession (other than as a student);
* **embryo** means a discrete entity that has arisen from either—
	+ the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
	+ any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears—
		- and has not yet reached 8 weeks of development since the first mitotic division;
* **gametes** mean sperm or an oocyte;
* **oocyte** means an ovum (egg) from a woman;
* **registered ART provider** means a person who is registered under Part 8 of the ART Act as a registered ART provider;
* **treatment procedure** means—
	+ artificial insemination, other than self-insemination; or
	+ assisted reproductive treatment.

# What is ‘sex selection’?

In the context of ART, ‘sex selection’ refers to the selection and transfer of an embryo on the basis of its genetic sex. At an ART clinic this is done through a genetic screening process called preimplantation genetic testing (PGT), preimplantation genetic diagnosis (PGD) or preimplantation genetic screening (PGS). While slightly different, these three terms are often used interchangeably at ART clinics. This guidance note uses the term PGD.

# What is preimplantation genetic diagnosis (PGD)?

PGD is a scientific procedure where an embryo is tested or analysed prior to being transferred into a woman for the purpose of achieving a pregnancy. While it is primarily used to screen for specific genetic or chromosomal variations, such as cystic fibrosis, it can also be used to determine the genetic sex of an embryo.

PGD enables ART clinics to select and transfer embryos that are not affected by a specific detected disorder or abnormality to prevent that condition from being passed onto any future children. In the case of sex selection, it can be used to select and transfer embryos only of a particular sex.

# Is sex selection legal in Victoria?

Section 28 of the *Assisted Reproductive Treatment Act 2008* (the ART Act) prohibits sex selection in Victoria, except in two situations:

1. *where it is necessary for the child to be of a particular sex so as to avoid the risk of transmission of a genetic abnormality or a genetic disease to the child; or*
2. *the Patient Review Panel has otherwise approved the use of the gametes or embryo for the purpose or a purpose of producing or attempting to produce a child of a particular sex.*

ART clinics and people seeking sex selection should be aware that, under section 28(1) of the ART Act, the prohibition on sex selection carries with it a penalty of 240 penalty units or 2 years imprisonment or both.

ART clinics should also be aware that, where it is necessary for the child to be of a particular sex so as to avoid the risk of transmission of a genetic abnormality or a genetic disease to the child under section 28(1)(a), sex selection may be performed without specific approval from the Patient Review Panel.

# What is the Patient Review Panel?

The Patient Review Panel (the Panel) is an independent body established under the ART Act to consider different types of applications involving ART, including applications for permission for ART clinics to carry out sex selection through PGD. Its members have specialist skills and are appointed by the Governor in Council, on the recommendation of the Minister for Health. Five Panel members together consider each sex selection application.

# What does the Patient Review Panel look at when considering sex selection applications?

When considering whether to approve an application for sex selection, the Panel takes into account:

* that sex selection is prohibited in Victoria except in limited circumstances as outlined above;
* the criteria for treatment under the Act (i.e. either infertility or that a woman is at risk of transmitting a genetic abnormality or disease to a child);[[1]](#footnote-2)
* the narrow exception provided by section 28(2) of the ART Act (i.e.. that sex selection is permitted to avoid the transmission of a genetic condition);
* the legislative context, including the purposes of the ART Act (which includes to regulate assisted reproductive treatment in Victoria); and
* the guiding principles set out in section 5 of the Act.[[2]](#footnote-3)

The key guiding principles relevant to sex selection applications are:

* the welfare and interests of persons born or to be born as a result of treatment procedures are paramount; and
* the health and wellbeing of persons undergoing treatment procedures must be protected at all times.

When the law says that the welfare and interests of persons born or to be born as a result of treatment procedures are “paramount”, this means that if there is a conflict between the welfare and interests of the child to be born, and the health and wellbeing of the patients seeking sex selection, any conflict must be resolved in favour of the child’s welfare and interests.[[3]](#footnote-4)

The Panel will also have regard to the *National Health and Medical Research Council Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research 2017* (the NHMRC  Guidelines) when making a decision about whether to approve an application for sex selection. In particular, the Panel notes that the NHMRC Guidelines only permit sex selection to **reduce the risk of transmission of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born**.

**As such, while the Panel considers every application on a case-by-case basis, applicants and ART clinics should be aware that applications for sex selection for reasons other than to reduce the risk of transmission for a** **genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born may not be able to be approved.**

# Making an application to the Patient Review Panel

## *Before making an application to the Panel*

The NHMRC Guidelines state, amongst other things, that “*to make informed decisions, it is essential that individuals or couples who seek PGT understand the technology and the potential risks and benefits of using the technology*” and that “*sex selection techniques may not be used unless the intended parent(s) have been provided with relevant information and counselling”.*

As such, prior to making an application to the Panel, applicants should have been provided with information by their ART clinic or other specialist about the risks of PGD, the chances of producing an embryo that is unaffected by the genetic condition, the likely success rates of achieving a pregnancy, and any alternatives to treatment.

Applicants should also have received genetic counselling on the following topics outlined in the NHMRC Guidelines:

* *current evidence and expert opinion on the impact of the condition, disease or abnormality on the quality of life of the person who would be born, including the anticipated symptoms, age-of-onset and the degree/spectrum or severity of the condition disease or abnormality*
* *the available therapies or interventions to reduce the severity, delay onset or minimise the impact of the condition, disease or abnormality*
* *the experiences of individuals and families living with any relevant condition, disease or abnormality*
* *the potential for stigma to impact on the perceived seriousness of the condition, disease or abnormality*
* *the extent of social support available to the intended parent(s) and the person who would be born*
* *the potential impact of the decision to use PGT may have on any child within the family unit who may be affected by that decision*
* *the possibility that all of the embryos may be affected by a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born*
* *that the genetic cause of some conditions, diseases or abnormalities is currently unknown and some of the genetic information obtained by PGT may be of unknown significance at the time*
* *that the clinic will continue to store the PGT results in accordance with the requirements of Chapter 9 of these Ethical Guidelines, and the clinic’s policy for the management of PGT results, including whether the clinic will communicate the ongoing significance of any results in light of new evidence/research*
* *the potential for PGT to identify genetic conditions, diseases or abnormalities that were not the subject of the testing, nor for which the intended parent(s) were counselled (an incidental finding) and the clinic’s policy for handling such an event.*

## *Supporting documentation required for an application*

Applicants are requested to submit the following documents with their application:

* a completed application form, signed and dated;
* a copy of a letter to the applicants from a doctor with specialist qualifications in human genetics and/or a genetic counsellor outlining:
	+ the nature of the identified genetic condition or abnormality;
	+ the impact and severity of the condition on each gender;
	+ the anticipated risk of transmission given the applicants’ family history;
	+ the anticipated reduction of risk of transmission if sex selection were to be approved;
	+ the availability, effectiveness and reliability of any testing;
	+ the reason(s) why sex selection using PGD is considered appropriate; and
	+ any available alternatives to PGD.
* a brief statement from the applicants setting out:
	+ details of any children they may have (including names, dates of birth and whether they have any known genetic or medical conditions);
	+ how the decision to utilise sex selection came about (this is particularly relevant if applicants have one child or more of the same gender that they are seeking to select against)
	+ the current impact of the identified genetic condition or abnormality on the family;
	+ the potential impact on the family if sex selection were to be approved but the applicants still had child who was affected by the identified genetic condition or abnormality;
	+ what personal and professional supports are available to the family both currently and if they were to have a/another child with the identified condition, even if sex selection is approved.
* any supporting medical assessments or documentation;
* where the proposed use of PGD for sex selection has been considered by an ethics committee or clinical review committee, any report of that committee;
* any additional materials that address the guiding principles set out above, including any information relevant to the welfare and interests of the child to be born, and how sex selection may protect or promote the applicants’ own health and wellbeing.

## *Additional information for autism spectrum disorder (ASD) applications*

Applications for sex selection to reduce the risk of autism spectrum disorder (ASD) should include the following additional information:

* details of the family history of ASD – this will generally relate to an existing child or children but may also extend to other family members;
* if available, the original clinical diagnosis of ASD by an independent health professional – this is generally in the form of a letter or report from a doctor, paediatrician, psychologist and/or speech pathologist; please note that this letter cannot be from the applicants themselves, nor from a family member or work or professional associate of the applicants;
* any other documentation confirming the clinical diagnosis of ASD;
* details of any treatment that the family member diagnosed with ASD has received and is currently receiving;
* cytogenic test results for Fragile X DNA and microarray analysis.

# Independent expert reports

Due to the complexity of some applications for sex selection, the Panel may consider it necessary to obtain advice from an independent clinical geneticist. In such cases, the Panel will seek the consent of the applicants to forward their application and supporting documents to an independent clinical geneticist for review. The Panel selects the geneticist and pays for the review. Any advice or report provided by the independent clinical geneticist to the Panel will also be provided to the applicants and they will have an opportunity to respond to that information if they wish to do so.

# The hearing

Upon receipt of an application, it will be reviewed by Panel staff and/or the Panel Chairperson. Applicants and/or clinic staff will be advised if any missing/additional information is required or requested.

**Applications will only be listed for hearing once they are complete and all documentation has been provided. Applications are not considered to be complete until missing or requested additional information has been received. If applications are incomplete but applicants insist on being listed for hearing, then the matter will be referred by Panel staff to the Panel Chairperson for review prior to listing for hearing.**

Once a hearing date has been allocated, applicants will receive a Notice of Hearing stating:

1. the nature of the hearing; and
2. the time and place of the hearing; and
3. that the applicants are entitled to be present at the hearing, to make submissions and to be accompanied by another person; and
4. that the hearing is not open to the public; and
5. that there is no right to legal representation at the hearing without leave from the Panel; and
6. the possible findings or orders that the Panel may make.

## *Applications considered on the papers*

For some applications, the Panel may consider that it has sufficient written information available to it to make a decision ‘on the papers’. This means that although the applicants are entitled to attend the hearing of their application, they do not have to. In these circumstances, the Panel will consider the application at the time and date stated on the Notice of Hearing and applicants will be advised in writing within 14 days of the outcome of their application. The Panel will not decide to not approve an application without providing applicants with an opportunity to respond any concerns raised by the Panel and without the opportunity to present their case at a hearing.

## *Applications where the applicants are requested to attend*

When face-to-face Panel hearings are convened, they are held at the Department of Health Head Office located at **50 Lonsdale Street, Melbourne, Victoria, 3000** unless otherwise advised. Upon arriving at 50 Lonsdale Street, applicants will need to pick up a security pass from the ground floor reception and make their way up to the level where the hearing is being held.

Every level has a foyer area with chairs and applicants should use their passes to enter the foyer and take a seat until they are invited into the hearing room by either one of the Panel members or a Panel staff member.

Panel hearings consist of a division of five Panel members including the Chairperson, a Deputy Chairperson and three other Panel members, at least one of whom will be an expect in child protection matters. Up to three Panel staff members may also be in attendance to take notes and/or provide legal advice to the Panel members.

Panel hearings generally last for an hour (or longer if required) and towards the end of the hearing applicants will be asked to leave the room for a short period of time to allow the members to discuss the application. At times, the Panel may also request to speak to one of applicants alone.

Where possible, the Panel will advise applicants whether the application has been approved or not on the day of the hearing but, at times, it will require more time to consider the application or may require more information before it makes its decision. If the Panel does not consider that it can make a decision on the day then it will advise applicants at the conclusion of the hearing and advise them of what will happen next.

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| **IMPORTANT NOTE:****In light of the COVID-19 pandemic, the Panel will conduct all hearings by videoconference using Microsoft Teams from April 2020 until further notice.** **Comprehensive instructions to assist applicants to participate in hearings conducted by videoconference will be provided together with the Notice of Hearing.** **Applicants who are unable to participate in a hearing by videoconference are advised to communicate with Panel staff as soon as possible upon receipt of the Notice of Hearing to formally request an alternative method of participating in the hearing (such as attending via teleconference, subject to the approval of the Panel Chairperson).** |

# 7. What does the Panel consider when making its decision?

The Panel must have regard to the legislative context, including the purpose of the Act (to regulate assisted reproductive treatment in Victoria), and the fact that, with very narrow exceptions, the selection of the sex of embryos is unlawful in Victoria.

The Pane must also have regard to the guiding principles of the Act set out in section 5.[[4]](#footnote-5) These are:

(a) the welfare and interests of persons born or to be born as a result of treatment procedures are paramount;

(b) at no time should the use of treatment procedures be for the purpose of exploiting, in trade or otherwise the reproductive capabilities of men and women or children born as a result of treatment procedures;

(c) children born as the result of the use of donated gametes have a right to information about their genetic parents;

(d) the health and wellbeing of persons undergoing treatment procedures must be protected at all times;

(e) persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital status, race or religion.

If there is a conflict between the welfare and interests of the child to be born, and the health and wellbeing of applicants, any conflict must be resolved in favour of the child’s welfare and interests.[[5]](#footnote-6)

## *Possible outcomes of a Panel decision*

The possible decisions that the Panel may make are:

1. that the use of the gametes or embryos for the purpose of attempting to produce a child of a particular sex is approved;
2. that the use of the gametes or embryos for the purpose of attempting to produce a child of a particular sex is not approved;
3. that that use of the gametes or embryos for the purpose of attempting to produce a child of a particular sex is approved subject to any conditions imposed by the Panel.

## *Notification of the Panel’s decision*

Where possible, the Panel will advise applicants whether sex selection has been approved or not via email or telephone communication by Panel staff on either the day of the hearing or the following day. At times, it will require more time to consider the application or may require more information before it makes its decision.

If the Panel does not consider that it can make a decision within 1-2 days of the hearing then it will advise applicants within that time frame and advise them of what will happen next.

***Certificate***

Once the Panel has made a decision, applicants will be provided with a certificate stating the decision within 14 days of the date that the decision was made. An electronic copy of this certificate will also be provided to the relevant ART clinic for their records.

Applicants should be aware that the Panel’s certificate will state what the genetic condition is and not simply that sex selection has or has not been approved.

Under section 91(3) of the ART Act, the Panel may impose any conditions it considers necessary and reasonable in the circumstances of the decision and, if the Panel chooses to place a condition on its decision, it will be stated on the certificate.

## *Reasons for decision*

The Panel also provides applicants with written reasons for its decision. These reasons will be provided to the applicants in due course after they receive their certificate.

Where an application has been approved, this document is not required to be presented to the ART clinic in order to undertake sex selection; the clinic only requires the certificate indicating the Panel’s approval of the application.

## *Review of a Panel decision not to approve an arrangement*

A decision of the Panel not to approve sex selection may be subject to review by the Victorian Civil and Administrative Tribunal (VCAT).

An application for review must be made within 28 days after the day on which the Panel’s decision is made.[[6]](#footnote-7)

For further information about applying to the VCAT for a review of a Panel decision, please visit <https://www.vcat.vic.gov.au/privacy-and-health-records/review-of-a-decision-by-the-patient-review-panel>.

# What happens if the Patient Review Panel approves sex selection?

## *Effect of Panel decisions*

A decision of the Panel to approve sex selection authorises multiple cycles of PGD using sex selection for the approved purpose. Providing an applicants’ circumstances do not change between cycles conducted, it will not be necessary to seek new approvals for each treatment cycle.

However, the Panel’s approval will only extend to one live birth. This means that a new approval will be required for any subsequent set of treatment cycles after a child has been born. Where an applicant has had approval for sex selection in the past, and makes a subsequent application, they do not need to provide all the same information again; they need only complete the application form and attach a letter from a geneticist noting that sex selection is still recommended in their situation at this time and any recent developments in genetic testing for that condition, if applicable. It is recommended that ART clinics contact Panel staff about such proposed applications.

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1. Section 10(2)(iii) of the *Assisted Reproductive Treatment Act 2008* (Vic). [↑](#footnote-ref-2)
2. *JS and LS v Patient Review Panel* [2011] VCAT 856 at paragraph 14. [↑](#footnote-ref-3)
3. *JS and LS v Patient Review Panel* [2011] VCAT 856. [↑](#footnote-ref-4)
4. *JS and LS v Patient Review Panel* [2011] VCAT 856 at paragraph 14. [↑](#footnote-ref-5)
5. *JS and LS v Patient Review Panel* [2011] VCAT 856. [↑](#footnote-ref-6)
6. *Assisted Reproductive Treatment Act 2008* (Vic), s 98. [↑](#footnote-ref-7)