



Australian Government  
National Health and Medical Research Council

BUILDING  
A HEALTHY  
AUSTRALIA

# Mitochondrial Donation Community Consultation Report



NHMC

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work on Mitochondrial Donation,  
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# Contents

|  |    |
|--|----|
| Acknowledgements.....  | 3  |
| Executive Summary .....  | 4  |
| 1. Introduction .....  | 6  |
| 1.1 Aim of the consultation .....  | 6  |
| 1.2 The Consultation Report.....   | 7  |
| 1.3 The Mitochondrial Donation Expert Working Committee .....                              | 7  |
| 2. Approach to consultation activities.....  | 8  |
| 2.1 Multi-modal consultation strategy.....   | 8  |
| 2.2 Resources.....   | 9  |
| 2.2.1 Mitochondrial Donation Issues Paper .....  | 9  |
| 2.2.2 Mitochondrial Donation Public Consultation video .....                               | 10 |
| 2.2.3 Webinar videos .....   | 11 |
| 2.2.4 Postcards and outreach at conferences.....   | 11 |
| 2.2.5 Social media and mailing list .....  | 12 |
| 2.3 Written submissions .....  | 12 |
| 2.4 Citizens' panel.....   | 13 |
| 2.5 Targeted roundtable .....  | 13 |
| 2.6 Webinars.....  | 14 |
| 2.7 Public forums .....  | 14 |
| 3. Stakeholder engagement.....   | 14 |
| 3.1 Media engagement.....  | 14 |
| 3.2 Engagement via NHMRC education activities .....  | 15 |
| 3.3 Overview of stakeholders who shared their views .....                                  | 16 |
| 3.3.1 Online submissions .....   | 16 |
| 3.3.2 Citizens' Panel .....  | 17 |
| 3.3.3 Targeted Roundtable.....   | 18 |
| 3.3.4 Comparison of engagement with Senate Inquiry .....                                   | 19 |
| 4. Outcomes of consultation .....  | 19 |
| 4.1 Analysis of online submissions .....   | 19 |
| 4.1.1 Methodology .....  | 19 |
| 4.1.2 Overview of themes .....   | 20 |
| 4.1.3 Summary of sub-themes related to theme 1: Outcomes of mitochondrial donation.....    | 21 |
| 4.1.4 Summary of sub-themes related to theme 2: The wellbeing and rights of children ..... | 35 |

|       |  |    |
|-------|--|----|
| 4.1.5 | Summary of sub-themes related to theme 3: Factors relating to egg donation and the donor .....           | 45 |
| 4.1.6 | Summary of sub-themes related to theme 4: Factors relating to the embryo in mitochondrial donation ..... | 53 |
| 4.1.7 | Summary of sub-themes related to theme 5: Implementation considerations .....                            | 63 |
| 4.2   | Stakeholder analysis of online submissions .....   | 72 |
| 4.2.1 | Quantitative assessment of submissions .....   | 72 |
| 4.2.2 | Stakeholder group perspectives .....   | 73 |
| 4.3   | Themes and outcome from the Citizens' Panel .....  | 73 |
| 4.4   | Themes from the Roundtable .....   | 74 |
| 4.4.1 | Current knowledge and understanding of mitochondrial donation .....                                      | 75 |
| 4.4.2 | Emotional welfare of prospective parents .....   | 75 |
| 4.4.3 | Suitability of alternative treatments .....  | 75 |
| 4.4.4 | Ethical and regulatory considerations .....  | 75 |
| 5.    | Final remarks .....  | 76 |
| 5.1   | Advice from Australian Health Ethics Committee .....   | 76 |
| 5.2   | Considerations specific for Aboriginal and Torres Strait Islander peoples .....                          | 77 |
| 5.3   | Considerations for other cultural or social groups .....   | 77 |
| 5.4   | Importance of education and community engagement in the future .....                                     | 79 |
| 5.4.1 | Misunderstandings in written submissions .....   | 79 |
| 5.4.2 | Misunderstandings of the Citizens' Panel .....   | 80 |
| 5.4.3 | Summary .....  | 81 |
|       | Appendix A – Mitochondrial Donation Expert Working Committee .....                                       | 82 |
|       | Appendix B – Summary of Media Coverage .....   | 84 |
|       | Appendix C – Online Submissions .....  | 86 |
|       | Appendix D – Targeted Roundtable Participant Organisations .....   | 90 |
|       | Appendix E – Citizens' Panel Position Statement .....  | 91 |

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NHMRC extends its thanks to everyone who engaged with the mitochondrial donation community consultation. Many individuals and organisations engaged in various ways and in a respectful manner regardless of their views and opinions. Thanks to all those who attended events, made submissions and otherwise participated.

NHMRC also wishes to note the bravery of those with lived experience of mitochondrial disease who shared their stories through their submissions, and express gratitude to them for doing so. It should also be noted that many who entered submissions recognised the severity of, and difficulty of living with, mitochondrial disease, and took care to frame their submissions with this acknowledgement in mind.

NHMRC acknowledges and gives thanks to the following for their valuable assistance and involvement throughout the process:

- the Mitochondrial Donation Expert Working Committee, for their advice on the process and their participation in many of the consultation activities
- Science in Public, for their work on the Mitochondrial Donation Issues Paper, video and postcards, and their expert guidance in engaging with the media
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- Professor Lynn Gillam for facilitating the Citizens' Panel process and the development of the Statement
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- Jurisdictional Chief Health Officers and departments for supporting and hosting the public forums.

The following report is the result of a process that could not have succeeded without the participation of the Australian community in its various forms, and we thank all for their contributions to this significant project.

## Executive Summary

Mitochondrial DNA disease refers to a group of inherited conditions that can cause serious health issues and, in severe cases, reduced life expectancy. Currently, there is no known cure, and treatment options are limited largely to management of symptoms. Between one in 5,000 and one in 10,000 Australians are estimated to develop severe mitochondrial DNA disease during their lifetime. The average lifespan of children with mitochondrial DNA disease is estimated to be between 3 and 12 years of age. However, mitochondrial DNA disease can affect people at any age – some individuals do not develop symptoms until their adult years.

Mitochondrial donation is a new assisted reproductive technology that seeks to reduce the risk of a child inheriting mitochondrial DNA disease from a woman carrying the condition. Mitochondrial donation involves combining the nuclear DNA from a male and female with the healthy mitochondrial DNA from a donor egg. Clinical use of mitochondrial donation for reproductive purposes is currently prohibited in Australia.

In March 2019, the Australian Government asked the National Health and Medical Research Council (NHMRC) to seek the community's views on the scientific, ethical and social considerations of the possible introduction of mitochondrial donation into Australian clinical practice. This request followed the report from, and Government response to, the Senate Community Affairs References Committee *Inquiry into the Science of Mitochondrial Donation and Related Matters*.

This Consultation Report provides the outcomes of the NHMRC's community consultation on the social and ethical issues related to mitochondrial donation.

The consultation was guided by the question:

'What are the views of the broader Australian community on the possible introduction of mitochondrial donation into clinical practice, once the scientific, ethical and social issues are generally understood?'

The overarching aim of this consultation was to consult with a range of different stakeholders between September and November 2019 and obtain informed opinions about the possible introduction of mitochondrial donation.

The consultation was guided by advice from the Mitochondrial Donation Expert Working Committee (MDEWC), which comprised Australian scientists, ethicists, clinicians, experts in law, and consumer representatives. It was designed to build on, rather than duplicate, the information gathered through the Senate Inquiry.

This Consultation Report describes the multi-modal approach to the consultation (Section 2), demonstrates how the consultation successfully informed and engaged with a broad range of community members (Section 3), and presents an analysis of the views of the Australian community on mitochondrial donation (Section 4). It also describes the resources that were developed to support the consultation and the successful use of media activities to encourage engagement from the general community.

The consultation modes used included online written submissions, a Citizens' Panel, a targeted roundtable, public forums and webinars. The Citizens' Panel was an innovative and particularly effective way of engaging community members who may not otherwise

have provided their views on mitochondrial donation. The Citizens' Panel Statement ([Appendix C](#)) captures the views that panel members developed after engaging with experts about the key issues and participating in facilitated discussions. These views may be indicative of views of general community members if they have the opportunity to learn about and engage with the issues associated with mitochondrial donation.

The major themes that emerged from the written submissions were:

- the outcomes of mitochondrial donation
- the wellbeing and rights of children
- factors relating to egg donation and the donor in mitochondrial donation
- factors relating to the embryo in mitochondrial donation, and
- implementation considerations.

The discussion of the themes and the related sub-themes includes examples of comments from the submissions to help illustrate the range of views provided by the community.

Finally, respondents to the online submissions process were asked about whether they supported the introduction of mitochondrial donation to prevent the transmission of mitochondrial DNA disease at this time. It is clear that there is a range of opinions in the community about mitochondrial donation, with a number of respondents being passionately opposed to its introduction while others are supportive. This range of views must be taken into consideration in any future work on this issue. A series of final remarks is provided in Section 5, including suggestions about the importance of continued community engagement and education.

# 1. Introduction

The National Health and Medical Research Council (NHMRC) funds high quality health and medical research, builds research capability, supports the translation of health and medical research into better health outcomes and promotes the highest standards of ethics and integrity in health and medical research.

The Australian Government asked NHMRC in March 2019 to seek the community's views on the scientific, ethical and social considerations of the possible introduction of mitochondrial donation into Australian clinical practice. This request was made in line with the Government's response on 20 February 2019 to the report from the Senate Community Affairs References Committee *Inquiry into the Science of Mitochondrial Donation and Related Matters*.

Clinical use of mitochondrial donation for reproductive purposes is currently prohibited in Australia. NHMRC is responsible for administering two relevant pieces of legislation: the *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act). NHMRC also regulates activities relating to certain uses of human embryos through the Embryo Research Licensing Committee.

Currently, the United Kingdom (UK) is the only country in the world to have specific regulations to permit mitochondrial donation for the prevention of the transmission of serious mitochondrial DNA disease in clinical practice. Regulations allowing some mitochondrial donation techniques were approved by the UK parliament in 2015 following scientific reviews of the evidence to examine safety and efficacy, and public consultation on the ethical issues related to mitochondrial donation. The UK public consultation was conducted by the Human Fertilisation and Embryology Authority (HFEA) in 2012 (before the regulations were passed) and included public workshops, surveys, and focus groups. The first licence to use mitochondrial donation was issued by the HFEA in 2017.

The National Academies of Sciences, Engineering, and Medicine (NASEM) in the USA have also examined the ethical, social, and policy considerations related to mitochondrial donation. This work was led by an expert committee and included public workshops, systematic literature reviews and written submissions. NASEM finalised its consultation and review processes and published its report in 2016. Mitochondrial donation remains prohibited in the USA.

Mitochondrial donation is in limited use in some other countries.

## 1.1 Aim of the consultation

The consultation was guided by the question: what are the views of the broader Australian community on the possible introduction of mitochondrial donation into clinical practice, once the scientific, ethical and social issues are generally understood.

The overarching aim of this consultation was to consult with a range of different stakeholders between September and November 2019 and obtain informed opinions about the possible introduction of mitochondrial donation. This meant that the consultation involved engaging and informing stakeholders about the complex interplay of scientific, social and ethical issues.

The consultation approach was designed to build on, rather than duplicate, the information gathered through the Senate Inquiry.

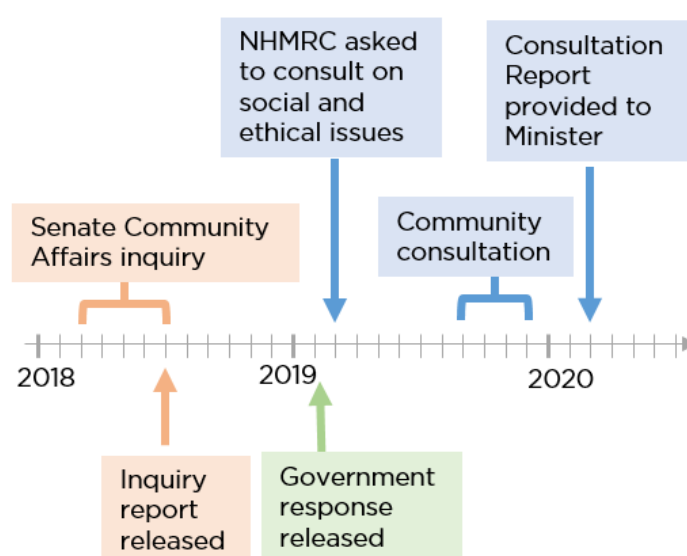


## 1.2 The Consultation Report

This Report provides an overview of the community's views on the potential introduction of mitochondrial donation into Australian clinical practice. It was produced alongside the *Mitochondrial Donation Expert Working Committee Statement to the NHMRC CEO on the science of mitochondrial donation*, which addresses the scientific questions from the Senate Inquiry Report.

This Consultation Report describes the approach that was taken for consultation, demonstrates how the consultation informed and engaged with a broad range of community members, and presents an analysis of the views of the Australian community on mitochondrial donation.

Figure 1 shows the timeframe for the key events that led up to the NHMRC community consultation on the social and ethical issues of mitochondrial donation and this resultant report.



**Figure 1.** Key events surrounding the NHMRC activities (blue) related to community consultation on mitochondrial donation. The public consultation took place from September to November 2019, and this Consultation Report was completed in March 2020.

## 1.3 The Mitochondrial Donation Expert Working Committee

The Government tasked NHMRC with establishing a panel of experts to provide advice on the issues identified by the Senate Inquiry, and develop the key questions to underpin community-wide consultation and increase community literacy on the social and ethical issues raised by mitochondrial donation.

The Mitochondrial Donation Expert Working Committee (MDEWC) was established in March 2019. It comprised members of the NHMRC Australian Health Ethics Committee and NHMRC Embryo Research Licensing Committee, as well as scientists, clinicians, ethicists, legal experts and consumer advocates (including the Mito Foundation).

## 2. Approach to consultation activities

This Section contains descriptions of each of the consultation modes used, during public consultation, along with the rationale for their use and a summary of the event that took place. A detailed analysis of stakeholder engagement during the consultation is presented in Section 3, and a detailed overview of the themes that emerged from the feedback received during the consultation is in Section 4.

### 2.1 Multi-modal consultation strategy

The community consultation encompassed several activities across different modes to obtain community views on the social and ethical issues associated with mitochondrial donation. The advantage of using a multi-modal approach was the ability to engage with a variety of stakeholders by using a range of methods to seek input, reaching a more diverse range of contributors than a single mode would allow. It allowed NHMRC to reach parts of the community who may not otherwise have engaged with this matter.

Acknowledging that the Senate Inquiry received submissions from a variety of individuals and organisations with an existing interest in mitochondrial donation, a key component of this consultation was capturing the views and attitudes of the broader Australian community. The primary mode for this was the Citizens' Panel, established to provide informed viewpoints from a diverse range of community members who did not necessarily have prior knowledge of mitochondrial donation. Additional modes included:

- obtaining written submissions
- webinars
- public forums
- a targeted roundtable event with relevant advisory groups, and
- outreach at conferences and other relevant events.

Overall, the timing of the consultation activities was staged to:

1. focus initially on information and education activities (development of resources to support consultation)
2. provide opportunities to interact with and ask questions of experts and stakeholders (webinars, public forums and Citizens' Panel), and
3. express and capture informed viewpoints (written submissions, Citizens' Panel, targeted roundtable).

The consultation was supported by a media strategy to promote engagement by the broader community (Section 3.1).

An outline of the timing and purpose of the consultation activities is shown in Table 1 and described in Sections 2.2–2.7.

| Time                              | Activity   | The main purpose was to...   |
|-----------------------------------|--|--|
| <b>September 2019</b>             | Mitochondrial Donation Issues Paper released<br>Postcards developed for distribution<br>Twitter account and mailing list established<br>NHMRC Online Services submission portal opened to public | Inform<br>Inform<br>Inform<br>Capture views  |
| <b>October 2019</b>               | First meeting of Citizens' Panel<br>Mitochondrial Donation information video released<br>First public engagement webinar<br>Targeted roundtable for professional stakeholders                    | Inform<br>Inform<br>Inform/support discussion<br>Capture views   |
| <b>November 2019</b>              | Final meeting of Citizens' Panel<br>Public forum held in Sydney<br>Public forum held in Melbourne<br>Second public engagement webinar<br>NHMRC Online Services submission portal closed          | Capture views/support discussion<br>Inform/support discussion<br>Inform/support discussion<br>Inform/support discussion<br>Capture views |
| <b>December 2019 – March 2020</b> | Analysis of community views obtained during consultation<br>Preparation of Consultation Report   | N/A  |

**Table 1. Outline of key activities for the NHMRC community consultation on the social and ethical issues raised by mitochondrial donation.**

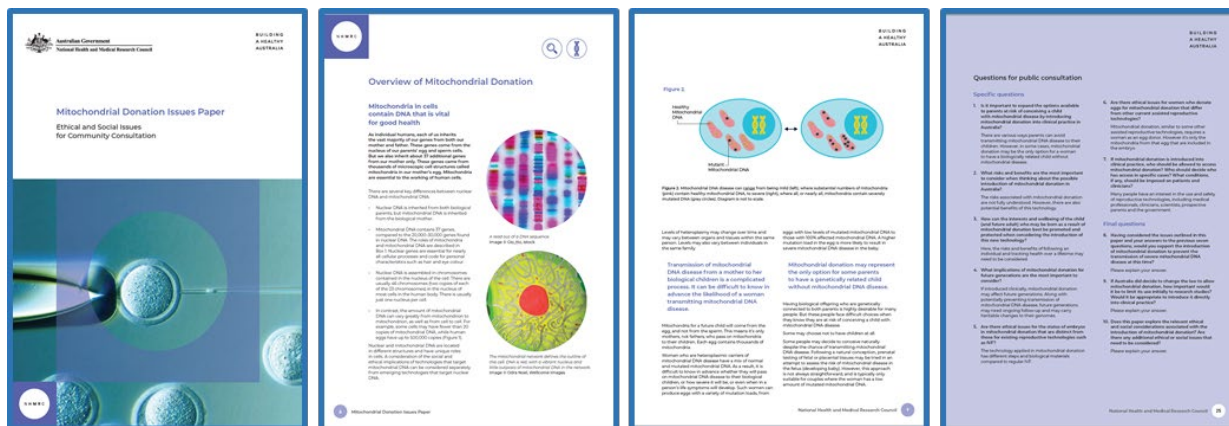
## 2.2 Resources

To support the public consultation a number of resources were developed. The resources were used to promote the consultation and to inform the community about the scientific, social and ethical issues associated with mitochondrial donation.

### 2.2.1 Mitochondrial Donation Issues Paper

An Issues Paper (Figure 2) was developed to underpin all consultation modes and act as an educative tool to allow people to engage in the consultation in an informed and meaningful way. It was aimed at providing sufficient and unbiased information for most people across the community to understand the social and ethical issues that need to be considered to develop an informed opinion about the possible introduction of mitochondrial donation into Australian clinical practice. It included basic descriptions of the science of mitochondria and mitochondrial disease, and the techniques for performing mitochondrial donation. Also included was a series of questions for people to consider in developing their views on the technology. These questions formed the basis of the topics addressed in the written submissions.

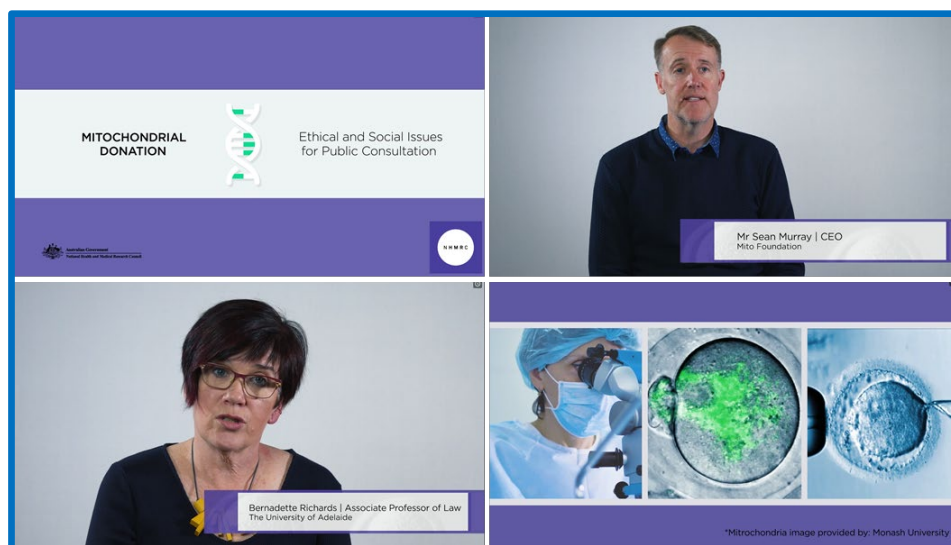
The paper was promoted by social media and other communications mechanisms, and was made available on the NHMRC website and public consultation portal. Printed copies were provided to participants at a number of face-to-face events.



**Figure 2.** Example pages from the Issues Paper. The Issues Paper was designed to present accurate information in an accessible and visually appealing way.

## 2.2.2 Mitochondrial Donation Public Consultation video

An eight-minute video (Figure 3) was developed to provide an overview of mitochondrial disease, mitochondrial donation and the related social and ethical issues. It was designed to be understandable by people with no prior knowledge of mitochondrial donation. The information was presented by a variety of experts, drawn mostly from the MDEWC. It was available on the NHMRC website and used at nearly all of the consultation activities to support informed discussion.



**Figure 3.** Example screen shots from the Mitochondrial Donation Public Consultation Video. In the video, NHMRC and experts drawn mostly from the MDEWC give an overview of mitochondrial disease, mitochondrial donation and the related social and ethical issues.

### 2.2.3 Webinar videos

The two webinars hosted during the consultation were recorded and the videos (Figure 4) were made available on the NHMRC website. The videos provided an educative resource with expert answers to many common questions about the science of mitochondrial donation, as well as expert information about the legislative implications and the social and ethical issues that are central to the possible introduction of mitochondrial donation.



**Figure 4.** Example screen shots from the webinar videos. Two webinars were held during the consultation period. Both involved an expert panel answering questions submitted by participants in real time. The videos were recorded and available on the NHMRC website.

### 2.2.4 Postcards and outreach at conferences

Postcards were produced to advertise the consultation activities and provide details of how people could be involved in the consultation through making submissions via the NHMRC public consultation portal. The postcards were distributed at various face-to-face events and through professional functions such as relevant scientific conferences. The consultation was also promoted by individual MDEWC members at conferences, during their individual presentations or on information slides displayed in between sessions.





**Figure 5. Front and back of the postcards.** Postcards were distributed at conferences and consultation events and encouraged people to visit the NHMRC website to make a written submission.

### 2.2.5 Social media and mailing list

Social media (Twitter and Facebook) were used throughout the consultation to promote the public forums and webinars, and to encourage people to provide their views via written submissions. A new Twitter account (@MitoNHMRC, see Figure 6) also posted short clips from the Consultation Video (Section 2.2.2), links to media coverage, and information about the activities of individual MDEWC members, such as appearances on radio or TV or publication of articles.

An email list was established to communicate information about the consultation to interested parties. In the consultation period 28 stakeholders received updates via this list.



**Figure 6.** A Twitter account was set up to support the public consultation on mitochondrial donation.

## 2.3 Written submissions

Written submissions on specific social and ethical questions of mitochondrial donation were sought through the NHMRC website (via the 'Online Services portal') throughout the consultation period to give all stakeholders an opportunity to provide their views. Public

consultation through the online portal provided a mechanism for interested parties to provide a detailed and considered response to issues outlined in the Issues Paper (Section 2.2.1) or encountered through any of the other consultation modes. The ten consultation questions were constructed to explore specific social and ethical issues, thereby encouraging submissions that built on the information already gathered through the Senate Inquiry process.

The portal was open for submissions from 23 September to 29 November 2019.

## 2.4 Citizens' panel

The Citizens' Panel was the primary mode for obtaining views from a range of different members of the Australian community on the social and ethical issues associated with mitochondrial donation. It involved taking a group of people who had likely had very little prior knowledge of mitochondrial donation, educating them on the relevant scientific, ethical and social issues, and then allowing participants to deliberate on the issues and refine their thoughts to develop a Citizens' Panel Statement.

The process did not aim to obtain a representative sample that could be used to infer whether the Australian community supports or opposes the introduction of mitochondrial donation into Australian clinical practice. Consequently, the final position of this particular Citizens' Panel should not necessarily be taken as the position that the Australian community as a whole would arrive at after following a similar educative process. However, the range of views will likely be similar since the process aimed at bringing a diverse group together, each with their own experiences and values, so that through education and engagement with each other, the types of issues important to people across the spectrum of the Australian community could be identified.

The Citizens' Panel met over two weekends. The first weekend (19–20 October 2019) was held in Adelaide and included presentations from several experts in the fields of science and medicine, law and ethics, as well as patient advocacy representatives, many of whom were drawn from the MDEWC. The focus was on participants learning about issues related to mitochondrial donation and engaging with the experts and each other to develop their initial viewpoints. The second weekend (9–10 November 2019) was held in Brisbane, and focused on answering the participants' questions, strengthening their understanding of mitochondrial donation and developing the Citizens' Panel Statement (Section 4.3). Participants were encouraged to discuss the overarching question with their communities and to incorporate their learnings from those discussions into the development of the statement.

## 2.5 Targeted roundtable

Key stakeholders were invited to participate in a roundtable discussion of the social and ethical issues associated with mitochondrial donation. Participation in the roundtable provided a forum for discussion between stakeholders with particular interests in and prior knowledge of the issues, and enabled specific jurisdictional issues to be raised. The event ran over half a day and was set up to enable communication with and between relevant stakeholders, giving NHMRC a fuller understanding of their priorities and concerns.

## 2.6 Webinars

Two webinars were held during the consultation period. The first webinar was held on the morning of 30 October 2019, and included the launch of the Consultation Video (Section 2.2.2). The second was held on the evening of 19 November 2019. The webinars were hosted at different times of day to encourage and enable participation from a broad range of people, including from across all states and territories.

Both webinars involved an expert panel drawn from the MDEWC answering questions submitted by online participants.

The key advantages of the use of webinars were that NHMRC could reach people across Australia, including remote and regional locations, and there was no limit to the number of people who could participate. Participants could interact with the material being presented and ask questions. Importantly, the webinars enabled participants to make an informed submission to the consultation via the NHMRC online submissions process.

The webinars were recorded and made available online, for the community to view or re-view at any time.

## 2.7 Public forums

Public forums were held in Sydney and Melbourne. Both involved showing the Consultation Video (Section 2.2.2) and an expert panel to facilitate discussion and answer audience questions. Panellists were drawn from the MDEWC.

Public forums allowed interested people from the community to engage with the consultation through a community meeting-style event. The forums focused on education and informed discussion. They allowed people to interact face-to-face with, and ask questions of, panellists and may have been a more accessible mode for people not familiar with webinars.

After the forums, participants were better equipped to provide informed submissions via the NHMRC online submissions portal.

# 3. Stakeholder engagement

This Section describes how the aim of the consultation, to consult with a range of different stakeholders and obtain informed opinions about the possible introduction of mitochondrial donation, was successfully achieved. This was due to the media strategy and the resultant level of media engagement, and promotion through educative activities (Section 3.2) and the variety of consultation activities conducted (Section 3.3).

## 3.1 Media engagement

A media strategy was developed and implemented to raise public awareness of the consultation and provide information to educate members of the public about mitochondrial donation and its associated social and ethical issues. The purpose was to give members of the Australian community the opportunity to make an informed contribution to the consultation. This media strategy allowed a wide range of stakeholders to be engaged through a variety of events and mechanisms.



Media engagement aimed at raising awareness of the consultation was successful in reaching a large number of people across the Australian community as well as a broad range of different stakeholders. It was focused to coincide with key consultation events to maximise its impact and allow for events in different capital cities to promote engagement with local media outlets.

Media releases and/or social media alerts were published to coincide with the following key events:

1. the first weekend of the Citizens' Panel (18–20 October)
2. the first webinar (30 October)
3. the second weekend of the Citizens' Panel (9–10 November)
4. the first public forum (11 November)
5. the second public forum (18 November), and
6. the second webinar (19 November).

During the mitochondrial donation public consultation period significant media interest was generated Australia-wide via a variety of platforms, including print media, television and radio. A report from the Mito Foundation on 8 November 2019 stated that the mitochondrial donation consultation appeared in the media 116 times with a cumulative audience of about 8 million people in Australia. Media coverage over 7–8 November 2019 included Sky News, 2GB, Prime 7 (Orange, Wagga Wagga), Southern Cross (Cairns, Rockhampton, Bundaberg, Sunshine Coast), 2SM, other radio outlets (3AW, 6PR, 2CC, 5AA, 4BU, 4BC, Power FM, ABC Perth, ABC Melbourne, Hot Tomato Gold Coast, Curtin FM), the West Australian, Herald Sun (Melbourne) as well as online syndication around Australia on News Ltd websites (Daily Telegraph, Courier Mail, Cairns Post).

A summary of the media activities is at [Appendix B](#).

## 3.2 Engagement via NHMRC education activities

The NHMRC mitochondrial donation consultation website was viewed 2,605 times between 1 October and 28 November 2019 (views external to NHMRC), which is a significant increase in traffic for the NHMRC website and showed that the community was engaged with this issue.

The Issues Paper (Section 2.2.1) was available in printed and electronic formats. During the consultation period 135 copies were downloaded from the NHMRC mitochondrial donation webpage and 200 copies were distributed at face-to-face events.

The Consultation Video (Section 2.2.2) was made available on the NHMRC website and was viewed over 2,000 times by the end of consultation period.

The first webinar had 71 live views with 2,100 post-event views in the consultation period, with a view rate of 42%. The second webinar came towards the end of the consultation period and had 14 live views and 231 post-event views during the consultation period, with a view rate of 47%.

Both public forum events saw a good turnout from the community and were successful in providing relevant information and engaging participants in the consultation. The Sydney public forum was attended by 28 participants and the Melbourne forum was attended by 47 participants.

Information on participants' demographics was not collected at public forums or webinars.

### 3.3 Overview of stakeholders who shared their views

The extensive media around the public consultation and variety of modes of engagement allowed for engagement with a diverse range of stakeholders.

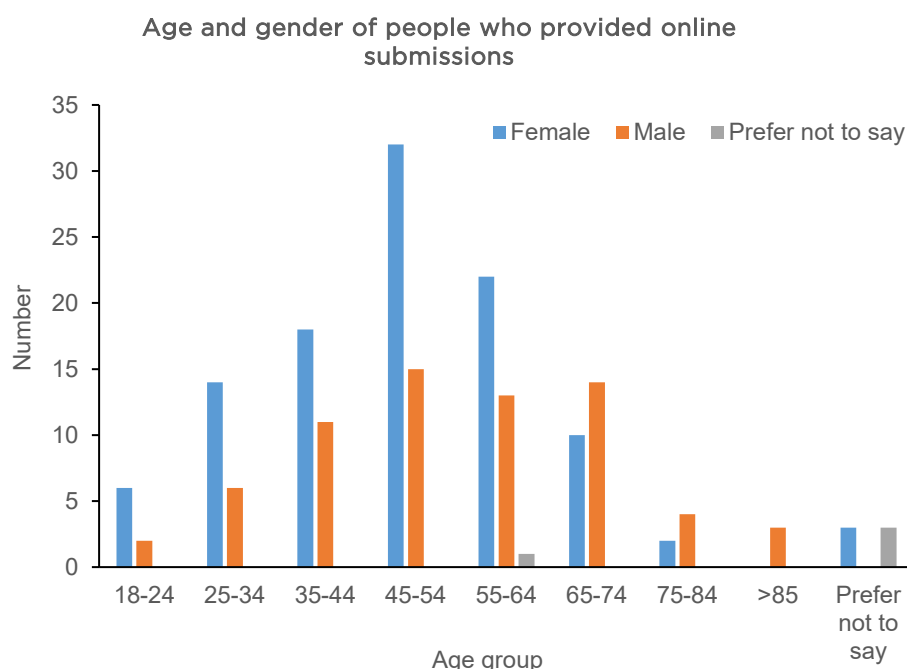
#### 3.3.1 Online submissions

To participate in the written submission process, submitters were asked to provide metadata such as whether they were an individual or organisation, the type of individual or organisation, gender, age and postcode. The numbers below rely on this self-reported information.

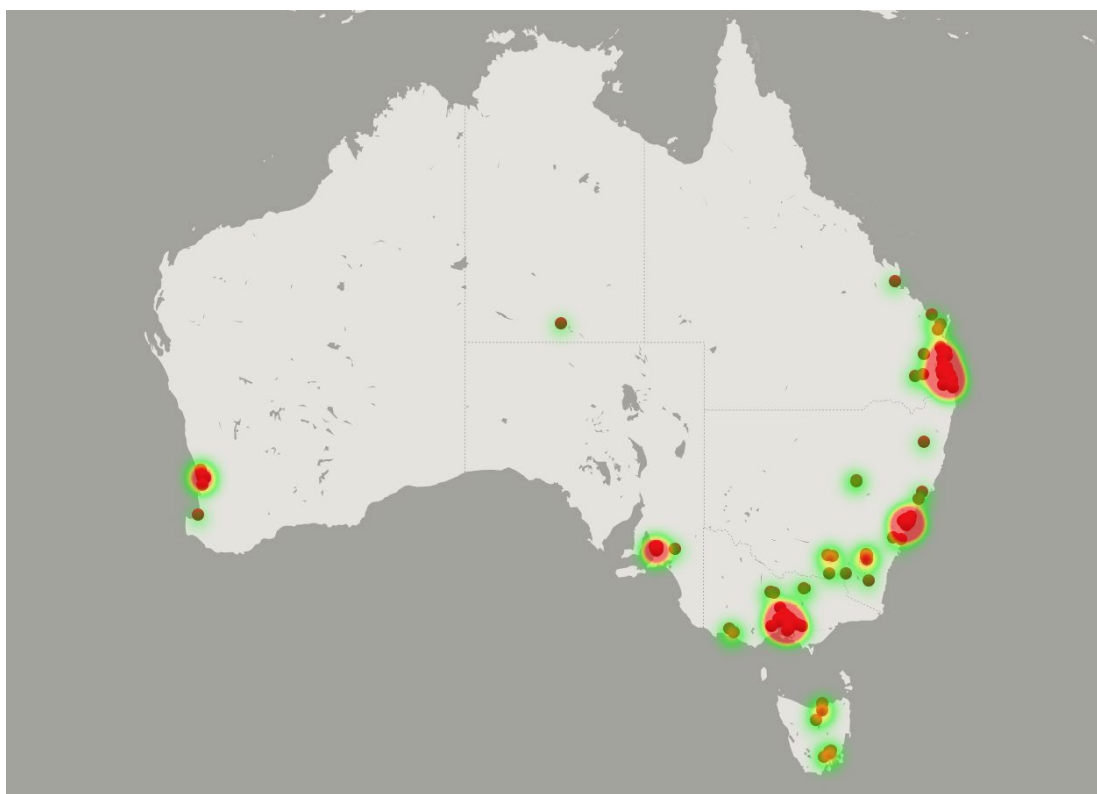
Online submissions to the public consultation were received from across Australia, with male and female respondents and all age groups also being represented (Figures 7 and 8).

One hundred and ninety-five unique written submissions were received during the consultation period, with four duplicate submissions also received. Most submissions (179) were received from individuals; however 16 organisations also participated, with each organisation likely representing the views of several people. A full list of submissions is at [Appendix C](#).

Most individuals identified as either community members or patients/patient representatives.



**Figure 7. Overview of the gender and age of individuals who provided written online submissions.** Analysis is based on submitters who identified as individuals, excluding duplicates (179 in total).

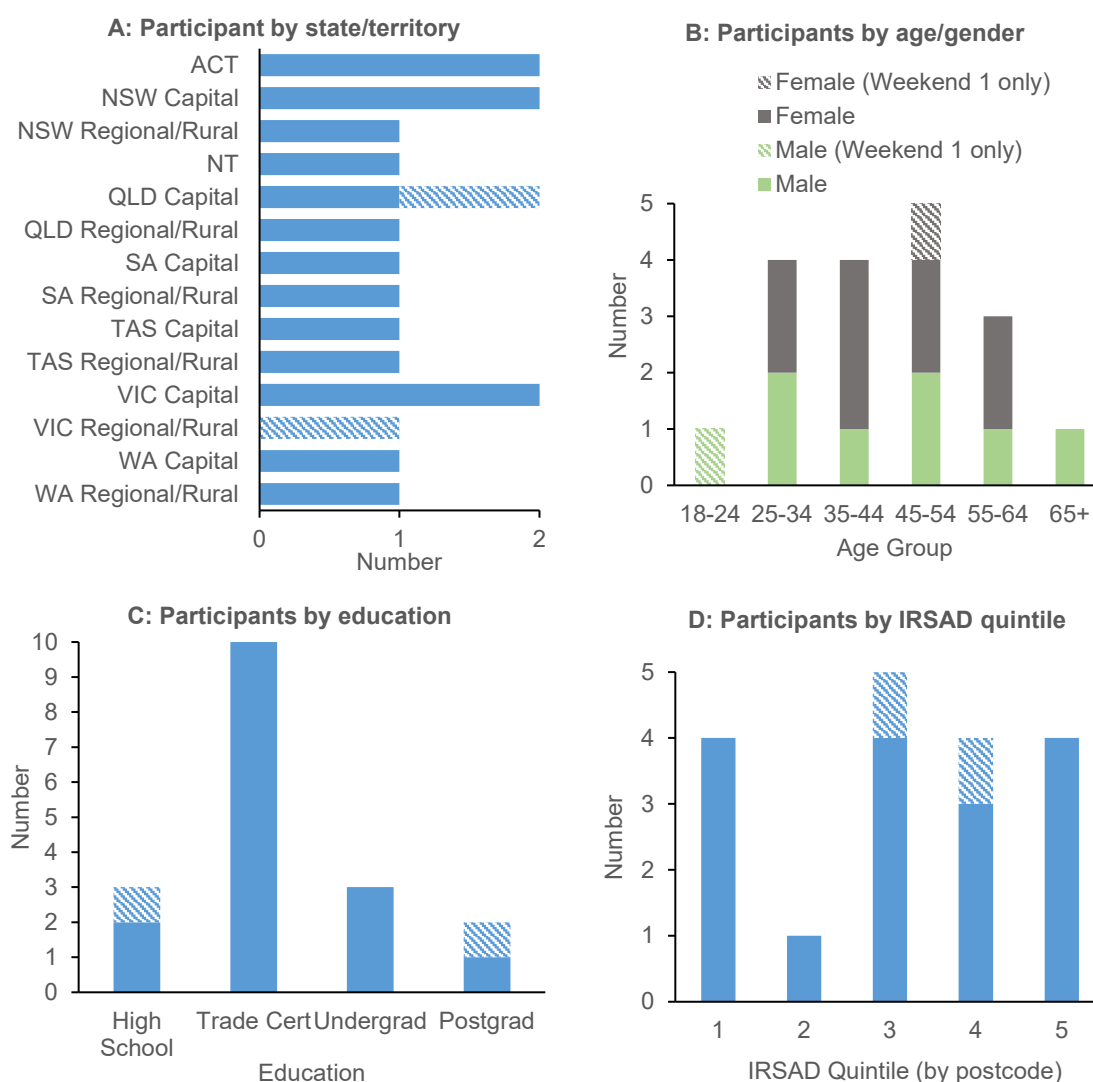


**Figure 8.** Overview of the location (by postcode) of individuals who provided written online submissions. The heat map was generated using the postcodes provided by the 179 individuals who provided a submission. Red colour indicates a high density of responses in that area.

### 3.3.2 Citizens' Panel

Eighteen participants attended weekend one of the Citizens' Panel, with 16 returning for the second weekend. The Citizens' Panel participants were selected to cover a broad demographic spectrum to allow a wide range of views from the Australian community to contribute to the discussion and resulting statement. Citizens' Panel participants were drawn from all states and territories, providing city and rural representation across a range of ages, socio-economic backgrounds and educational backgrounds (refer to Figure 9).

Participants discussed a wide range of topics between themselves and with a variety of experts. Through this process, they developed and wrote a Statement that encapsulated their views on the possible introduction of mitochondrial donation into Australian clinical practice (Section 4.3).



**Figure 9. Overview of demographic information for the participants on the Citizens' Panel.** Participants were recruited from across Australia (A), and included males and females from a range of age groups (B). Participants were chosen to ensure a variety of educational backgrounds (C) and calculation of IRSAD (Index of Relative Socio-economic Advantage and Disadvantage) based on the postcodes of the participants' addresses revealed that participants were drawn from areas with different economic and social conditions. In A, C and D, blue indicated participants present for both weekends and cross-hatching indicates participants present for the first weekend only.

### 3.3.3 Targeted Roundtable

Twenty-six stakeholders representing relevant academic and advisory bodies attended the targeted roundtable. Attendees included representatives from the Association of Australian Medical Research Institutes, the learned academies and the Fertility Society of Australia, as well as jurisdictional representatives (full list at [Appendix D](#)). The discussion was facilitated by MDEWC members, led by the Chair of the Embryo Research Licensing Committee. NHMRC recorded the key ideas that emerged from this meeting (Section 4.4).

### 3.3.4 Comparison of engagement with Senate Inquiry

Analysis of the stakeholders reached through the public consultation identified that, while there was some overlap, this process significantly expanded on the number of submissions provided to the Senate Inquiry and obtained input from a wider range of stakeholders (Table 3). The Senate Inquiry received a higher proportion of submissions from academics than the public consultation. While the number of academic submissions was roughly the same for both processes, the Senate Inquiry only received one submission from someone identifying as a community member whereas the public consultation received 90 submissions from people identifying as community members. Similarly, the Senate Inquiry received 13 submissions from patients or the patient perspective while the public consultation received 36.

|              | Public consultation mode |                 |                     | Senate Inquiry submissions |
|--------------|--------------------------|-----------------|---------------------|----------------------------|
|              | Online submissions       | Citizens' Panel | Targeted roundtable |                            |
| Individuals  | 179                      | 16              | N/A                 | 33                         |
| Organisation | 16                       | N/A             | 23                  | 22                         |

**Table 2.** Comparison of the number of individuals and organisations who participated in the public consultation activities with the Senate Inquiry. This data excludes duplicate submissions. Information on demographics was not collected at public forums or webinars and these events have not been included in the table below.

## 4. Outcomes of consultation

### 4.1 Analysis of online submissions

#### 4.1.1 Methodology

The analysis of the online submissions was conducted as follows:

- Two people read each submission in full and the key words and phrases were identified.
- The key words and phrases were examined and grouped according to similarity to identify emerging themes.
- Comments in submissions were then classified according to these emerging themes and sub-themes by two people, which allowed comments for a specific theme to be compared from across all submissions. This classification was done in an Excel spreadsheet to allow data to be filtered, sorted and analysed.
- Themes and sub-themes were named by reviewing the content of each theme and identifying a phrase that described the ideas contained in each theme.
- This process was conducted iteratively to ensure that comments were classified appropriately and all themes and sub-themes were captured.

Although the online submissions were based on ten questions, a review of the submissions demonstrated that questions often contained content relating to a number of themes, and that comments related to each theme could potentially be derived from the responses to

several different questions within a submission. As such, the results from this analysis are presented by theme rather than by question.

#### 4.1.2 Overview of themes

The major themes that emerged from the submissions were grouped into five areas:

- outcomes of mitochondrial donation
- the rights and wellbeing of children
- factors relating to egg donation and the donor in mitochondrial donation
- factors relating to the embryo in mitochondrial donation, and
- implementation considerations.

Within each of these themes, sub-themes were identified that reflected different though related facets of the overarching theme. The Sections below describe these themes and sub-themes and the variety of views that were put forward. Examples of comments are provided from submissions to help illustrate the range of views encapsulated by the different themes.

The comments do not necessarily reflect the views of NHMRC or the MDEWC and may contain factual inaccuracies. Note that Section 5.4 provides a discussion of some of these factual inaccuracies. The comments were derived from submissions and may be quoted in part or in full from a response to a given question. The quotes are included verbatim with no editorial changes, except to remove offensive, identifying or superfluous content (indicated as [...]).

The themes and sub-themes are summarised in Figure 10.

|  |   |  |
|--|---|--|
| <b>Theme 1: Outcomes of mitochondrial donation</b><br>Sub-theme 1A: Genetic relatedness<br><i>The importance of genetic kinship between parents and children. Does not focus on the donor.</i><br>Sub-theme 1B: Disease and disability prevention<br><i>Mitochondrial donation as a means of preventing disease and disability.</i><br>Sub-theme 1C: Choice<br><i>The importance or otherwise of reproductive choice for prospective parents.</i><br>Sub-theme 1D: Socioeconomic impacts<br><i>The social and financial ramifications of introducing mitochondrial donation into clinical practice.</i><br>Sub-theme 1E: Unknown, unforeseen or unintended consequences<br><i>The consequences of mitochondrial donation that may not be fully understood or recognised at this point in time.</i> | <b>Theme 2: The wellbeing and rights of children</b><br>Sub-theme 2A: Health and wellbeing of the child<br><i>The impacts of mitochondrial donation on the health and wellbeing of any resulting children.</i><br>Sub-theme 2B: Rights of the child<br><i>Considerations of the rights of children resulting from mitochondrial donation.</i><br>Sub-theme 2C: Genetic heritage<br><i>The impacts on genetic heritage and related concerns for any resulting children.</i>  | <b>Theme 3: Factors relating to egg donation and the donor</b><br>Sub-theme 3A: Donors' rights and responsibilities<br><i>The rights and responsibilities of donors in the mitochondrial donation process.</i><br>Sub-theme 3B: Impacts on donors<br><i>The impacts on donors of undertaking egg donation for mitochondrial donation.</i><br>Sub-theme 3C: Considerations regarding egg donation<br><i>Views on egg donation associated with mitochondrial donation.</i>   |
|  | <b>Theme 4: Factors relating to the embryo in mitochondrial donation</b><br>Sub-theme 4A: Status of the embryo<br><i>Views on the moral status of the embryo in mitochondrial donation.</i><br>Sub-theme 4B: Genetic composition of embryos and resulting children in mitochondrial donation<br><i>Views on embryos and any resulting children who have genetic material from three individuals.</i><br>Sub-theme 4C: Manipulation of genetic material in embryos<br><i>Views on the genetic modification of embryos in mitochondrial donation.</i> | <b>Theme 5: Implementation considerations</b><br>Sub-theme 5A: Access to mitochondrial donation<br><i>Views on who should have access to mitochondrial donation, and under what conditions.</i><br>Sub-theme 5B: Whether and how mitochondrial donation should be introduced into Australia<br><i>Views on whether and/or how mitochondrial donation should be introduced in Australia</i><br>Sub-theme 5C: Legalising and/or regulating mitochondrial donation<br><i>Views on whether and/or how mitochondrial donation could be legalised or regulated in Australia.</i> |

Figure 10. An outline of the themes and sub-themes identified by analysis of the online submissions, with a brief description of each sub-theme.

### 4.1.3 Summary of sub-themes related to theme 1: Outcomes of mitochondrial donation

#### Sub-theme 1A: Genetic relatedness

The sub-theme of preserving genetic relatedness was a key consideration across numerous submissions and was recognised as an important outcome of mitochondrial donation. Many respondents highlighted that mitochondrial donation would allow for a couple to have a genetically related child, whilst reducing the risk of mitochondrial DNA disease. There was broad acknowledgement that having a genetically related child is extremely important for many couples:



“The main benefit of donation is that a small number of affected women can have a biologically related child.”

“The technology rests on the significance of the parental desire for the child to be genetically related to both parents [...] we recognise that this desire may be strongly held by some couples and that it cannot be dismissed as illegitimate.”

“The potential benefits to families affected with mitochondrial DNA disease is significant as it would allow them to have a genetically related child who would be unlikely to be affected by a mitochondrial DNA disease.”

Whether the prospective parents’ desire for a genetically related child was seen by respondents as a compelling reason for introducing mitochondrial donation varied greatly across submissions.

Many submissions highlighted that a range of alternative options for having a child, other than mitochondrial donation, were currently available to prospective parents:

“While it is understandable that parents would like to have a biologically related child, there are other options to have a child, that do not compromise ethical and moral boundaries or create potential future hazards for the child.”

“There are several existing options for women and couples with a risk of transmitting mtDNA disease to their offspring to become parents. One option is to use a donated egg or embryo together with IVF. Adoption is also a theoretical possibility, but is not likely to be practicable.”

Several submissions also emphasised that genetic relatedness is not a necessary condition for the formation of parental and familial bonds:

“Motherhood does not have to be biological, and research should consider alternative ways to prevent diseases which don’t cross ethical and moral boundaries on human embryo experimentation.”

“Being a parent is an action involving commitment to the life of a child, such as in the case of adoption, rather than simply a biological conception.”

“Clinical and research experiences suggest that individuals/couples facing complexities in having children (owing to transmission of heritable diseases and/or diagnoses increasing prospects of childlessness) do turn to and embrace alternative non-biological family formation options such as for instance donor assisted conception, thereby providing a viable, established, biologically risk reduced option.”

“I have accompanied couples who in various circumstances have been considering the use of a donated egg, or donated sperm, or both. To use donated gametes involves letting go of a dream - the dream of having a child which is genetically related, which is ‘flesh of my flesh and bone of my bone’. Letting go of this dream is hard. It involves much grieving. Even so, it is possible, and many of the couples whom I’ve accompanied have grieved and also made the decision to use donated gametes. While their children were conceived using a donated egg, donated sperm or both, I do not believe that their love for their children is in any way inferior to the love of other parents for their own children who are genetically related to them.”



A number of submissions acknowledged that while there are other options for having children available to those with mitochondrial DNA disease, none satisfy both the desire for genetically related offspring and for offspring to have a reduced risk of developing mitochondrial DNA disease. Mitochondrial donation was identified by some submissions as a way to expand the range of options available to prospective parents.

“Despite other reproductive options, biological kinship is very important to some people and for a variety of reasons. Mitochondrial donation stands alone as the only method to both ensure genetic relation to the child and completely circumvent inherited mitochondrial disease.”

“At present, egg donation is potentially the only option to prevent the transmission of mtDNA disease, however, future children are then only genetically related to the father and not the mother. Mitochondrial donation will broaden reproductive options to patients affected with mitochondrial diseases for which there is no other option available.”

Several submissions emphasised that a number of assisted reproductive technology (ART) interventions currently employed in Australia are specifically used to ensure that a person can have a genetically related child. That is, Australia justifies the wish for a biologically related child already for conditions other than mitochondrial DNA disease. These submissions indicated that mitochondrial donation could be used as a way of affording this option to those affected by mitochondrial DNA disease:

“The reproductive freedom of such prospective parents would be enhanced by the introduction of a reproductive option that would allow them to have a healthy, genetically related child. Many people very highly value the opportunity to have genetically related children. We currently support this value through a range of assisted reproduction techniques. This would enable those options to extend to those with a risk of passing on mitochondrial disorders to their genetically related children who will go on to develop mitochondrial diseases.”

“It is also important to consider the benefit that prospective parents will receive by being able to have a genetically related, healthy child. Many people highly value genetic relatedness in their immediate family. It is a value that is typically endorsed and supported through providing IVF treatment and other assisted reproduction techniques in public healthcare, rather than relying on adoption.”

“The fact that mitochondrial donation provides the only path for some to have a genetically related child without mitochondrial disease is a strong justification for allowing it. Society allows the use of a variety of technologies to ensure a genetically related child in other situations. For example, if a man is experiencing issues with fertility, we allow the prospective parents to use in-vitro fertilisation (IVF) and associated assisted reproductive techniques (e.g. intracytoplasmic sperm injection (ICSI) in order to have a child who is genetically related to both parents. In these situations, we allow parents to access technologies such as IVF, even though donor gametes and adoption are available to them, because we recognise the value people place on genetic relatedness.”

### Sub-theme 1B: Disease and disability prevention

The prevention of mitochondrial DNA disease and associated disability as a key outcome of mitochondrial donation was a recurrent theme across the written submissions. Many respondents indicated that mitochondrial donation represented an important option to prevent or reduce the likelihood of mitochondrial DNA disease:

“The most important implication of mitochondrial donation for future generations is that they will be born with the best chance of not developing mitochondrial disease. Preventing (or at least reducing) the transmission of mitochondrial disease to future generations is a significant benefit and one which many families are desperately seeking.”

“Mitochondrial donation may affect future generations in the prevention of transmitting the disease, therefore the following generations will not suffer the debilitating and potentially fatal affects of mitochondrial disease. That is, without a doubt, the most important affect.”

“It ought to be an option available, for those family members of mtDNA inherited mitochondrial disease, to prevent future generations from developing the disease.”

A number of respondents indicated that alternative options for preventing the transmission of mitochondrial DNA disease were already available to prospective parents, and therefore introduction of mitochondrial donation was unnecessary:

“Using donor eggs to Prevent the mother passing on the disease is already available.”

“Full egg donation already Fully prevents this disease being passed on from the mother. No benefit from further increased risks.”

“As I have said, the transmission of such a disease can be prevented by mothers not having children.”

However, submissions from proponents of mitochondrial donation emphasised that, unlike mitochondrial donation, alternative options do not allow prospective parents both to prevent transmission of mitochondrial DNA disease and to have a child who is genetically related to both parents:

“Currently, parents at risk of transmitting a genetic disease encoded by nuclear genes, have options to prevent this from happening while still having a child with their genetic makeup. Parents at risk of transmitting a mitochondrial DNA disease to the child through their mother, do not have that option. Introducing mitochondrial donation would allow them the same opportunity to prevent transmitting genetic disease to their children as couples with a risk of transmitting nuclear genetic disease.”

“Existing options are very limited and none produce a biological child.”

Some submissions expressed doubts about the efficacy of mitochondrial donation in preventing mitochondrial DNA disease and suggested that, because of this, its introduction would be problematic:

“Since legislating for mitochondrial donation in Britain in 2015, no healthy babies have been born through mitochondrial donation [...] This

experimentation in genetic engineering is unproven in preventing disease [...]"

"There is an unknown risk of knowing how well it will work of preventing the disease in the future generations [...]"

"There is no guarantee that disease can be prevented 100% with this technique. Changes could still be passed down to future generations and affect those people."

"There is no evidence to suggest this is a fail safe successful option. It's not fair to give false hope to parents who are already desperate and distressed."

"There are other avenues to avoid transmission that do not involve experimenting with the lives of embryos when there is insufficient evidence to demonstrate that the process will be successful."

A number of respondents raised concerns about the potential impacts of trying to prevent mitochondrial DNA disease and disability using mitochondrial donation. Several respondents with personal experience of mitochondrial DNA disease expressed views about the impacts of serious disease or disability and suggested that it would be preferable to prevent this if possible:

"I've watched the way my sister had struggled and been bullied for her disability as a result of the mitochondrial disease. As a result of watching what my sister has been through I've considered not having a family myself."

"I was unaware I had mitochondrial disease when I had my child. After diagnosis specialists advised to not have any more children due to the inherent risks of future children also having mitochondrial disease. I would not wish to pass this disease along to any child, so I decided to not have any more children [...] I would not take any risks in having a child potentially who could have a severe disability from mitochondrial disease."

However, a number of other submissions, including one from a person with a mitochondrial DNA disease-related disability, raised concerns about exacerbating negative social perceptions and treatment of people with a disability. These submissions suggested that negative impacts needed to be considered if mitochondrial donation was introduced (see also Section 5.3):

"we risk creating a culture where funding of research of treatments and care for those with mitochondrial disease is removed or lowered because society will consider that the parents chose to have children with mitochondrial disease as opposed to taking the option to genetically manipulate such children, and therefore the parents should bare the cost of such a decision."

"The main concern I have for future generations, is for those still born with mitochondrial disease either through the parents' choice not to pursue mitochondrial donation, spontaneous mutation, or secondary mitochondrial diseases (mutations not in mitochondrial DNA). As the technology becomes more accessible, we should be vigilant not to demean or be condescending to those living with the disease and we should continue to provide a high-standard of care. I'm speaking more broadly to concerns of disability

activism and understanding that those with the disease should not be considered 'defective' or in need of fixing, but supported to self-determine."

"If in clinical practice [mitochondrial donation] may be freely available and will be used to remove disabilities that can be managed well such as [my disability (details of disability removed to protect privacy)]. We need to change community views on disability not remove them from existence."

Some respondents expressed concerns that if mitochondrial donation was introduced as a means of preventing mitochondrial DNA disease and associated disability, this could have negative impacts on prospective parents' reproductive choices:

"At the same time, there is also the risk that women would feel obliged or pressured to use the technology of mitochondrial donation if it were available. It is often taken for granted that procreators should be free to make decisions about reproduction – including when, how, with whom – based on their own values. But this autonomy is typically limited to actions that do not cause significant harm to others, prompting questions about what constitutes harm, and what is significant enough as to place limits on liberty. Further, there is good evidence that women often feel encouraged and even coerced into using technologies to avoid potential disabilities once this is a possibility, and are seen as responsible for causing harm to their child (and to society) if they don't use them. For instance, women with children with Down Syndrome often report negative responses in regards to prenatal testing, including from strangers, along the lines of "didn't you test?". We can anticipate a similar social pressure to use technologies to avoid disabling conditions in children where those technologies are available, regardless of the specific circumstances of the woman, her values, and the often significant health burdens of the technology itself."

"The choices of prospective parents should be respected also, as there are many values other than a normative conception of health that may weigh more heavily in their reproductive choice. As medicine becomes increasingly powerful and accessible we should continue to examine our values and empathise with people of diverse abilities and physiologies."

### Sub-theme 1C: Choice

Individual choice about reproductive options was emphasised across a number of submissions and was identified as another possible implication of mitochondrial donation. For some respondents, mitochondrial donation represented an expansion of available options for those at risk of passing on mitochondrial DNA disease to their biological children. These submissions often emphasised the primacy of the prospective parents' choice in determining whether or not they would use this option if it was made available:

"Many families at risk of having a child with mitochondrial (DNA) disease, are left to balance their desire to have a child with their desire to avoid passing on the condition. This option adds a compromise available for couples, which would be an important step for many families. Of course, some may choose that this is not an option for them (again, financial, emotional or social issues), but to be an option would be important."

"I feel that this is an important choice that the parents of said child should be given as mitochondrial disease can shorten the child's life span. If there

was a way to prevent a child from being born with the disease and the mother could have a safe and healthy pregnancy the introduction of mitochondrial donations should be considered.”

“In the context where a technology exists that gives people the option to have a child and at the same time avoid passing on an inherited condition, it is important to make the technology available to individuals who might benefit from it, so that people can choose whether they want to use it or not.”

“Having lost my mother and brother [content removed to protect privacy] to this awful disease, I have realised the importance of having our own family and knowing how special it is to have inherited my moms smile and caring personality. I often look in the mirror and see a lot of her in me. We want to share the special genetic aspects with each other as parents. While it may not be everyone with mito’s choice, this procedure should be accessible and an option to parents at risk.”

“This procedure should definitely be an option in Australia and allow generations of change. This is our last chance to have a child, we have done everything we possibly can but have run out of options. We have so much love for a child and know we are making the most responsible choice by not just naturally conceiving and bring a sick child into the world just for our own benefit.”

Submissions opposed to the introduction of mitochondrial donation emphasised the range of options currently available for prospective parents to choose from and suggested that these options should be considered or expanded further, instead of introducing mitochondrial donation:

“It may be sad for those who know they are at risk, but maybe the simple choice of “we can’t have a child” should be considered.”

“Parents need to be counseled about the risks of conceiving no matter which disease and supported to make an informed choice. There should also be better options for couples to adopt children in this country for parents that feel that they don’t want to take the risks, even mores so given the amount of children that get aborted because they are unwanted.”

Proponents of the introduction of mitochondrial donation highlighted the inadequacy of other options for many people with mitochondrial DNA disease, and considered this technology as a means of providing a viable option:

“Just as there are many management paths a person with cancer can choose, or end-stage heart failure, or infertility struggles, families with mito (in particular women with a mtDNA mutation) wishing to plan a pregnancy are being denied any viable option at all except to either ‘risk it’ (which includes prenatal diagnosis to much degree) or ‘go elsewhere’ or ‘abstain’. Now that there is finally a light at the end of their dark tunnel of choices, and finally a true definitive medical option, mitochondrial donation is being subject to a far more intense scrutinization than many current, well accepted, mainstream medical managements within Australia [...].”

Some submissions highlighted the issue of choice in relation to future generations, including those who may be born from mitochondrial donation. For instance, several

respondents who were opposed to the introduction of mitochondrial donation suggested that the choice to use mitochondrial donation could potentially detract from or impact on the choices available to others, including any children resulting from mitochondrial donation and subsequent generations:

“No human has the right to temper with DNA that way, as this also means making decisions for other generations and taking away their choices.”

“I think it doesn't consider the wider implications. For example it gives some parents with a specific disease the right to have DNA changed children, whereas others don't have that right, and should have parents the right to choose their babies DNA in the first place. It also doesn't include enough the rights of the baby. Here parents make a choice about the babies future, that is even beyond what is done so far. It does not include any rights the baby and therefore the future adult might have.”

“I am also aware that the risk of being a nation of truly compassionate people is destroyed when we use and discard human life for the sake of others. Sacrifice of ones life for another is a truly compassionate and beautiful thing, but only when it's chosen by the one choosing to lay down their life. These embryos used have no say, no voice and no choice about what happens to them, but they are fully alive at the time of conception. Using embryos for any purpose, no matter how noble the cause, is at it's root still cruel and removes choice.”

Several respondents who supported the introduction of mitochondrial donation, also considered the issue of choice for children born from mitochondrial donation:

“If you gave my daughter the choice to live a life without a Mitochondrial Disease, or live with a Mitochondrial Disease which would torture her and eventually kill her? I'm 100% certain she would choose to live without such a disease and be surrounded by the incredible amount of love and opportunities that we had planned our life around for her. ”

“Similarly, in today's society, many children must undergo life-saving procedures such as chemotherapy and organ donation, a decision that may appear obvious at the time, and in a way, often forced upon a parent because non-treatment may be considered a form of neglect. Remember also that a child has no say in their treatments at a young age. However, do we ever stop or fully consider the long-term effects on the child during these “life-saving” decisions? [...] chemotherapy can have life-long affects in the areas of fertility, growth, organ damage and raised cancer risks. This choice overall can seem irrelevant when it comes to curing their childhood cancer, however, when the types of chemotherapy agents chosen for the job will have differing long-term sequelae (e.g. infertility vs organ damage), who has the final say in the best interests and well-being of their child? Similarly, in organ donation, the child will as a consequence be subjected to the life-long use of extremely potent immunosuppressive treatment along with its side effects and potential harm to their offspring. Again, how well considered were the life-long interests and well-being of the child in that life-saving moment?”



### Sub-theme 1D: Socioeconomic impacts

Many respondents explored the socioeconomic impacts of mitochondrial DNA disease and mitochondrial donation in their submissions. Many proponents of mitochondrial donation highlighted the individual and health systems costs associated with care for individuals with mitochondrial DNA disease. Responses often rationalised that the introduction of mitochondrial donation would reduce these costs and, consequently, provide a broad benefit to the community:

“An important community consideration is the reduced strain on the healthcare and social services systems. Severe symptoms including repeated seizures and loss of motor control can mean that people of all ages have to stop working and may need full time care. Mitochondrial donation would remove this pressure and greatly reduce the economic health costs.”

“The total lifetime burden incurred by those impacted with mitochondrial disease (mito), and the cost to the social and healthcare systems, far outweighs the cost of mitochondrial donation.”

“The most important implication of mitochondrial donation for future generations is that they will be born without mitochondrial disease, which doesn’t just impact the person but also significantly impacts the wider family, friends, carers, and the entire community, economy and health system.”

“[Mitochondrial donation] also offers our nation some excellent health economics opportunities, as the complex needs of those of us who are affected by mitochondrial disease require intensive advice and treatment by the medical system. Furthermore, mitochondrial disease limits our economic productivity, and results in us needing to be supported by state-funded disability services, including the Disability Support Pension.”

“Without question, there are significant health economics benefits for our community. Over the past four years of my mitochondrial disease, there has been a significant impact on the health system as I have visited many clinicians across the country, as well as the impact to the community of my disability support pension. These are costs that would be saved if future generations are prevented from acquiring the genetic pre-requisites for mitochondrial diseases.”

“It would enable limited health resources that would otherwise have been spent on treating mitochondrial disease to be spent managing or supporting patients with other life threatening, disabling conditions. These costs are significant.”

In contrast, submissions opposed to mitochondrial donation in Australia highlighted the potential negative economic impacts associated with its introduction:

“Australia has limited resources available for research and healthcare. Given the manifest risks and ethical problems raised by mitochondrial donation, these techniques should be rejected.”

“Medically at child born from the procedure would require monitoring and who pays for that needs to be considered. The health system publically

funded should not be burdened with that monitoring, and parents whom opt for the procedure may not be financial enough to do so.”

“There is no real way to do this without the commitment of a lot of money and follow up programs with doctors, physiotherapists, psychologist for at least the first 20 years of life. The cost of this would be astronomical and for the benefit that may possible come ( as this technology is still in development) and are not guaranteed, I do not believe that it would be viable...”

Some of these respondents suggested that any financial resources allocated to the introduction of mitochondrial donation could instead be used for other purposes:

“Why not spend the money and research time on finding ways to increase the availability and effectiveness of treatments and therapies to help people manage their symptoms.

The health care and support systems could use monies to give more physical , psychological and practical support to individuals and families affected by MD.”

“Cost /benefit consideration for the community...who will pay, I assume government and if so would that money be better spent to combat health problems that have a much broader impact, for example, childhood obesity?”

In contrast, some proponents suggested that mitochondrial donation represented an opportunity to re-route already allocated funds in the healthcare and/or disability support sector for the care of people with mitochondrial DNA disease to its prevention:

“Then you have the financial burden on the family and also our national health system. NDIS funding is quite substantial once approved, wouldn't this money be better spent to eliminate rather than treat?”

A number of submissions also addressed the question of the unforeseen costs of mitochondrial donation if it were introduced:

“Are we comfortable inducing perturbations and potentially increasing the risk of the child developing other significant diseases? What will be the financial (and insurance) burden? Can we be certain that these children won't sue for damages?”

“The risks of human genetic manipulation are not known. If this form of manipulation is undertaken (which it shouldn't) lifetime health tracking of the individual, and of their offspring, and the costs thereof must be seriously considered.”

“Future health is clearly important as this would not only be traumatic for the recipient and their family, but also result in a burden to the Australian health care system. However, a child with mitochondrial disease will currently be a significant burden to the Australian health care system and it is likely that this risk would be outweighed by a reduction of the current spending. That is not to say that it is beneficial to opt for one illness over another unless that illness can be significantly slight in comparison with mitochondrial disease.”



### Sub-theme 1E: Unknown, unforeseen or unintended consequences

There was broad agreement across the submissions, by both proponents and opponents of mitochondrial donation, that there are many unknowns in relation to mitochondrial donation and its consequences. Whether or not the unknowns related to mitochondrial donation were seen as reason not to implement it varied with support for or opposition to its introduction:

“The benefits of greatly reducing the risk of transmitting mitochondrial DNA disease far outweigh the unknown risks that remain with the technique.”

“The implications for future generations are unknown, we will only know by taking a tiny step of faith, with the correct safeguards in place so this can be done as responsibly as possible. I believe it is clear that it is not a leap of faith.”

“The parameters in this area are so unknown. Leaving aside the ethical issues, which themselves should prevent it being made legal, the potential consequences of this practice are so wide reaching and so complex that no-one could suggest they fully understand them. It is a leap into the unknown which should be avoided.”

A number of respondents asserted that the efficacy of mitochondrial donation in preventing mitochondrial DNA disease was unknown:

“This experimentation in genetic engineering is unproven in preventing disease”

“There is an unknown risk of knowing how well it will work of preventing the disease in the future generations, but also how the new DNA could adversely impact the future generations.”

“Scant evidence to indicate the efficacy of [mitochondrial donation]”

In addition to concerns about the efficacy of mitochondrial donation in preventing mitochondrial DNA disease, a significant number of respondents expressed fears about possible unintended or unforeseen consequences. These included the possibility that mitochondrial donation might cause other as yet unknown harms to children born of this technology, and future generations:

“The implications of mitochondrial donation for future generations that are the most important to consider are the long term effects on future generations. There may be unknown detrimental effects on the human genome due to our messing around with nature. Along with potentially preventing transmission of mitochondrial DNA disease we may in fact potentially be causing a new transmission of mitochondrial DNA disease that is man made”

“Of course it is important that we work on the process and outcome of mitochondrial donation to ensure that with providing the prevention of one problem we are not opening the door to other problems.”

Some submissions also highlighted that if mitochondrial donation were introduced, possible negative long-term consequences could remain unknown for an extended period:

“Long ongoing medical studies would be required. And risk of bad outcomes not being known for many many years when it is too late. We have previously had bad outcomes from unknown risks - famously like Thalidamide babies.”

“[...] trying to fix a specific problem with the babies DNA in order to avoid them becoming sick with one specific disease opens up a whole range of unknown problems. It would take a lifetime of observing these babies growing up and potentially their future children in order to find out what other problems such a procedure could cause.”

Some respondents emphasised the potentially irreversible nature of these unintended consequences, once introduced, and the impacts of these on society more broadly:

“The creation of such children could have uncontrollable and unforeseeable consequences, affecting future generations, and modifying genetic heritage in an irreversible way, inevitably affecting the human species as a whole. It is a dangerous intervention involving genetic engineering, which affects the whole of humanity.”

In addition to concerns about the unintended or unforeseen impacts of mitochondrial donation on children born of this technology and future generations, a number of submissions expressed concerns about a “slippery slope” of other unintended consequences, including genetic engineering, if mitochondrial donation was introduced:

“[...] the risks are not fully understood legally morally and will become a slippery slope with anything goes in the hands of those without ethics a sound moral compass.”

“If it's introduced at all, it won't matter who is the gatekeeper to begin with, because sooner or later everyone wanting to access the technology will demand to be their own gatekeeper.”

“once these practices are introduced, initially restricted access, is usually liberalised”

“It is the proverbial opening of the flood gates to further genetic engineering applications than can reverse genetic conditions by single gene deletions or additions, enable corrupt institutions or organisations or governments to manipulate human genes and embryos for their own gains. Do we want genetic engineering of humans? What is a human?”

“Once the technology is established, it is likely that what is initially put forward as assistance in exceptional cases would become more routine. There are already plans to extend the use of mitochondrial donation to infertility treatment and it seems likely that, if approved, there would be pressure to use it for other forms of genetic modification. One United States fertility doctor talking about mitochondrial donation says “Everything we do is a step toward designer babies ... With nuclear transfer and gene editing together, you can really do anything you want.””

“Introducing Mitochondrial donations for the good of very few people will not just pose unknown future risks to the babies involved, but also opens the door to other DNA tempering in embryos for other reasons. It is just the

next step towards "DNA enhanced children", where parents can decide which DNA parts their child can have."

"‘Slippery slope’ argument for opening gateway to genetic modification of the human genome, which could potentially lead to cosmetic/non-health related alterations."

One organisation acknowledged that introducing mitochondrial disease could contribute to public perceptions of a slippery slope related to genetic engineering, and suggested that these perceptions should be addressed:

"Another identified risk has been the perception that changing the legislation will create a "slippery slope" in terms of introducing gene editing techniques. While the legislation will be carefully amended to ensure this does not happen, at the same time the public need to become more familiar with gene based therapies (not necessarily gene editing) because they will be increasingly developed, for example as a priority area of the MRFF's Genomics Health Futures Mission."

In addition to the comments about a slippery slope from mitochondrial donation to genetic engineering, a number of respondents were also concerned about the slippery slope effects of legalising mitochondrial donation on the status and treatment of embryos:

"IVF [with its callous destruction and trade of embryos is ethically wrong. It] has paved the way for this present debate and proves 'slippery slope' ethics. Once we allege that it is ok to use embryos for IVF, donation, experimentation it the debate ceases to be about whether it is ethical to destroy human embryos and becomes a debate about the circumstances in which we can do it. Proponents use IVF to defend the MD proposal to further extend the socially endorsed destruction of human life because it has already been legitimised by IVF. The argument then becomes, as embryos are destroyed in IVF, it's ok to destroy embryos for other purposes. Soon, it becomes any purpose, and at any gestational age."

"I do not support the introduction of mitochondrial donation - as it exacerbates existing ethical, social and psychological issues arising already from embryonic research and IVF programs and opens the door to yet more issues particularly in relation to paternity."

"As I understand the existing laws regarding protection of embryos would need revoking or revising to enable mitochondrial donation. I feel this would open up a Pandora's box and that there are sufficient already unresolved issues to address ahead of this."

While the unknown elements of mitochondrial donation were highlighted by those opposed to its introduction as a reason to prohibit it, those supporting its introduction often expressed different views. While there was broad acknowledgement across the submissions that not all outcomes of mitochondrial donation are known at present, many submissions suggested this as a rationale for implementing it alongside ongoing research to obtain more data on the technology and its outcomes:

"According to current evidence, mitochondrial donation is likely to increase the probability of having a child who is not affected by mitochondrial disease. However, transgenerational effects and possible heritable conditions need to be carefully considered (which may include unknown

unknowns such as communicable diseases). Though the child could benefit from living a life without mitochondrial disease, it is possible that mitochondrial donation may carry unknown heritable changes and long-term follow-up will be essential to understand these...There should be ongoing research using animal models and collecting human data to determine whether any small amounts of mutant mitochondrial DNA carried over in to the embryo remain at a constant level in accessible body fluids and tissues and whether the individuals show any phenotypes that could be related to use of the technology.”

“Given so much is unknown, limit [mitochondrial donation] to research studies. Once more research is done, either here or [overseas], then introduce into clinical practice.”

A number of responses also likened mitochondrial donation, with its unknowns, to other medical interventions, and suggested that these unknowns should not prohibit introduction of the technology:

“This perceived risk of unknown ‘side-effects’ is always present with any new treatment or intervention and mitochondrial donation has already met the high-standard required by rigorous clinical trials. I believe it prudent to follow-up with the first-adopters of mitochondrial donation, with their consent, to assess any longer term effects related to the biological questions that may remain, however I see no need for further validation of its efficacy or safety as a treatment.”

“All scientific techniques come with some kind of risks attached because it is the unknown we don’t fully understand the risk but by follow-ups and doing more studies and research perhaps we can understand it better and in turn protect these individuals interests and wellbeing.”

“The paper outlines some of the unknowns about the safety of mitochondrial donation, including the potential risk of incompatibility between nuclear DNA and donor mitochondrial DNA (haplotype incompatibility), and the possibility that the donor has a “low dose” of mitochondrial DNA disease. This latter risk (of the donor carrying an undetected or undiagnosed genetic disease) also applies to currently accepted technologies such as donor sperm and donor egg used both by infertile couples and couples avoiding transmitting a known genetic disorder. Therefore this small risk cannot logically be used to deny couples the option of mitochondrial donation.”

“One of the most important aspects I consider is how effective the technology is - both in the short term (mutant load is avoided) and long term (health consequences of being conceived from this technology). Many of these will remain unknown for years to come, however, I liken it to other technologies for which there is little long term follow up (or wasn’t when it was introduced on a wider scale) - transplant, including bone marrow, IVF and PGD, risk-reducing mastectomy etc.”

#### 4.1.4 Summary of sub-themes related to theme 2: The wellbeing and rights of children

##### Sub-theme 2A: Health and wellbeing of the child

A significant number of submissions emphasised the health and wellbeing of any children resulting from mitochondrial donation as a key consideration. Many respondents suggested that mitochondrial donation would in itself promote the health and wellbeing of any resulting children, through the prevention of mitochondrial DNA disease:

“The health of the unborn child is obviously important, but when you are mitigating a risk that would otherwise have their life limited to a few short years, it seems to me that the overall wellbeing of the child (and future adult) is benefited even if they have some health or emotional effects as a result.”

“Introducing mitochondrial donation to Australia will greatly benefit those who are born as a result of the technology...The risks to the child’s health and welfare should be weighed against what might happen to a child who would otherwise be born with mitochondrial disease. It is very likely that the harms of mitochondrial donation will be far less than the harms of severe mitochondrial disease.”

“If the child was born without mitochondrial donation, they may very well die before reaching adulthood. Mitochondrial donation would offer the child a chance of a life without disease or very late onset of symptoms with a majority of their lifetime mitochondrial disease symptom free.”

“On balance, it seems that the potential risks associated with mitochondrial donation are likely to be less severe than the known risks of a woman with mitochondrial DNA disease passing the condition on to her children, and would be offset by the significant benefit of avoiding the transmission of the mitochondrial DNA disease to a biological child.”

However, other submissions suggested that it would be impossible to promote the interests of children if they were born as a result of mitochondrial donation:

“The interests and wellbeing of the child (and future adult) who may be born as a result of mitochondrial donation could not be truly promoted and protected when considering the introduction of this new technology because there are too many unknowns and the danger of unforeseen side effects on humankind are too great a possibility.”

“Precisely to protect these potential children, the technology should not be introduced. To introduce this technology would be to treat these children like lab experiments.”

Many submissions suggested that mitochondrial donation may result in possible risks to the child’s health and wellbeing:

“The largest concern is the complete lack of understanding regarding the risks associated to the health of the baby.”

“Changing the human genome - we don’t know what implications this will have for future generations. Health problems could be created by this technique. There is no possible way to assess all the risks. There is always a

risk that the child can develop mitochondrial disease from another source, whether it be environmental factors creating disease or nuclear DNA. They could also be affected by other diseases not considered during donation. I don't see a benefit in changing a natural process - only pitfalls."

"The risks of damage to the child conceived with mitochondrial donation from adapting to the donor DNA could have long term detrimental effects on its metabolism, health, longevity which has been seen in research involving animals. The risks to the general population from a child with different mitochondrial DNA to all other Australians when they give birth to offspring is too great to allow it to happen here as their offspring will be different and will affect the gene pool."

In fact, there was broad agreement across submissions that there may be some unintended consequences for the health and wellbeing of children born from mitochondrial donation. As such, there was strong support for measures that could address this, including long-term health monitoring or tracking:

"it may be necessary to follow the health of this individual who may be born from this new technology throughout his/her lifetime, to make sure that this does not cause any problems to his/her health."

"In order to understand the implication of this technology it will be necessary to monitor the health of any children born through mitochondrial donations."

"This is a new technology and the projected longterm medical wellbeing of children born as a result of MD is currently unknown. Therefore, the wellbeing of MD-conceived children is best promoted by thorough and systematic medical follow-up, at least until the age of legal adulthood, and possibly thereafter."

Respondents viewed health tracking not only as an important way to ensure the child's health and wellbeing, but also as a way of assessing the overall safety and efficacy of mitochondrial donation:

"In order to understand the implication of this technology it will be necessary to monitor the health of any children born through mitochondrial donations."

"The "safety" of [mitochondrial donation] is unlikely to be established by the birth of any number of apparently healthy children: determining that [mitochondrial donation] does not risk the health, or otherwise impose an undue burden on the future child, will ultimately require tracking and studying its implications for the physical and psychological health of those who are brought into existence over their entire lifetime."

"Perhaps doing a follow-up regularly would be good to protect the interests and wellbeing of the child (future adult) but also ensuring that the technique is effective. All scientific techniques come with some kind of risks attached because it is the unknown we don't fully understand the risk but by follow-ups and doing more studies and research perhaps we can understand it better and in turn protect these individuals interests and wellbeing."

In addition to long-term health monitoring, a number of submissions suggested other provisions to promote the wellbeing of children resulting from mitochondrial donation:

“As the person conceived through mitochondrial donation is unable to consent before the fact, their wellbeing and interests should be weighted heavily in later healthcare or research. I suggest that a long-term healthcare plan should be offered and discussed in great detail with prospective parents prior to undertaking mitochondrial donation. Collaborating with patients, clinics, healthcare professionals and social workers to build a robust and foresighted framework around mitochondrial donation is the best way I can envision that families and individuals born through mitochondrial donation will be informed, protected and respected long-term.”

“Make support network for children of mitochondrial donation where they can get in touch with each other and share stories (if applicable/wanted)”

### **Sub-theme 2B: The rights of the child**

The rights of any child resulting from mitochondrial donation was a recurrent theme across submissions.

Many respondents highlighted the importance of the child’s rights and those of the future adult, especially in light of the possible need for medical monitoring, following mitochondrial donation:

“Tracking health would be easy at first, when the child is young. It is hard to track the health of an adult who doesn’t wish to be part of a study. There is no guarantee that the adult would be consenting to have their health tracked over time.”

“It is likely to be challenging to ethically track individuals’ health without providing undue burden on the individual.”

“In order to understand the implication of this technology it will be necessary to monitor the health of any children born through mitochondrial donations. This is burdensome and will continue for their lifetime. Such tracking may also be required for subsequent generations.”

“If [the child] has to attend regular health monitoring check-ups throughout its life, that should be seen as a benefit. If, as might be expected in teenage years, the child prefers to ignore the benefits of regular check-ups, they at least have had a life.”

“Government should consider whether participation in research and health follow-up for a defined number of years should be a condition of accessing the technique. It may be reasonable to request this follow up until the child is old enough to consider whether they wish to continue to participate.”

Some submissions suggested that while it was important to protect the rights of the child, and to try to avoid medicalising the child, so too was the need to obtain data on the safety and efficacy of mitochondrial donation:

“The child should also be able to expect that their privacy will be protected and they will not be identified as having been born as a result of the technology. However, privacy concerns will need to be balanced with the



need for clinical and research access to information to inform ongoing evaluation of the technology.”

“[We support] the follow up of these children’s health in a manner that appropriately balances the need of the community to build further evidence about mitochondrial donation with the requirement to protect the individual from being over-medicalised.”

Some respondents wrote that these impacts of potentially medicalising the child due to medical monitoring would also be expected if mitochondrial donation had not been used, and the child had developed mitochondrial DNA disease:

“[...]the child or future adult is likely to have their health or ill-health monitored whether they are born as a result of mitochondrial donation or not [...] People with mitochondrial disease are forced to use the medical system often whilst, considering the arrangements in the UK and the discussion paper, it seems likely that Australia would introduce a system by which children born from mitochondrial donation have medical and other follow-up as part of the legalising the procedure. Looking at those arrangements, it seems likely that any so-called ‘medicalisation’ of a child born as a result of mitochondrial donation would be a lesser burden than the interventions, attendance at doctors, tests and other potential requirements involved with having mitochondrial disease. Having said that, it is important to not over-medicalise any individual regardless of the circumstances of their birth and care should be taken to introduce as ‘light touch’ a regime as is reasonable under the circumstances.”

“Some consider a risk of mitochondrial donation to be the medicalisation of the child. If a child is born as a result of mitochondrial donation, it could mean they start their life viewed as a medical subject, which may be exacerbated by ongoing medical monitoring. They will hence be denied the chance at a ‘normal’ childhood. However, it is important to note that in the absence of mitochondrial donation, these children will either not be born (as their parents will choose not to have children), or will be born with mitochondrial disease. There are thus no children who will be denied a ‘normal’ childhood as a result of mitochondrial donation. Furthermore, it is unclear whether children who are born as a result of mitochondrial donation will be viewed any differently in the future from children who are born through IVF or other assisted reproductive technologies.”

Other respondents suggested that considerations about the rights of any child born following mitochondrial donation are similar to those for children conceived via other ARTs:

“Monitoring and long term follow up of children conceived in this way is not unprecedented - many of the babies conceived from IVF were followed in a similar manner. Part of the challenge is considering them as part of the ‘greater good’ rather than as individuals worthy of privacy/anonymity and a life free from being ‘medicalised’. It is challenging to consider that the child has not ‘consented’ to being born from this technology, as this is also not unprecedented - IVF, prenatal dx and even sexual partner selection are all methods of choosing the genetic composition of a child who has not consented to being conceived/born. part of the challenge will be ensuring our psychosocial framework and support for these children exist - as the



progeny of three genetic parents - especially whether this is exceptionally different to being 'chosen' or 'forced to exist' as in the case of infertility, nuclear DNA risk etc."

"Does the baby/adult really need to be promoted? Don't we all know the name of the first IVF baby but was she promoted - hasn't she gone on to lead a very fulfilling/quiet life? I understand from a clinician's point of view that monitoring would be of great assistance to them but what if the baby emigrated and lived overseas, what if this procedure became an everyday occurrence- would tracking health still be important??? Do we still track the health of babies born from other reproductive methods?? Perhaps initial tracking would certainly be of benefit to monitor the health of the individual but a lifetime ..... mmmmm not sure on that."

A number of submissions also suggested strategies for limiting the potential medicalisation of the child born from mitochondrial donation:

"...by providing counselling for such children to help them manage the impact of long term follow-up and the resulting risk of medicalised lives..."

"...it is important to not over-medicalise any individual regardless of the circumstances of their birth and care should be taken to introduce as 'light touch' a regime as is reasonable under the circumstances."

"Education and well informed consent with appropriate counselling are critical in decision making about participation in mitochondrial donation. A particular focus on future supports the child may need and how this can be tracked and followed up or implemented over a lifetime is required. There are already models in surrogacy and gamete donation that can be applied."

"I suggest that a long-term healthcare plan should be offered and discussed in great detail with prospective parents prior to undertaking mitochondrial donation. Collaborating with patients, clinics, healthcare professionals and social workers to build a robust and foresighted framework around mitochondrial donation is the best way I can envision that families and individuals born through mitochondrial donation will be informed, protected and respected long-term."

"To protect a child's wellbeing surrounding this, each iteration of appointments and testing would need to be done in such a way that no trauma or stress is put on the child so that the idea of being tested or checked on throughout their life would just seem like a routine process, no different to going to the dentist for a check up."

"It is important to remember that currently children of women known to carry mitochondrial DNA mutations are often followed up and monitored to detect disease early. Such follow up and monitoring is usually every 1-2 years if the child is asymptomatic and does not involve invasive testing unless symptoms are present. Follow up after mitochondrial donation could similarly be at widely spaced intervals for asymptomatic individuals and be largely observational with invasive testing, including blood tests, only occurring if clinical symptoms or signs develop. If it is deemed necessary, mitochondrial DNA testing can be done on urine. More invasive testing may occur in adults who are then able to give informed consent for such tests."

Concerns for the rights of any child born from mitochondrial donation was also reflected in respondents' views about the child's privacy:

"It would also be in the best interests of those born as a result of mitochondrial donation that their identity is protected from public disclosure. We know that due to illogical public attitudes, a young person whose genetic makeup is a point of interest and may experience difficulties."

"Apart from the health risks associated with the technology [...] we note that there are risks to the privacy of the future child who may well be subject to a life time of medical surveillance and review...While anti-discrimination law does offer some protection we would argue strongly for the introduction of appropriate regulatory limits that protect the future child from incursions on their privacy and discrimination on the basis of their unusual genetic profile."

"The privacy of the child and family may be compromised if ongoing follow up information is collected."

Many submissions considered measures that would serve to protect the privacy of families and children resulting from mitochondrial donation:

"[We support] mirroring the UK protocol. In the UK, respecting the right to privacy of couples has led to an agreement to not publish results of individual pregnancy outcomes, at least in the short term. [We understand] that this may be perceived as delaying the timeframe in which safety and efficacy can be assessed. While we acknowledge the intent of the UK process, we would anticipate that in Australia, it should be possible to establish a more transparent balance between ensuring that no identifying information is published while still enabling results to be published in a timely manner to allow evaluation of the program."

"There may also be social impacts that apply primarily to the children who are involved in clinical trials (as opposed to if and when Mitochondrial Donation becomes an accepted medical procedure), due to the need for enhanced long term follow up, and due to the likely public interest in them. We could address these risks to their social wellbeing...by safeguarding their privacy (given how the media has reacted to the UK developments it is safe to assume that the Australian media would be interested in when such children are born, etc.)"

"I believe the privacy of the individual should be strictly protected until 18 years of age and beyond, unless the individual chooses to identify themselves as an adult."

"I do not even know how to promote and protect the child's interests and wellbeing, authorities will need to be very secretive and selective on who to give the information to about the child's origins in case discrimination occurs."

"[...]the privacy of the child may be compromised if ongoing follow up information is collected. Whilst this information is important in determining the safety of mitochondrial donation, it is important that follow up is not too onerous for families to mitigate the risk of 'medicalising' the child. We

also feel it important that the objectives and goals of proposed follow-up are discussed with the family (i.e. follow up to monitor the child's wellbeing and also to inform the safety and application of mitochondrial donation), emphasising the intention to minimise the burden of follow-up while maintaining privacy. If a family really does not want to participate in a follow up program, that wish should be respected, but recognise it is non-ideal. In essence, we feel that follow up should be about partnering with family to support them in the way that suits them best."

"Maintain their privacy...But still track and disseminate their child's health information in a de-identified, responsible way to contribute to further research to help understand their biology"

"[...] keep their identity anonymous to the general public"

"Poorly orchestrated publicity from affected woman and researchers has the potential to expose individuals to privacy concerns that may reduce affected families willingness to share health data of children born using the technique. We need to learn from mistakes in the UK experience. I believe these risks can be mitigated with targeted research...and better management of cases..."

Respondents also emphasised the role of consent in considering the rights of children born as a result of mitochondrial donation. The fact of the child not having given consent to be born as a result of mitochondrial donation recurred as a consideration across submissions:

"This child/adult gave no consent to be used and created this way and may still have to live with mitochondrial disease or other unknown complications [...]"

"As the person conceived through mitochondrial donation is unable to consent before the fact, their wellbeing and interests should be weighted heavily in later healthcare or research."

"In mitochondrial donation, the only person involved who cannot give consent is the child who may be born. It is particularly troubling that the child who cannot consent carries all the risk."

"In many ways, children with three biological parents are a brave experiment which will have a significant effect on a person not-yet-born who is unable to consent to the procedure."

However, other submissions suggested that the child's inability to give consent prior to mitochondrial donation was the same for any child, whether they resulted from mitochondrial donation or not:

"[...] one of the causes of concern [...] was the fact that the unborn child does not have the opportunity to consent to be conceived using Mitochondrial Donation. My issues with this concern is that [...] I think you would be hard to find any child that as consented to be conceived with or without and medical intervention."

The issue of consent and the rights of the child was also raised in relation to any health monitoring that would be required following mitochondrial donation:

“Part of the challenge in trying to obtain this follow up is patient vulnerability (and perception of coercion) and consenting to such ‘research’ that could have tremendously serious consequences.”

“This is a difficult question as there is no way to get an unborn child’s consent to the possibility of being monitored throughout their entire life.”

“The “safety” of [mitochondrial donation] is unlikely to be established by the birth of any number of apparently healthy children: determining that MRT does not risk the health, or otherwise impose an undue burden on the future child, will ultimately require tracking and studying its implications for the physical and psychological health of those who are brought into existence over their entire lifetime. That is to say, longitudinal studies will be essential. Given that the children born after use of [mitochondrial donation] will not have consented to the use of the technology ethical issues will arise regarding their participation in such studies.”

Some respondents suggested provisions to preserve the child’s autonomy in relation to consent for health tracking:

“There will be advantages in maintaining an understanding of the health outcomes of people conceived via mitochondrial donation; however, participation in a follow up program should be voluntary, and should not be a requirement of access to the technology. It would be advantageous to obtain parental consent to participation in a follow up program; however, once the child is 18, new consent will need to be obtained for further follow up.”

### Sub-theme 2C: Genetic heritage

A significant number of submissions raised the issue of whether any child resulting from mitochondrial donation would have access to information about his or her genetic heritage, including details of the donor of the mitochondria. Some submissions emphasised that it would be important for any such children to have access to this information:

“[The child] should be able to know the identity of all three donors. They should be able to know if they have any half brothers/sisters born when one mitochondrial donor is involved in multiple births to different couples.”

“Some ethics issues include...breaching the child’s right to know who their parents are.”

“[Mitochondrial donation] endangers the right of children to know who their biological parents are, and where their ancestry is from.”

“The child may be interested knowing in the identity of the mitochondrial donor and seek a relationship with her and/or the donor may seek to have a relationship with the child. The option of supporting the donor and the child to have a relationship needs to be considered in the context of the welfare of the child, as well as the rights of the donor.”

“There needs to be consideration of the rights of the child to know or have access to information about the mitochondrial donor.”

“the child growing up might want to know who donate the DNA and might want to get to know the donor. But those emotional issue would probably be less present in comparison to the form of IVF that includes the whole egg or sperm of another person.”

“It is important for donor offspring to know their origins, and whatever the outcome of this consultation, it is vital that mDNA donation is not introduced without full transparency for the child.”

“We are also taking away the rights of the child to ‘know and be cared for by his or her parents’ (Article 7 of the UN Convention on the Rights of the Child). The ‘rights’ of children have been agreed upon in order to protect children. With this three-parent IVF, we are stripping away the rights of children and going completely against any attempt to protect them. We already have a ‘stolen’ generation of IVF children, and introducing this new genetic engineering will create a further ‘stolen’ generation that does not know its biological parents or its full biological medical history.”

“[We submit] the biological link between gamete donors and the children who result is of profound significance, which is the reason these links must be recognised and respected. This includes the right for children to know all their parents. Tobin points out ‘... the primary point is not the usefulness of this information but access to it being a moral right. That is to say, the idea that one is entitled to know one’s biological parents should be understood primarily as a (moral) right to know the truth about one’s conception as a (or, perhaps, the) fundamental aspect of knowledge of one’s own identity’. This is about more than ensuring donor-conceived people have access to records and contact details for their biological parents. It is ensuring that the technology is not used so as to prevent a child from knowing the identity of his or her biological parents. Rather it should be a tool for ensuring that the person’s right to be identified as the natural child of a biological parent is always respected and that the person’s right to have access to his or her biological parents is always respected (even in circumstances in which the law has arranged that he or she cannot make an inheritance claim).”

Some submissions highlighted that these issues also occur in other contexts and are not unique to mitochondrial donation:

“On a broader social scale, mitochondrial donation raises the important question of whether there is an intergenerational ‘right to know’ one’s genetic origins. This already arises with existing assisted reproduction technology (e.g. sperm or egg donation), and even in cases of non-assisted reproduction (e.g. misattributed paternity, which can be revealed as an incidental finding of genetic testing for medical or recreational purposes).”

Some submissions suggested that the child does not need to know details of their genetic heritage, including information about the donor of the mitochondria:

“I believe that this procedure should be viewed as similar to organ or tissue donation. The emphasis should be on creating a healthy human being who was in need of donation from another person to allow them to be healthy and set them up for the best and healthiest life from the beginning. I don’t

believe that the donors details need to be disclosed to the child at any stage, just as with organ donation.”

“We believe it is more appropriate to view the mitochondrial donor as akin to an organ donor, rather than a ‘biological parent’ in the way a sperm or egg donor may be viewed. While mitochondria have broad biological functions, there is little evidence to suggest that individual variations in mitochondrial DNA produce any fine-grained differences on someone’s character, in the same way that variations in nuclear DNA do. When we compare healthy individuals very few, if any, differences between them will be due to differences in their mitochondria. There is thus a much weaker interest for individuals in knowing the identity of mtDNA contributors, compared to nuclear DNA contributors.”

Submissions that emphasised the importance of the child having access to information about their conception, including information about the mitochondria donor, made suggestions about how best to facilitate this:

“It would also be necessary to have a clear framework that establishes whether the child has a right to know the identity of their mitochondrial DNA donor. Australia has moved away from anonymous gamete donation, with all states now requiring that donor-conceived young adults are able to access identifying data about their genetic origins. This is similar to the UK, which moved to a system of permitting the identification of donors to donor-conceived young adults in 2005. Even so, the United Kingdom has determined that children born of mitochondrial donation ought not have access to identifying data of the donor as adults. This is because the approach taken in the United Kingdom is that the mitochondrial donor is not a genetic (or legal) parent and, consequently, the resulting child has no right to know the identity of the donor. ”

“Genetic counselling may also assist children born through the procedure in the long-term to address their genetic heritage, how it differs from their peers, and how they understand the role of the mitochondrial donor as the ‘third parent’ in their birth. It should be noted, however, that children born from donated gametes may also face similar issues as they come to understand the role of their genetic parents and their social parents.”

“A child born from this technology should, at minimum and consistent with the approach to mitochondrial donation in the UK, have the right to know non-identifying information about their genetic background. Or, more preferably and consistent with current NHMRC ART ethical guidelines(5), the child should be able to access identifying information about the mitochondrial donor. Access to this information will be important from a social and ethical point of view, but also from medical and research follow up perspectives.”

“We should encourage transparency regarding the circumstances of our children’s birth whether it be with IVF, donor gametes, surrogacy or indeed adoption.”

“The person conceived from mitochondrial donation should be allowed the right to request information about the egg donor upon reaching 18 years.”

#### 4.1.5 Summary of sub-themes related to theme 3: Factors relating to egg donation and the donor

##### Sub-theme 3A: Donor's rights and responsibilities

Many submissions considered the donor's parental rights to and responsibilities for any resulting child. Some submissions suggested that the donor may wish to have access to or make a claim on any child resulting from her donation:

"However small a contribution a donor makes can potentially cause parental claim to the future child."

"I think IVF is different from Mitochondrial donation because IVF only involves two parties and the other involves three, which raises ethical issues regarding custody of the children should the child want all three parents to be involved in their life."

"The donor may feel an obligation or attachment towards the child in the future and want to be a part of their lives, however may be conflicted as only a small component of the egg was donated. Similarly, the donor may believe there is less of an obligation and be completely against contact from the child that was conceived."

"What about the rights of the mitochondrial donor? Will our courts fill up with cases fighting for the right for custody to their child?"

Some submissions suggested that the donor should not have any particular rights to or responsibilities for any child resulting from her donation:

"Having made the donation, the donor should not be regarded as having any further rights in the matter."

"I think there are few women in Australia who would see mitochondrial donation as meaning they are a 'third parent'. To me, it is closer to organ donation, which is a perfectly acceptable practice."

"Mitochondrial donor should have no involvement with child. Three parents too confusing."

Some respondents rationalised that the donor would not or should not have any particular parental claim on a child resulting from her donation because only the mitochondrial DNA would be donated:

"In the UK system, the donor is not recognised as a 'parent' as their nuclear DNA is not passed to the child. As such, the woman who donated the egg would have the same rights as any other organ donor e.g. umbilical cord blood donors. We support this approach being followed in Australia, and believe it should be clearly communicated to all parties in advance."

"One ethical issue for a woman donating eggs for mitochondrial donation may relate to rights once the child is born. But as it is just the mitochondria being donated, and not the nuclear DNA, I personally don't believe the donor should have any status or rights as a 'parent'."

"The ethical issues differ slightly with mitochondrial donation from other reproductive technologies. Only the Mitochondrial DNA is used for



mitochondrial donation, not the nuclear DNA. Therefore, you have a child that is born with over 99% of the mother's genetic makeup unlike whole egg donation used in IVF techniques. This mitochondrial DNA donation can be seen as a gift from the donor – there are not the same ties that an egg donor would feel as opposed to a mitochondrial DNA donor.”

“The fact that the donor is not donating their nuclear DNA means that they should not be seen as a ‘parent’ of the resulting child, and should not have any legal rights.”

However, other submissions stated that the mitochondrial DNA was still an important factor in considering the potential parental rights of the donor:

“All three DNA donors should be considered biological parents. Although there are only a few genes on the mtChromosome, mtDNA contributes massively to the total amount of DNA that is required to conceive a healthy embryo. Even in adult cells, there is more mtDNA than nuclear DNA.”

Some submissions proposed that it was difficult to know what the relationship between the donor and child should or could be, because mitochondrial donation had not previously existed:

“The challenge in representing the ‘rights of parentage’ as they would be defined in this setting is of interest - the ‘rights’ of children and donors in relation to egg/sperm/embryo donation were ignored for several years before steps were taken to address this. It would be important to consult more widely on public opinion regarding the status of a ‘mitochondrial donor’ compared to the donors that exist currently and what right to privacy/anonymity and of inclusion/identifiability exist. In considering the context of donation in this setting, I expect that the underlying motivation would be much the same of current egg donors.”

“The key medical difference is that woman who donate eggs for MD would become genetic progenitors of a child with three genetic progenitors, rather than two [...] The key new factor brought by MD is that there is no norm or expectation forged by social experience of the status of relatedness through mitochondrial DNA as opposed to relatedness through nuclear DNA in determining either a status or a role in the child's life. That said, norms and expectations in nuclear DNA have also changed over generations and there is no stable answer that fits all experiences and relationships.”

Other respondents suggested that it would be helpful to draw from existing ART laws, regulations and practices in determining how to manage parental rights and responsibilities in the case of mitochondrial donation:

“As with surrogacy arrangements, there is nothing stopping the intended parents and intended mitochondrial DNA donor from entering a private contractual agreement setting out arrangements for the future.”

“Since less than 0.1% of the genetic material of the donor is likely to be incorporated in the child born through MDo, I would expect that the donor would not expect that fact to influence what would be a clearly altruistic gift. If there were any concerns on that issue (eg about ‘semi-parental’ access or other matters), I am sure that they could be settled by a legal

agreement prior to donation as I understand currently happens for regular IVF donors (where close to 50% of the genetic material may come from the donor)."

"The one ethical / legal difference would be the "parental" status of the mitochondrial donor. However, this would be a further variant to what we have with sperm donors, egg donors and surrogates."

Although concerns about parental rights were especially dominant across submissions, respondents also raised a number of other rights and responsibilities pertinent to the donor. This included the donor's rights regarding the use of her donated egg(s):

"The donor would have no control over how her DNA is used."

"I believe however there should be a choice for the donor as to how she would like her donations used."

"From my understanding, the donors are informed and aware of how their egg/sperm/embryo donation will be used and for what purpose."

"From my understanding, the donors are informed and aware of how their egg/sperm/embryo donation will be used and for what purpose. Mitochondrial donation would and should be granted the same respect as other egg donors in Australia, whose eggs may be used for either various IVF techniques or embryonic stem cell research (particularly using SCNT)."

Additionally, the donor's right to confidentiality or anonymity was recognised by many respondents as an important consideration. Some respondents suggested that the donor should have the option to donate their mitochondria anonymously:

"I believe that women who donate eggs for mitochondrial donation should have the same rights as those who act as organ/tissue donors. In this case, the organ donor (or their family) does not know the identity of the recipient and the recipient does not know the identity of the donor (unless they are a family relative or recruited by the patient). Medical information about the women who have donated eggs for mitochondrial donation could be made available to the recipient without disclosure of the identity of the individual."

"Women should have the option to donate eggs anonymously for the purpose of mitochondrial donation, which is not currently the case for donations for IVF."

"Details of mitochondrial donor must be kept confidential to all."

"We do not agree that the same donor identity laws should apply as for embryos created with donor gametes. While we endorse the retention of genetic information on a mitochondrial donor if necessary for health purposes, we do not agree that they should be regarded as a gamete donor or a genetic parent. The science is very clear on this and the law should be clear to make that distinction."

In contrast, other respondents believed that the donor should be identifiable:

"I think it is important that the donor is identifiable."

“ [We hold] the view that women donating their mitochondria should be potentially identifiable, as are women donating eggs for IVF. While the UK legislation prevents a woman being identified, this is not in line with existing Australian IVF practice. Informed donor consent is critical and needs to be built into the process.”

“A child born from this technology should, at minimum and consistent with the approach to mitochondrial donation in the UK, have the right to know non-identifying information about their genetic background. Or, more preferably and consistent with current NHMRC ART ethical guidelines(5), the child should be able to access identifying information about the mitochondrial donor. Access to this information will be important from a social and ethical point of view, but also from medical and research follow up perspectives.”

The importance of the donor’s right to informed consent was frequently emphasised across submissions, often to address some of the issues raised above:

“In Australia, we already have well-tested and proven protocols and safeguards in place that govern how any person voluntarily participates in existing medical technology processes (e.g. donating sperm, eggs, blood, other body parts). Appropriately and effectively, government regulation and clinical processes ensure that the person is informed of possible and likely consequences, and provides unambiguous consent on the basis of that information.

There is no reason why those seeking to donate their mitochondrial DNA cannot be subjected to the same or parallel system of safeguards.”

“No, women who donate eggs for mitochondrial donation will need to give their consent to do so. Whilst it is important to ensure that this choice is one that informed and given freely, it should be assumed that women involved in this procedure are capable of making this decision and reaching their own views about whether to proceed with it.”

There were a range of specific issues identified which respondents said the donor should be informed about before consenting to donating for mitochondrial donation. These included:

- that there are risks to the donor’s health inherent in the egg donation process:

“The risks of hormone injections and egg retrieval do have it’s own risks, but if it done voluntarily with full disclosure of the risks or done as part of an egg sharing program as is being done in the UK, I can’t see this being a major ethical issue.”

- that the donated egg(s) or part(s) of the donated egg(s) will be used for mitochondrial donation:

“If the technology was permitted (which it should not be) then women who are considering donation must be fully informed of the type of procedure and the impacts upon the ovum (egg) or zygote (baby).”

“I believe that the donors should be made aware of the purpose of their donated eggs and for them to make informed decisions about this.”

“The women who donate their eggs for this donation must be made aware of the use of the egg and what part will be used. Thus insuring the women know there is no tie to the donor genetically. The DNA is not part of their makeup”

“With existing assisted reproductive techniques, an egg donor may assume that her donated egg will very likely result in live births whereas, in mitochondrial donation, a ‘significant proportion’ of each donated egg will be destroyed. The egg donor’s nuclear genome will not be transmitted to a child. There is some evidence that the desire to pass on genetic material is a significant motivation for egg donors (Gezinski et al 2016). As this would not be achieved through mitochondrial DNA donation, this is one aspect in which egg donation for MD differs from existing reproductive techniques. We feel that this information would need to be disclosed to women prior to donation.”

- that there are potential risks and uncertainties associated with mitochondrial donation and its outcomes:

“They should be made aware of the potential for as yet unknown incompatibilities between their mito DNA and the nuclear DNA of the patient that may contribute to potentially persistent alterations that are not a complication with standard egg donation.”

- and the nature of the relationship of donors with any resulting children:

“[...] donors should be made aware of the future involvement from their end (or rather lack of) and ensure that they agree to this. I believe that they should be informed and in agreeance that this donation would be similar to that of organ/tissue donation and that there would be little to no generic transfer, rather mitochondrial DNA transfer for the purpose of having a healthy child. I believe that conveying this message would allow for better selection of donors and clear expectations of what the procedure aims to achieve and the boundaries and involvement in terms of post-procedure, pregnancy, birth and so on.”

### Sub-theme 3B: Impacts on donors

There was broad acknowledgement across many submissions that donating eggs can have a number of impacts on the donor. For instance, the physical health impacts of undergoing the process required to harvest eggs for donation were identified as potentially significant:

“There are significant risks and inconvenience to the women who will be asked to provide eggs to enable these procedures”

“There are also risks associated with IVF for both the mother and the mitochondrial donor, such as development of ovarian hyperstimulation syndrome.”

“The imposition on those women who decide to provide their eggs cannot be overestimated [...] There’s also a serious risk to the health of women providing eggs. Cussins and Lowthorp point out that “egg extraction poses a number of serious risks, including memory loss; depression; joint, muscle, and bone pain; formation of blood clots; seizures; ovarian hyperstimulation syndrome (OHSS); and even death.”

“Any form of egg donation is hazardous for the donor, as the process of inducing egg production involves tinkering with her natural biological processes.”

However, many of these physical health impacts on the donor were recognised as being relevant to egg donation generally, and were not specific to egg donation for the purposes of mitochondrial donation:

“We also should take into account the risks that the egg donor might encounter, due to the donation procedure. However, egg donation and its risks are already a part of existing assisted reproduction methods. There is no additional risk to the egg donor from mitochondrial donation.”

Some submissions suggested that egg donation for the purposes of mitochondrial donation would entail some additional physical health impacts over and above egg donation for the use in other ARTs:

“In addition to the procedures which an egg donor must undergo, mitochondrial transfer requires synchronisation of ovarian stimulation of the affected woman and donor so that egg retrieval may occur on the same day...The donor may also have to be tested for mitochondrial compatibility, which requires intrusive muscle biopsies.”

A number of submissions also raised concerns about the potential impacts of mitochondrial donation on the mental health of the donor:

“Donating DNA could make a woman feel as they are giving away a part of them that is now part of a baby. This could make the woman feel emotionally confused when in consequence they are not allowed to have contact with that baby. In return, the child growing up might want to know who donate the DNA and might want to get to know the donor. But those emotional issue would probably be less present in comparison to the form of IVF that includes the whole egg or sperm of another person.”

“regret, depression, or many other symptoms could become significant [for the donor]”

“How is this going to affect donors even if initially OK with it, a future change of mind, could see them feeling quite devastated.”

“There could be risks and benefits with the introduction of mitochondrial donations, the benefits are not fully known at the moment, what happens when this is introduced into the fetus and it doesn't work, how will the donors react then?”

In contrast, a small number of respondents suggested positive mental health impacts on donors associated with their involvement in mitochondrial donation:

“Donors may feel a sense of contribution to the greater good”

### Sub-theme 3C: Considerations regarding egg donation

A number of submissions raised a range of factors relating to egg donation broadly and for the purposes of mitochondrial donation more specifically. Some submissions suggested that egg donation for the purposes of mitochondrial donation was essentially the same as egg donation for other ARTs:

“If eggs can be donated for IVF, eggs should be able to be used/donated for this issue. Why should we discriminate and say eggs can only be used for IVF.”

“The ethical issues for a woman to donate her eggs for mitochondrial donation are no less than those faced by women who donate eggs without mitochondrial donation unless you count the reduced incidence of inherited disease of a mitochondrial origin which has lifelong effects on the child and healthcare industry.”

“No there is no ethical issues for women who donate eggs for mitochondrial donation that different from other current assistance productive technologies.”

“Noting that a woman’s motivation to donate eggs may change depending on how the egg is likely to be used, we do not consider that the ethical issues relating to egg donation for mitochondrial donation differ significantly from the ethical issues associated with egg donation for existing assisted reproductive technologies. Therefore, we consider that current arrangements regarding identification of donors should be applied to mitochondrial donation.”

However, several submissions raised the issue that there are currently limited numbers of donated eggs available for use in ART in Australia and that the introduction of mitochondrial donation would further increase the demand for donated eggs:

“The issue is their limited number of eggs being given at the cost of a terribly unpleasant procedure to remove them and little benefit to them doing so resulting in very few women participating in australia.”

Some submissions also suggested that mitochondrial donation would potentially require more donated eggs than other ARTs to achieve the successful outcome of a live birth:

“the main ethical issue for me is the inefficiency of the process. It would be unethical to make a donor go through enough cycles to collect 100 eggs, which will be what will be needed initially, or will be used by an inexperienced team”

“Both MST and PNT require significant supplies of human eggs, both for research and for the techniques if they are permitted. Eggs can only be found by seeking out willing adult women to provide their ova. Neither PNT nor MST have high success rates, so would need more eggs than for IVF.”

Other submissions highlighted that prospective parents seeking egg donations for the purposes of mitochondrial donation had fewer options for sourcing donor eggs compared to those sourcing them for use with other ARTs:

“In third party reproduction, female family members are regularly sourced as donors. As all embryonic mitochondria are derived from oocytes, female familial donors are thus precluded impacting upon donor options/numbers.”

“There is a considerable risk of developing of introducing laws and techniques to allow research and mitochondrial donation and then not being able to provide the service because of lack of suitable egg donors....I am really not sure where they will come from as I understand the eggs need

to be fresh so that rules out brining them in from overseas and that the egg donor must not be a relative to the mother and we know that families are currently the source of many donated eggs.”

“It is difficult to source donor eggs as no related family member can be used for this purpose and frameworks to access altruistic non-related donors are not well supported in Australia.”

Some submissions suggested that one way to address shortages of donor eggs would be to incentivise or encourage the donation of eggs:

“it would be reasonable to consider initiatives to encourage altruistic egg donation to assist couples with mitochondrial disease.

If mitochondrial donation is permitted in Australia, and if there is then an initiative to encourage altruistic egg donation, this initiative must encourage egg donation both for mitochondrial donation and for the already existing treatment whereby the donated egg would be fertilised by the sperm of the prospective father. To encourage egg donation for mitochondrial donation without at the same time encouraging egg donation for the existing treatment would create a perverse incentive which could effectively limit a couple’s choices, rather than offering them genuine choice between the existing treatment and mitochondrial donation.”

Other submissions expressed concerns about the potential for women to be exploited by any introduction of financial incentives to donate eggs:

“The process of mitochondrial donation can only occur with egg donation. We have concerns for ART offspring in the event of gamete donor anonymity as well as for the egg donor herself. It is known that egg donation is potentially dangerous due to the risks of associated hormonal stimulation. As a result, egg donors can be difficult to find. This leads to pressure from lobby groups to introduce payment for gamete donation, which leads to vulnerable women being financially-coerced into undergoing a potentially life-threatening harvesting procedure. This is unethical.”

“There is considerable concern about the objectification of women, embryos and children as in many ART procedures. The call on egg donors also contributes to the objectification of women. Increasingly women are being called on to donate eggs for sub-fertile couples, for homosexual couples, for therapeutic practices such as mtDNA transfers. Women are not spare parts providers. The demands made of these women in these processes is costly in time and in terms of health risks. It is expected that this is all to be done altruistically. Indeed, it would be inappropriate to offer any financial compensation as that could result in coercion of economically disadvantaged women and recruitment of eggs from third-world countries – problems already occurring with off-shore surrogacy.”

“Allowing inducements would mean treating the human body and hence the person as a mere commodity, undermining the existing social capital in existing systems of donation that depend on altruism and a commitment to the common good, and exploiting the poor who lack alternative ways of earning an income. Individuals and the common good are best protected by maintaining the existing prohibitions on trading in human eggs.”



Some submissions suggested other options for addressing the shortages of donated eggs:

“Currently, more and more women are choosing to freeze their eggs in anticipation of infertility later in life at the point when a life partner has been identified. Given the drastic shortage of donor eggs in Australia for reproductive purposes it is likely that such shortages would also occur for mitochondrial donors. However, making careful advance provision for the donation of unused frozen ova for this purpose may be one way to ensure provision of mitochondrial donation without exposing additional women who are donors as non-patients to the risks and invasiveness of IVF treatment.”

“I think that finding egg donors will be tricky and perhaps we would need to have an approach more like that for blood or organ donors where you are donating for the good of the community rather than to an individual.”

There were also other concerns raised about the destruction of donated eggs in undertaking mitochondrial donation, with some respondents arguing that this was not the purpose for which women donated their eggs:

“Women donate eggs so they can become babies, not so they can become dispensable foetuses.”

“Women who donate eggs do so assuming they will assist to give life not give their potential life to be experimented on, created and then destroyed. It’s a totally different purpose.”

Finally, issues related to guidelines and regulations for egg donation in the context of mitochondrial donation were raised:

“Whilst rigorous implications counselling guidelines for IVF and donor assisted conception participants (i.e. women who donate their eggs) are established, these are yet to be developed for mitochondrial donation.”

“An egg donor’s decision to donate may not be a presumption to DNA germline modification. That is, donors involved in third party reproduction are fully informed how their gametes are used for creation of an embryo for the benefit of another couple but may object to the experimental biological modification of their gametes/mtDNA.”

“Experience and research in the kind of information and contact that have been developed in assisted reproduction using donor gametes might be instructive in establishing a best practice to support the mitochondrial donation process.”

“Maybe the egg donors won’t feel so connected as its only the mitochondria that being donated, could be good or bad, donors may come forward more readily because there wont be so much genetic connection or they may not come forward for that same reason.”

#### **4.1.6 Summary of sub-themes related to theme 4: Factors relating to the embryo in mitochondrial donation**

Numerous submissions expressed views on the nature of embryos, their constituent genetic materials, and how these would be treated in mitochondrial donation.

Although the Issues Paper (Section 2.2.1) stated that “other forms of ART, including those that are already in clinical use” were not being considered through this consultation, many submissions raised issues or views related to the current use of embryos in ART. It is important to note that for many people, it is not possible to separate the different technologies and issues related to embryos are considered important for all of the different technologies. As such, some of these views, whether or not they relate specifically to mitochondrial donation, are described below.

#### Sub-theme 4A: Status of the embryo

The status of the embryo was an important matter addressed by a significant number of submissions. A large proportion of respondents expressed the view that embryos are living human beings that should be treated as inherently valuable and given the chance to live:

“THE EMBRYO MUST BE RESPECTED AS A FELLOW-HUMAN.”

“[...] life of an embryo should be treated with the utmost respect as human [...]”

“Embryos are humans at an early stage of life and they must be protected from deliberate harm.”

“As science has now shown a complete human being exists at the moment of conception - it only needs time and protection to attain fullness.”

“The incipient human form is sacred from the very moment of conception.”

“For many people, including myself, we see an embryo as a human at the very beginning of life. To discard embryos for this technique I believe is morally wrong. Each person has rights, and we should fight for the rights of those not yet born. This should include the rights of those in the research laboratory.”

“As science has now shown a complete human being exists at the moment of conception - it only needs time and protection to attain fullness.

Human life is absolutely precious regardless of what stage of development it is in.”

“Human dignity is the dignity unique to human beings and the basis of all human rights. This human dignity is possessed by each and every human being, irrespective of their age, sex, race, abilities, or any other quality. Since human life is continuous from conception to natural death, the inherent dignity and right to life of every person must be respected from the moment that the first cell of the human zygote is formed by whatever means it comes to be. The practice of ART clearly compromises the human dignity of people in the earliest stage of their development.”

Respondents who took this view often also opposed mitochondrial donation, indicating that mitochondrial donation was unethical because it would entail the creation and destruction of embryos, thereby denying those embryos the chance to live:

“Yes, there is the entire issue of creating an embryo for the expressed purpose of killing it. That’s a big deal!”

“There is also the added certainty of embryos having to be destroyed in the process in order to create an embryo with ‘no defect’. I understand that embryos are destroyed in regular IVF as well, and I do not agree with this either, but this is a step further with the CERTAINTY of having to destroy embryos in order to create another embryo.”

“Mitochondrial donation involves destroying multiple viable human embryos that are not needed once the third embryo is created. If this third embryo is not free from mitochondrial disease, this will also potentially be destroyed.”

“It is still immoral to create embryos with the sole purpose of destroying them. IVF embryos are not usually deliberately created for destruction. Both methods - maternal spindle transfer and pro-nuclear transfer involve deliberate creation and destruction of at least 2 human embryos, and in practice more, to create a third embryo. No method is possible without destroying a life in the process.”

“Ethically, the fact that no mitochondrial donation is possible without the destruction of at least one embryo (and likely many more) makes this technology totally unacceptable.”

A large number of these submissions raised concerns about the use and destruction of one embryo in mitochondrial donation to allow for the creation of another embryo with healthy mitochondria:

“The proposed procedure would now actively and deliberately kill another human life, in order to get “parts” from the conceived human being, in order to create a perfect baby free from a genetically passed on serious health issue.”

“Some embryos should not be considered disposable and / or just for use of particular genes. This is very different to existing IVF where every embryo has a chance of life.”

“Pronuclear transfer (PNT) must not be allowed as a method of mitochondrial donation because it kills human life which has already been conceived and which should receive protection and care. The embryo (person) which is sacrificed (killed) in Pronuclear (PNT) is not given any opportunity to be implanted in the womb and the intention from the start is to destroy this life to benefit the second life. The ethos of “do no harm” does not permit taking one innocent human life to save another. If this were so then killing people to harvest their organs would be justifiable.”

“the embryos in mitochondrial donation was created to be destroyed and harvested. It is like creating a human being only to harvest their parts. It is a very sad and tragic case of human playing God. The ethical issue is mostly the same but to create a human life in order to destroy it is very immoral and unethical, that is where the difference lies between IVF and mitochondrial donation.”

“Embryos would be created as spare parts for others.”

“It is immoral to kill one embryo in the hope of helping another embryo.”

"It is important to prevent mitochondrial donation. As I understand it, mitochondrial donation involves a number of living individual human beings at the embryo stage of development, and, in the process of ensuring a certain individual human being at the embryo stage of development receives mitochondrial donation, this process involves the destruction - death - of one or more other individual human beings at the embryo stage of development. Ethically, we have a case of commodification of humans at the embryo stage of development - weighing one as more useful than the others because all are seen as just of utility value relative to the wishes of adults. This is unconscionable."

In contrast, those who supported mitochondrial donation often acknowledged that embryos would be destroyed in the process of mitochondrial donation, but did not necessarily see this as unethical. Some proponents of mitochondrial donation viewed the embryos intended for use in mitochondrial donation as equivalent to those used in other ARTs and did not perceive any additional ethical considerations as being relevant in mitochondrial donation:

"Despite the different steps taken to create them, we do not consider that the ethical issues for the status of embryos conceived via mitochondrial donation differ from other existing assisted reproductive technologies."

"Embryos should be treated the same as they currently are in ivf."

"I don't believe the ethical issues are any different from existing reproductive technologies."

Furthermore, some of these submissions raised the fact that embryos are frequently destroyed or discarded in current practices, and mitochondrial donation would be no different in this respect:

"Embryos are destroyed at present in IVF/PGD when they are considered unsuitable for transfer. There are also eggs/sperm that are destroyed, again, being unsuitable for use (ie 'look unhealthy'). In the setting where two embryos are created, with the expectation that only one (albeit a combination of the two) would go on to transfer is an interesting concept. Because, although as a reductionist approach you could say one is destroyed, in reality, both are destroyed in the creation of a 'new' embryo and I'm not sure you can therefore state there is a net-loss of one embryo. If a technique is used whereby the egg is modified, then no embryos were destroyed any more so than a failed period/ovulation. I suppose the differentiating factor would be that the 'destroyed embryo' was not unsuitable for transfer for any reason other than it was not the 'correct' maternal DNA complement. I am not sure that constitutes sufficient reason for special ethical status, especially when you consider it is acceptable (and I believe it should be) to undertake a termination of pregnancy for ANY reason, including timing, paternity etc."

"I don't believe there are any ethical issues for this particular procedure, no more than what would occur with ICSI or other specialised IVF procedures. Having gone through 10 cycles and 45 embryos in the PGD process, we decided to donate our embryos to research. Our personal perspective is that we want our baby to be healthy. It is through IVF and PGD that we are able to determine which embryo is healthy or not. While we view each egg

and embryo as a living being, we also want them to be healthy enough to survive. We respect each embryo a great deal, so much so that we do not want any suffering down the track and would rather donate them to research for a greater purpose. None of this is easy for us as future parents and we so desperately want a child - we see them as alive and always potential babies, but we have to consider what is best for them, not us."

"The use of embryos in mitochondrial donation raises no additional ethical concerns compared to currently accepted practices, such as IVF or embryo research. Ethical concerns raised by the use of embryos in mitochondrial donation are similar to those raised in the context of IVF and embryo research. Many of these issues are already addressed by Australian policy (which, inter alia, permits the discarding of excess embryos in the context of IVF). There is one key difference between mitochondrial donation and IVF/PGD: that the main technique for mitochondrial donation of pronuclear transfer necessarily involves creation and destruction of an embryo. However, if PGD is considered as a key alternative to mitochondrial donation, then this is also highly likely to involve the destruction of an embryo(s) (as well as prenatal screening, further along in the process of development). In fact, the number of embryos that are destroyed in the normal course of ARTs and in the normal course of reproduction absolutely dwarfs that of the number of embryos that would be destroyed during the process of mitochondrial donation. Mitochondrial donation thus raises no novel concerns regarding the moral status of the embryo when compared to other practices."

However, several organisations supporting the introduction of mitochondrial donation indicated that the creation of embryos that would be destroyed as an outcome of their intended use was an important difference between mitochondrial donation and other currently available ARTs:

"One ethical issue distinct from other ARTs that may concern donors, recipients, religious groups and others within the community is that the pronuclear transfer technique necessitates the creation of a zygote/embryo with the intention of being discarded. This is different to IVF or PGD, where embryos are created on the basis they will hopefully progress through development. Though in truth, ART techniques result in a proportion of embryos that do not progress for various reasons. Despite the concerns about the status of embryos generated for the technique, it will be of utmost importance that the methodology used for mitochondrial donation is the best available and by weight of evidence the safest for the child who is born from the technology."

"There is one key difference between mitochondrial donation and IVF/PGD: that the main technique for mitochondrial donation of pronuclear transfer necessarily involves creation and destruction of an embryo. However, if PGD is considered as a key alternative to mitochondrial donation, then this is also highly likely to involve the destruction of an embryo(s) (as well as prenatal screening, further along in the process of development). In fact, the number of embryos that are destroyed in the normal course of ARTs and in the normal course of reproduction absolutely dwarfs that of the number of embryos that would be destroyed during the process of mitochondrial donation. Mitochondrial donation thus raises no novel

concerns regarding the moral status of the embryo when compared to other practices.”

Furthermore, while some proponents of mitochondrial donation acknowledged that embryos would be used for the purposes of providing another embryo with organelles, they did not view this as unethical:

“This question makes me think of stem cell research. Technically you are taking from an unborn life form. However the said life form does not have the capacity to think or feel any form of pain or suffering from the process. If it can be used to benefit a vast majority of people with this disease and eventually cure them so that the damaged cells are bred out, I can’t see a problem with it. But it’s a matter of opinion at the end of the day. I can definitely understand why some people would have an issue with this.”

“The organelle donation of a mitochondria again introduces no new argument. We also allow the donation of sperm, eggs and other embryos to be carried by what the law now deems as the ‘natural mother’, and even another woman to incubate a child for us (i.e. surrogacy). The many complex ethical issues arising from these techniques have all been addressed and accepted, and should similarly apply to mitochondrial donation.”

#### **Sub-theme 4B: The genetic composition of embryos and resulting children in mitochondrial donation**

The fact that mitochondrial donation would result in embryos with genetic material from three individuals was frequently addressed across submissions. A large number of submissions referenced the concept of a “three parent baby” or “three parent IVF” in considering the genetic composition of embryos and children resulting from mitochondrial donation. For many respondents, the idea of an embryo or child with genetic material from three individuals was a cause for concern for a range of reasons. Some of these concerns related to the naturalness of the genetic constitution of the resulting embryo or child:

“I believe in my opinion it is unethical to have a child formed from 3 parents. It goes totally against nature’s natural laws of conception.”

Other respondents cautioned that combining the genetic material from three people was unethical given its potential social ramifications, including especially for the constitution of the family:

“Creating three parent children is unethical as it breaches ethical norms of society.”

“Yes, there are distinct ethical issues in mitochondrial donation because the line of ‘parent’ is being blurred even further, towards being erased completely. Biologically, a human being can only be conceived by TWO parents. So, having these embryos being engineered from THREE parents is crossing a very dangerous ethical line.”

“We believe that the responsibilities of parenthood extend beyond the donation of gametes to the upbringing of the child. This is not intended in the instance of mitochondrial donation, severing the normal bond between genetic mother and child.”

“Changes to the law would leave our society open to a catastrophic path of messing with human genetics. This is a ‘three parent child’ despite the objection in the paper that this is an inaccurate representation. The fact is the child would not be in existence without the genetic material of all three participants, despite how minimal the mitochondrial DNA is compared to the nuclear DNA. The mitochondrial DNA donation is essential for the experiment. We are already in ‘designer baby’ territory. Use resources for non-biological options to become more accessible to parents ie. Adoption.”

Other respondents also expressing concerns suggested that the resulting embryo or child would be qualitatively different from other human beings:

“Whilst I don’t fully understand the process as a lay person, my understanding is that this would introduce producing a baby that has practically three parents, something that has never happened in human history before as it has been biologically impossible. Again, this is introducing a type of “hybrid” humans for the sake of some parents wanting a healthy child.”

“There is a further ethical dilemma here as the child now has DNA from the donor some from its mother and is genetically different from all other human beings. This could affect its ability to produce children and could cause a stigma to it from marrying and having children in the future.”

In contrast, proponents were often critical of the “three parent baby” description of mitochondrial donation, suggesting instead that the mitochondrial DNA that is donated through this process does not have a meaningful impact on the identity or personal characteristics of the resulting embryo or child:

“I understand the resistance to mitochondrial donation on these ‘ethical’ grounds was inevitable and should be discussed, but find the often employed term ‘three-parent baby’ is dishonest and pejorative. The ethical dilemma over the source/s of genetic material, seems to me over-blown and misunderstood. Firstly, mitochondrial DNA contains only a mere 37 genes that encode the oxidative phosphorylation machinery required for energy production and RNAs for the maintenance of mitochondria themselves. These few genes are a tiny fraction of the total number of genes in a cell and smaller fraction of total gene products (ie. isoforms) produced by a cell. Secondly, except for the mutations that result in mitochondrial diseases, the mitochondrial genome does not encode any characteristics discernable to our unaided faculties at the phenotypic level, like nuclear genes may; the typical concerns regarding inheritance of traits (eye colour, intelligence, height etc.) are not relevant here. Furthermore, without mtDNA sequencing there is no way one could ever remark: ‘You have your mother’s mitochondria’, as if there was any qualitative attribute or affect inherited.”

“I don’t believe that there are ethical ramifications because in mitochondrial donation, only the mitochondria is used and it only codes for about 37 proteins ONLY related to energy production. All family traits are located in the nucleus.”

“The argument of 3 parent babies is sensationalist media hype. The mitochondrial DNA has little impact on the characteristics of the child.”



“Mitochondrial transfer is sometimes misleadingly described as 3 parent IVF. While IVF is necessary to transplant the organelles, this is more accurately described as transplantation. Three people are not having a child together with a mix of characteristics, any more than a person with a heart transplant becomes mixed with the donor in any important way. Solid organs like the liver or kidney also contain DNA from the donor, just as mitochondria do. But we wouldn't say a child who receives a liver or kidney now has “3 parents.” It is absurd. It is equally absurd to say a child who has been cured of mitochondrial disease has three parents [...] The mitochondria carry tiny amounts of their own DNA, which follows the mother's line but these code only for the energy metabolism of the cell. They serve no other important or morally relevant function. There are many kinds of foreign DNA in our bodies. Our cells contain DNA from viruses. There are 10 times as many bacteria in our gut (which have their own DNA) than there are cells in our bodies. It is DNA in the nucleus of our cells that has the important influence over who we are and how we develop. This is NOT affected by mitochondrial transfer.”

A number of respondents suggested that mitochondrial donation entails fewer ethical issues than other ARTs that use whole donor eggs because only the mitochondrial DNA is used and this does not influence the personal characteristics of the resulting offspring:

“There are no ethical issues that would be any different from IVF – if anything there would be less ethical issues as it is only the mitochondrial DNA that comes from a donor, not a whole donor egg.”

“[...] because the mtDNA does not directly influence physical traits we normally associate with inheritance from parents, it is ethically less contentious. The ‘3-parent baby’ label here is very misleading and counterproductive.”

“There would be less ethical issues with mitochondrial donation as opposed to IVF as only the Mitochondrial DNA is extracted from the donor egg, the whole donor egg will not be used.”

“Healthy mitochondria do not impart different characteristics among individuals. So the ethical issues concerning donation of eggs that contain the donor's nuclear DNA do not apply.”

“The NHMRC has identified that mitochondrial donation differs from traditional IVF as it involves producing an embryo that has mitochondrial DNA from an egg donor in addition to the nuclear DNA of both parents. Although this is different to existing IVF technology, the fact that the embryo receives the nuclear DNA from both parents and that the donated mitochondria do not impact on the physical, intellectual or behavioural characteristics of the child should mean that there is less ethical concern than for current reproductive technologies in which both the mitochondria and the female nuclear genes come from the donor. The ethical issues have already been extensively investigated and debated in the UK and other countries and further debate is unlikely to add significantly to current knowledge.”

However, a number of submissions suggested that to minimise the role of the donated mitochondrial DNA for the resulting embryo and child was problematic:

“The resulting offspring will have DNA, or genetic inheritance, from three adults. While proponents of mitochondrial donation downplay this issue by comparing it with the comparatively larger number of genes (nuclear DNA) from the gestating mother, nonetheless mitochondrial DNA from the donor is retained and may be used with current technology to identify ancestry.”

“Of course there are. The idea that 99.9% of what makes the child is from the nuclear dna. This is not longer accurate. Every week more is learned about the mitochondria and how it makes us who we are. I am who I am because of my mitochondria. I live with a mitochondrial disease that causes [my disability (details of disability removed to protect privacy)] and removing my mtdna changes who I am.”

“Scientists argue that the egg provider contributes only 0.1% of the total genetic makeup of the newborn. Yet Baylis says ‘this fact is irrelevant to the accuracy of the claim that there are three genetic parents’. The inclusion of a donor’s mtDNA ‘could make such a significant difference to the resulting person’s life so as to make them ‘a different person’.”

“Enthusiasts for legalizing the technique sometimes downplay the significance of the contribution of the woman who provides the mitochondrial DNA. But even if the genetic contribution is numerically small, it is nonetheless crucial: if the technique is successful it will be this part of the DNA which will lead to a child free from mitochondrial disease.”

#### **Sub-theme 4C: Manipulation of genetic material in embryos**

A large number of submissions reflected on the ethical considerations of manipulating or altering genetic material in embryos. Many submissions conceptualised mitochondrial donation as a type of genetic engineering of human beings, which was perceived as unethical:

“I believe it is never ok (no matter the circumstance) to bioengineer human beings- this includes mitochondrial donation. Altering/adjusting/adding to/taking away human biological cells and trying to play God is not ethical nor moral nor smart.”

“No. Although mitochondrial disease is devastating for approximately 60 individuals and their families annually in Australia, engaging in genetic engineering with unforeseen and potentially irreversible consequences is not a proper or reasonable response.”

“No, I do not support Mitochondrial Donation. It involves the DNA of 3 human parents into one human. While I understand that some ground has been covered with the introduction of IVF and Stem cell usage, I reject genetic engineering of humans. I feel that it is potentially very dangerous in the right, and definitely the wrong, hands. In the past, at times, we have made serious errors of judgement despite the best intentions; it is my firm belief that this could be a future one.” (152)

Some submissions raised ethical concerns about the use of mitochondrial donation to modify embryos to produce children with perceived improvements or customisations:

“This process would introduce so many more steps and stages in the process of fertilisation, growth and implantation of required embryo and

discarding of others. The intervening stages of obtaining the desired perfect embryo causes alarm bells to go off. We must accept that some steps are just too far from natural to be good for society.”

“I hate the thought of creating embryos in order to destroy them even if they are to create a super human who is free of severe mitochondrial DNA disease. This experimentation in genetic engineering is unproven in preventing disease but deliberately destroys human life and should never be allowed. Legislators have a duty of care to protect both born and preborn humans.”

“It is disturbing to enter into this way of thinking, that we can modify our children when they do not suit us. Once breached, this will encourage more and more genetic manipulation to create custom babies, modified skin tone to meet the trends of the day can become the result of this.”

Other submissions disagreed with the idea that embryos resulting from mitochondrial donation are equivalent to gene-edited or “designer” babies:

“We don’t want to create a ‘designer’ baby - we just want a healthy baby that does not have to experience what we have experienced emotionally and physically.”

“It is extremely disappointing that we don’t have access to this life saving technology all because people might design the sex of their baby or have designer babies. Mitochondrial donation is about replacing the faulty mitochondria with a healthy mitochondrial and not having the physical appearance of the baby.”

Some submissions argued against the notion that mitochondrial donation is a type of genetic engineering, and a number of alternative ways of viewing it were suggested:

“[Mitochondrial donation] is NOT genetic engineering, as the sanctified nuclear genes remain untouched, and introduces no more ‘alien’ DNA than an organ transplant....”

“From an ethical perspective, mitochondrial transfer is most accurately described as a form of transplantation, or “micro-organ” transplantation. Mitochondrial transfer is essentially the transplantation of healthy mitochondria to people with diseased mitochondria, just as we might transplant one kidney from a healthy person to a child with kidney failure. But this transplantation is at the microscopic scale: organelle transplantation.[...]Because the nucleus of the cell with the DNA instructions is not affected, this is not genetic engineering that could be used to create designer babies. If parents had two children, one who was normal and one who had had a mitochondrial transfer, you would not be able to tell which one had had the transplant. They would both be a mix of their parents’ characteristics, just as any other child is.”

#### 4.1.7 Summary of sub-themes related to theme 5: Implementation considerations

##### Sub-theme 5A: Access to mitochondrial donation

Most submissions considered who should have access to mitochondrial donation and under what conditions if it was introduced in Australia. Some of those opposed to the introduction of mitochondrial donation stated that no one should have access to it:

“Nobody should have access. The role of Government is protect the people and as such needs to ban such procedures. No conditions just an outright ban”

“No-one under any circumstances should be allowed to offer or receive this service”

However, other submissions supportive of mitochondrial donation gave a variety of views about who should have access to the technology and under what circumstances. Some submissions suggested that mitochondrial donation should be available to any woman with mitochondrial DNA disease:

“Any family or individual who is a carrier should have access to mitochondrial donation.”

“Any mitochondrial disease patients/prospective parents who wish to have an unaffected biological child should be eligible for mitochondrial donation.”

Many submissions specified that relevant family history or diagnosis of mitochondrial DNA disease would be necessary conditions for accessing mitochondrial donation:

“Only those proven/tested diagnosed/family history of the disease should be allowed to receive mitochondrial donation.”

“Donations should only be available where a woman has established mitochondrial disease.”

“The only people that should be able to access mitochondrial donation should be women who have been clinically diagnosed with a pathogenic variant in their mitochondrial DNA.”

Some submissions indicated that access to mitochondrial donation should be dependent on the degree of risk of transmission of mitochondrial DNA disease to potential children in the absence of the intervention:

“Access to mitochondrial donation should be limited to those individuals at high risk of passing mitochondrial DNA disease on to their children. Existing testing and other mechanisms should be utilised to identify these individuals as appropriate.”

“People at serious risk of passing on mitochondrial disease to their children should have prioritised access to mitochondrial donation.”

“Only those at risk of passing on severe mitochondrial disease should be allowed to access the technology.”

Other submissions emphasised that access should be contingent on the severity of the mitochondrial DNA disease that may be transmitted to potential children:

“Any woman with a diagnosed mtDNA pathogenic variant should be considered for access to mitochondrial donation, particularly those with

above threshold mutational load and in circumstances where preimplantation genetic testing of embryos is not likely to increase reproductive confidence.”

“Until more is known, ONLY those who know they will pass on a life threatening condition should be able to access the experimental procedure.

NO ONE should be allowed to access this procedure if all they are trying to do is reduce the risk of a child having a disability that is not life threatening and can be managed well through life.”

“Only those at risk of passing on severe mitochondrial disease should be allowed to access the technology.”

Respondents also suggested other access criteria for mitochondrial donation. These included a range of demographic, medical or forensic factors:

“I would like to see all at risk woman or woman who have delivered a baby with mitochondrial disease have access to this donation technology.”

“Australian citizens should have first priority and there should be a maximum age limit of 40.”

“I would like for all affected women to have access unless it is medically unsafe for them to receive the donation (such as an AOD addict or a cancer patient) and/or they are a convicted perpetrator of crimes against children and/or under 18 years or over 40 years.”

“Patients who have exhausted all medical options should be allowed to access mitochondrial donation.”

Some submissions suggested that mitochondrial donation could be made available for applications other than the prevention of mitochondrial DNA disease:

“While a more controversial use of the technology, would be to allow women in same sex relationships, for example, who wish to create a child with genetic material from both of them, as the debate currently stands there is no clear argument why, if the technology is proven safe, it should not be made generally available.”

However, the idea of broader access to mitochondrial donation beyond the prevention of mitochondrial DNA disease was explicitly rejected in other submissions:

“Only couples with proven need for mitochondrial donation in order to avoid high risk of mitochondrial disease in their children should be allowed to access mitochondrial donation. Access to the technology should be highly regulated (similar to in the UK) so that it is not exploited and marketed to other people where it would have no proven benefit or instances where couples simply desire to have two biological mothers.”

“Clinical use of mitochondrial donation could be limited to cases of intending mothers with mtDNA disease with high mutation loads and high risks of mtDNA disease in their offspring in order to decrease the risk of mtDNA disease in the child. This would mean that the technique could not be used, for eg, for age-related infertility (to replenish older oocytes) or to enable both members of a female same sex couple to contribute DNA to the conception of the child.”

“While it may not be everyone with mito’s choice, this procedure should be accessible and an option to parents at risk. The groundwork has been done in the UK and Australia are in a strong position to be able to offer this with strict regulations and access criteria to ensure it is used for the purpose of stopping this terrible disease and having a healthy child”

Many submissions indicated the access to mitochondrial donation should be carefully regulated. Specifically, many respondents suggested that patient access should be regulated:

“Access would need to be a rigorous process, involving most importantly Metabolic Physicians who consider the parents as potential recipients; also IVF Specialists in this area, psychologist, genetic counsellor - essentially ONLY a dedicated Team.”

“There needs to be very stringent processes into who is able to access this as it is a very specialised and niche group of people who would need it. I think there needs to be a varied panel of doctors patients even and ethical professors who can help as a group to triage through who should be able to access this technique.”

“The interest of the child/adult must be protected by having strict guidelines on who can access this technology.”

“Only people at risk of passing on mitochondrial disease to their children should be able to access mitochondrial donation. This should be strictly limited to those circumstances and that should be made clear in the legislation.”

“Access should be determined by some appropriately skilled and informed organisation within an appropriate regulatory regime.”

Further, a number of submissions suggested that clinicians’ and treatment clinics’ access to mitochondrial donation should also be regulated:

“An oversight regulatory body, such as the NHMRC Embryo Licencing Committee or a subcommittee thereof, supplemented with appropriate mitochondrial clinical and genetics expertise, should assess and determine appropriate access to mitochondrial donation – from both an IVG clinic and a patient perspective.”

“IVF centres that may offer this service need to be reviewed and regulated for quality control.”

“Mitochondrial donation is a new technique. The safety and welfare of children born through the technique is the primary consideration. Therefore, it is important that regulation ensures that MD is only carried out by suitably qualified centres which can support both the donation process and then long term follow-up of children born using the technique. Once again, the need for well-regulated practitioners applies to existing assisted reproductive technologies, as well as to other medical procedures.”

“clinics should require a license to practice this. It would be a specialized field that requires specialized technologies and clinicians, therefore it should be regulated to specifically licensed clinics.”

Respondents often suggested that clinicians or other experts should be involved in making decisions about who should have access to mitochondrial donation:

“Assessment for suitability should involve clinicians and scientists who are experienced in diagnosing and managing mitochondrial disease.”

“Clinicians with expertise in the treatment and care of patients with mitochondrial disease should be involved in the decision making as to who should have access in specific cases. This is because many clinical aspects pertaining to the affected mother need to be considered (e.g. health of the mother during pregnancy, prognosis of the mother’s condition/mitochondrial disease, ability to care for a child, mental health and capacity to parent a child etc).”

“The technique should be offered to women who have a demonstrated risk, or history, of having children with high levels of mutated mtDNA. The catalogue of disease-causing mtDNA mutations is now large and still growing. A panel of clinical and basic researchers with expertise in mtDNA disease should be convened to assess the evidence behind all requests.”

“The only people who should be allowed to access Mito donation are women with Mito genes which cause mito disease. This should be decided by a panel containing at least neurologists, and geneticists. It would have to be decided on by family history. Hopefully it would not have to wait for the first child to be afflicted by Mito.”

Additionally, some submissions suggested additional conditions that should be imposed on those seeking to access mitochondrial donation, including counselling, genetic counselling and/or participation in follow-up medical monitoring:

“Potential parents should be required to undertake genetic counselling and education counselling before being permitted to undertake mitochondrial donation.”

“Potential parents should be required to undertake counselling and participate in ongoing monitoring and follow-up of the child, which would be expected to be similar to the process in the UK.”

A number of submissions raised the issue of equity of access for those seeking to access mitochondrial donation as an additional consideration:

“[Access] Should not be discriminatory ultimately”

“Access must also be equitable.”

“Yes, from a philosophy of access and equity this technique will enable people who might otherwise not have children to have genetically related offspring.”

Some submissions addressed potential financial and/or geographical barriers to mitochondrial donation that may create access inequities:

“Access should be supported under government healthcare schemes to limit economic barriers.”

“However, what is critical is that obtaining a licence to engage in this technology should be available and accessible to applicants across Australia, whether they live in Sydney or Coober Pedy, and whether they are rich or poor.”



“Geography will need to be a consideration for equity of access.”

“It is important to acknowledge the geographical challenges in Australia which might make licensing of eastern states clinics inaccessible for South Australian patients.”

A number of submissions suggested that not legalising access to mitochondrial donation could also be unethical:

“In the context where a technology exists that gives people the option to have a child and at the same time avoid passing on an inherited condition, it is important to make the technology available to individuals who might benefit from it, so that people can choose whether they want to use it or not.

Knowing that the technology is available, but not having access to it, creates an inequity for people who could benefit from this technology.”

“It could be perceived as discriminatory to prevent people with a family history of mitochondrial disease from accessing mitochondrial donation technology for the purposes of having a genetically related child, when we allow people with issues of infertility or family histories of a variety of other conditions to use PGD and IVF to ensure the birth of an unaffected child.”

“If we don’t legislate, people who can afford it will go overseas. They will potentially bring back into the Australian health system the problems of having this technology in a perhaps less regulated environment. That increases inequity as well: people who can afford it will go somewhere else and use the technology.”

“We must also consider, if the risks of mitochondrial donation are seen to outweigh the risks of mitochondrial disease, the morality of denying Australians access to this potentially life-saving technique.”

#### **Sub-theme 5B: Whether and how mitochondrial donation should be introduced into Australia**

Many submissions addressed the matter of whether and how mitochondrial donation should be introduced in Australia. Some respondents stated that mitochondrial donation should not be introduced:

“It should not be permitted full stop”

“It should not be introduced.”

“Again, this ethical and social morass can be avoided by refraining from mitochondrial donation.”

Some respondents opposed to the introduction of mitochondrial donation indicated that, if it was to be introduced in Australia anyway, then it should be limited to research only:

“I think limiting it to research studies initially would be essential. However, I hope it is not introduced at all.”

“Any change in the law to allow mitochondrial donation would be morally repugnant. However, if the choice had to be between two evils, the lesser evil of research only would be preferred.”

“It would be essential to make sure the technique was only used in research at this point.

It would not be appropriate to introduce it to clinical practice. There are too many unknowns.”

A number of respondents who expressed support for mitochondrial donation also recommended that further research should be conducted before it could be introduced into clinical practice:

“Needs researching first”

“As much as I would love to see it introduced immediately into clinical practice, with 100% positive results, I firmly believe that it should be introduced initially for research.”

A number of submissions supportive of mitochondrial donation recommended that further research into its safety and efficacy should be conducted, before being considered for clinical practice in Australia:

“It would not be appropriate to introduce the technique directly into clinical practice in the first instance. In 2016, the UK HFEA recommended that “it is appropriate to offer mitochondrial donation techniques as clinical risk reduction treatment for carefully selected patients”. They noted that a number of potential safety risks were considered to be small, but they have not been definitively excluded. Therefore, if Australian legislation was to allow mitochondrial donation, it should be initially limited to a clinical research setting, to ensure that optimal data can be collected and published about safety and efficacy, and associated issues such as service delivery, cost, safety, and impacts on individuals and families.”

“Although there has been unregulated use internationally and the procedure has been approved in the UK, we really do not know if the procedure is safe or effective. As will any new drug or device we require appropriate research trials before a procedure is approved by the appropriate authorities such as the TGA. As such the initial approval for mitochondrial donation should be to allow “research” as per the standard initial steps in new medical treatment.”

In contrast, other respondents supported the idea of introducing mitochondrial donation directly into clinical practice in Australia:

“Limiting it to ‘research studies’ will merely continue the birth of children who will then succumb to slow and painful deaths. The research in the UK is already way ahead. Our experience over the next few decades will add to UK (and other) data, to provide far better data than limiting the process for an indeterminate period to ‘research’.

YES, introduce into clinical practice.

This follows from the above. The only way that risks will become known, and accurately quantified, will be by undertaking the procedure in a ‘large’ cohort that will provide clear statistical answers within an acceptable period, e.g. a decade, rather than tenuously small trials that will not provide answers for many decades, or may never provide sufficient data.”

“I think it would be fine to introduce it directly into clinical practice as long as the families who decide to use it, know that it hasn’t been tried and tested yet.”

Some respondents suggested that mitochondrial donation could be introduced into clinical practice in Australia alongside ongoing research:

“I believe research using model systems should be supported in Australia at the same time that legislation is developed. A problem here is that no research is possible (nor should be in my view) on human embryos that would be destroyed. Other model systems should be supported with research to gain the best technical knowledge on comparing mitochondrial donation techniques (eg in larger mammalian species in addition to mouse studies which are limited in translation to the human). Ultimately the first few births of children using the optimal technique will be the research of greatest value, with attendant risks. My understanding of listening to affected women is that these risks are understood. In other words, yes I believe it appropriate to introduce it directly into clinical practice in a limited form, alongside further basic research.”

“Making the technology available clinically would be ideal, providing that there is appropriate regulation regarding eligibility criteria and there is some provision for follow up of the children conceived via mitochondrial donation. Encouraging participation in a research study would allow for oversight of eligibility and also clinical outcomes.”

“Our preferred model for the introduction of mitochondrial donation would be directly into clinical practice, with research participation and follow up either strongly encouraged or as a condition of access. Children should not be born as the result of a research study.”

“I think given the length that the UK has gone to approving this technique there is some leeway and urgency in which it needs to be introduced straight into clinical practice however we would not be here without research and so I feel it is very important to continue with research studies but I don’t think it is fair to limit it to the studies perhaps more lengthy process as it is introduced into clinical practice is something to think about rather than just limiting it to studies.”

Part of the rationale for introducing mitochondrial donation into clinical practice provided by some respondents, was a perceived sense of urgency in terms of the need for this technology:

“Research should continue alongside the introduction of the procedure to the community directly. I think there is an urgent need to introduce this into clinical practice as soon as this is approved through government.”

“I believe this should be directly introduced to clinical practice, further delays will preclude certain families from accessing this technology and ever having their own biological child.”

“I believe it is more appropriate to introduce it to clinical practice. I would not like to see this technology delayed any further. Research would not necessarily reveal any more information and would hold the same ethical issues.”

“The sooner we can get it out there to protect our children the better”

“I would like to see it go directly into clinical practice as the UK did the research and have been doing mitochondrial donation for 5 years now. We are a little bit behind and in the meantime families with a high risk of producing a mito child are in limbo.”

Other respondents rationalised that legalising mitochondrial donation would be important to prevent Australian families from seeking this treatment overseas:

“Given no choice in Australia, potentially our families will go somewhere else for this technology—and somewhere that is less clinically safe. It is not going to be easy for Australians to access the technology in the UK, but we know that it is occurring in other parts of the world without the safeguards that the UK offers.”

“Yes if for no other reason than to continue to prohibit it in Australia when it is available overseas will mean that women who wish to utilise the technology will have to travel to do so.”

“Permitting mitochondrial donation might also reduce potentially harmful forms of medical tourism by increasing healthcare accessibility for Australians. If mitochondrial donation is not permitted in Australia, Australians may seek access to this technology in jurisdictions with different regulations. For example, mitochondrial donation has already been performed in Mexico, where regulations surrounding the procedure are less stringent. Making mitochondrial donation accessible in Australia will avert couples from seeking out the procedure elsewhere, including in countries with lower safety standards.”

### Sub-theme 5C: Legalising and/or regulating mitochondrial donation

There was a range of views about whether and how mitochondrial donation could be legalised and/or regulated in Australia. A number of respondents indicated that mitochondrial donation should not be legalised:

“Against legalizing.”

“Australia should not change the law to allow this.”

“The law should not be changed.”

“I don’t believe Australia should allow mitochondrial donation.”

“An outright ban is the only option.”

“Australia should never allow mitochondrial donation.”

Some respondents opposed to mitochondrial donation emphasised the need for its use to be restricted, if it was introduced:

“I can’t express strongly enough how much I sincerely hope the law is not changed. In the unfortunate event that sufficient representation declares this technology to be for the greater good, it should be limited as much as possible to avoid significant destruction of human life and damage to the community gene pool.”

“It is even more offensive ethically to be experimenting on embryos with no hope for life, however, should MD be legalised, limitations should be imposed at every stage.”

“The most restrictive conditions should be imposed to prevent the deliberate destruction of human embryos and the unethical exploitation of vulnerable individuals.”

“If it gets through, it needs layers and layers of protections around it. It should be like jumping 10 hoops before one could access such technology. But, here’s hoping it’s not passed.”

“This technology should not be introduced. If it is, access should be highly restricted.”

Many submissions that favoured the introduction of mitochondrial donation also expressed strong support for its regulation, if introduced:

“I would support the introduction of mitochondrial donation IF access was highly regulated and extensive research is conducted in appropriate animal models in order to better understand any future risks that may emerge.”

“It is important that appropriate legislation is developed to regulate mitochondrial donation to support the clinical practice in Australia.”

“It will be important that mitochondrial donation is regulated and that initially only a small number of teams (clinical and laboratory) be allowed to offer the technology. This will ensure that the teams offering the technology develop expertise. Initially 2-3 licences should be offered. It would be sensible to initially have a limit of only one licence in any state/territory. These teams should have a proven track record in in-vitro fertilisation techniques and their associated laboratories should need to demonstrate their ability to safely perform the mitochondrial donation.”

“There should be government guidelines”

A number of respondents referenced the licensing system in the UK as a form of regulated access to mitochondrial donation that could be employed in Australia:

“This should be highly regulated and entry to this technology should only be allowed for the purposes of reducing risk of mitochondrial disease. As in the case in the UK, a license should be applied for first.”

“Conditions should be similar to those in the UK - licenses for providers and patients, strict frameworks and follow-up.”

“In the UK there is a process of licensing where both the family and the clinic have to be licensed. This seems sensible.”

“[We] recommend adopting a two-phase approach as implemented by United Kingdom’s Human Fertilisation and Embryology Authority (HFEA) – in which the first phase involves licensing of IVF clinics with specialist skills in mitochondrial donation and relevant ART techniques, and the second requires full review of each application. In Australia, accreditation by the Reproductive Technology Accreditation Committee (RTAC) is required for use of any ART application. Accreditation from RTAC requires ART clinics

to comply with ART laws and the related guidelines. Similar standards must also apply to facilities for mitochondrial donation.”

Some submissions recommended that specific protections and provisions be included in legislation, regulation, and/or guidelines in the event that mitochondrial donation was legalised:

“In the event that mitochondrial donation is introduced, [we strongly recommend] that rigorous counselling and regulatory conditions currently in place for third party reproduction are applied to this novel area with considerations not only for the prospective child (future adult) but all stakeholders.”

“The IVF industry is big business and MD will only fortify the profits for medical professionals and the companies who employ them. Independent oversight by a disinterested party is essential to ensure that the opportunity for exploitation is minimized.”

“Government body should oversee establishment of national eligibility criteria and allow only a few accredited centres to offer a service. Planning for ongoing monitoring should be part of a pre-treatment agreement.”

In contrast, a small number of submissions suggested that specific regulation or conditions for mitochondrial donation would not be required:

“It does not seem sensible to prescribe conditions for the use of the technology; however, it makes sense to maintain a commitment to evidence based practice and apply standard principles of medical ethics: autonomy, beneficence, non-maleficence and justice, to guide access and use of the technology.”

## 4.2 Stakeholder analysis of online submissions

### 4.2.1 Quantitative assessment of submissions

Question 8 of the public submission process asked respondents whether they supported the introduction of mitochondrial donation to prevent the transmission of mitochondrial DNA disease at this time. Overall, respondents were fairly evenly split between those supportive of the introduction of mitochondrial donation at this time and those opposed.

Individuals provided a variety of reasons for why they held their views.

A common theme among many of the responses opposed to the introduction of mitochondrial donation was the use of embryos, with the destruction of embryos in the process considered to be unethical. Another recurring theme among opponents was the unknown risks of creating children with DNA from three people, with some identifying this as an issue for future generations and the human gene pool.

A number of responses supportive of mitochondrial donation cited that one reason for their support was the opportunity for the birth of healthy children free from mitochondrial disease, avoiding the impact of the disease on a sufferer and their family. While a number of respondents accepted risks with the procedure, those supportive of introduction tended to regard the benefits as outweighing the risks. A number of respondents stated that mitochondrial donation should initially be part of a clinical research study and that

use of mitochondrial donation would only be appropriate for some circumstances, such as when there is a significant risk of disease. Some respondents also stated that appropriate oversight mechanisms would need to be in place, including restricting use to clinics with the appropriate expertise.

#### **4.2.2 Stakeholder group perspectives**

A range of individuals and organisations made submissions, some of whom were also engaged through other consultation mechanisms such as the targeted roundtable or public forums. Organisations and individuals represented a variety of stakeholder views, including scientific/clinical, patient advocacy, religious, academic/ethical, and jurisdictional.

Most submissions from individuals identifying as scientists and organisations representing clinicians and scientists were supportive of the introduction of mitochondrial donation, though there was acknowledgement that there remains some uncertainty about the potential risks. Consequently, the support was generally for a cautious introduction, possibly confined to a research study, and within an appropriate regulatory environment. In their support, a number of the submissions referred to the HFEA scientific review process as providing support for their position.

Submissions from respondents from a patient perspective and patient representative/advocacy groups who made submissions were generally supportive of the introduction at this time. The benefits of mitochondrial donation in preventing mitochondrial disease and avoiding the associated burden experienced by sufferers and their families was a major theme for this support.

Organisations representing religious stakeholders and individuals presenting religious views were generally not supportive of the introduction of mitochondrial donation. Across the submissions were a range of safety and ethical concerns, including the safety of the resultant child and risks to the human germline, respect for the right to life and human dignity, and ethical issues with the creation of people with three biological parents.

Submissions from state health authorities were split. The factors underpinning this disparity were differing views on the safety of mitochondrial donation and whether the current risks outweigh the benefits.

### **4.3 Themes and outcome from the Citizens' Panel**

The social and ethical issues that the Citizens' Panel regarded as the most important to consider in relation to the possible introduction of mitochondrial donation into clinical practice are described in the Citizens' Panel Statement ([Appendix E](#)). The Statement was written by the Citizens' Panel with the assistance of the facilitator.

The key issues described in the Statement include the importance of having the option of mitochondrial donation, the rights and wellbeing of the child to be born, factors relating to egg donation and the donor, issues relating to the prospective parents, and implementation considerations. The Citizens' Panel raised similar themes to other consultation modes, in particular the themes raised in online submissions (see Section 4.1); however there were also some differences.

Similar to online submissions, a key issue for the Citizens' Panel was the prevention of mitochondrial disease and the prevention of suffering caused by mitochondrial disease. The Citizens' Panel placed significant importance on these benefits of mitochondrial



donation. The Statement provided views on how mitochondrial donation could be implemented in a fair and ethical way to reduce the burden of disease. The majority of the Citizens' Panel considered that any risks to a child born following mitochondrial donation would be lower than if a child was born without mitochondrial donation being used.

Issues related to the egg donor and the egg donation process were also of significant importance for the Citizens' Panel, such as the ways in which egg donors could be protected from coercion and potential harm and the relationship between the donor and prospective child.

Also similar to online submissions, the Statement describes the concerns of a minority of the Panel that mitochondrial donation should not be allowed due to the potential unforeseen or unintended consequences, and the impact on future generations.

One key difference to the themes that emerged from online submissions is that the Statement notes that a lengthy time would be required to implement legislative change, and that this would allow for more data on the outcomes of mitochondrial donation to become available and for research on large animals to be conducted. The Panel were particularly interested in understanding the process, including the legislative and regulatory changes, that would be required for the introduction of mitochondrial donation into clinical practice. In contrast, this was not as important an issue in the online submissions and there appeared to be various levels of understanding of the process for implementation.

Other key differences are that the Statement does not specifically refer to, or evaluate the usefulness of, other reproductive options that may be considered by prospective parents before using mitochondrial donation, and it does not refer to issues related to the status of the embryo. In contrast, these issues were raised in several of the online submissions.

Finally, online submissions were received from academics in ethics, law and philosophy, and as such, some of the more complex ethical arguments expressed in the online submissions are not reflected in the Statement. For example, the notion of the unborn child not being able to provide consent is not addressed in the Statement, and there is also very little mentioned about the complexity of the relationships between the prospective parents, the child and the donor in the Statement.

## 4.4 Themes from the Roundtable

There was considerable overlap between the issues raised in online submissions and in the Citizens' Panel Statement, and those raised at the roundtable. The main areas of overlap were the outcomes of mitochondrial donation techniques, impacts and implications relating to prospective parents, and considerations for implementing mitochondrial donation into clinical practice. However, there were also key differences, which reflected the expertise and experience of the scientific, medical and regulatory specialists present at the roundtable.

The most prominent areas that were discussed from these specialist perspectives were: the current knowledge and understanding of mitochondrial donation; the emotional wellbeing of prospective parents; the suitability of alternative options; and ethical and regulatory considerations. Below is a brief description of the main emerging themes of discussion for each of these areas.

It should be noted that the purpose of the roundtable was for stakeholders to discuss their views and to develop their understanding of mitochondrial donation, to inform their

written submissions. Participants were not asked for their views on whether or not they supported the introduction of mitochondrial donation into Australian clinical practice or to come to a consensus position.

#### **4.4.1 Current knowledge and understanding of mitochondrial donation**

Roundtable participants discussed the remaining unknowns and uncertainties related to mitochondrial donation, and which areas required more research, and agreed that research using large mammals and humans would be valuable. Roundtable participants were in particular concerned with gaps in the current understanding of the functions and biology of mitochondrial DNA. There was much discussion about the importance and potential impact of haplotype matching and the lack of knowledge around interactions between mitochondrial DNA and nuclear DNA. It was noted that this lack of knowledge could impact the advice that fertility specialists and genetic counsellors provide to relevant prospective parents if mitochondrial donation was introduced into clinical practice in Australia.

#### **4.4.2 Emotional welfare of prospective parents**

Fertility specialists, genetic counsellors and clinicians who work with people with mitochondrial disease expressed significant concerns about the emotional welfare of prospective parents. It was highlighted that prospective parents with mitochondrial disease often share the same drive as many other prospective parents to conceive a healthy, genetically related child. Participants working with people in IVF settings noted the work they do in counselling individuals and couples through currently available options, and how they have helped prospective parents build happy and healthy families regardless of genetic lineage. While it was acknowledged that mitochondrial donation would be the best – and perhaps only – option for prospective parents to have genetically related children free of mitochondrial disease, the appropriateness of continuing to place such strong emphasis on genetic relatedness was questioned.

#### **4.4.3 Suitability of alternative treatments**

Clinicians and researchers agreed that while there were other options available to prospective parents wanting to have genetically related children, in practice these options had limited suitability. In terms of assisted reproductive technologies, it was noted that options such as preimplantation genetic diagnosis and amniocentesis do not measure reliably the level of mitochondrial DNA mutations, so the risk of having a child with mitochondrial disease is not reduced with these options. Other therapies were also considered, such as gene therapy; however it was agreed that they were still in the early stages of development, or were otherwise inaccessible to most people due to costs or regulatory issues.

#### **4.4.4 Ethical and regulatory considerations**

Several issues were raised during the roundtable that related specifically to the possible implementation of mitochondrial donation into clinical practice:

- There were concerns about the suggestion of limiting access to this treatment to males. It was noted that, while sex selection is currently used in IVF to prevent other significant diseases, restriction of mitochondrial donation to male embryos raises very different ethical issues. Participants were generally not in favour of restricting treatment availability in this way.

- Participants discussed the management of long term health tracking for those born through mitochondrial donation. While they shared concerns raised by the broader community regarding over-medicalisation of children, they also discussed the likelihood of individuals consenting to long term tracking, and the possibility that this would be perceived as dehumanising. It was suggested by several participants that advice be sought from experts in longitudinal health research, particularly cancer treatment trials, in designing appropriate systems and processes if mitochondrial donation was introduced into Australian clinical practice.

Clinicians and researchers also noted the complexities involved in making any changes to legislation or regulations, as relevant documents relate to both research and clinical practice. All participants expressed a desire to be involved in further consultation regarding updates to legislation and regulations and to contribute their specialist knowledge and expertise, should it be decided to introduce mitochondrial donation to Australian clinical practice.

## 5. Final remarks

### 5.1 Advice from Australian Health Ethics Committee

The Australian Health Ethics Committee (AHEC) is an NHMRC principal committee established under legislation, and is responsible for offering advice on ethical issues regarding human health and developing guidelines for human research.

AHEC provided high-level advice during the consultation on mitochondrial donation and reviewed this Consultation Report. AHEC Members endorsed the multi-modal approach to consultation and advised that the resultant consultation successfully informed and engaged a broad range of stakeholders from the Australian community about mitochondrial donation. AHEC advised that the summary of the consultation outcomes (Section 4) presented the complexity of the views raised in an appropriate way.

AHEC confirmed the need for continued community consultation should the Government choose to proceed with implementing mitochondrial donation in law and clinical practice. In addition to the groups mentioned in Section 5.2 and 5.3 below, AHEC advised that there might be other groups such as particular religious groups for whom the technology would pose specific challenges and who may need to be consulted about any changes.

AHEC advised that, if the Government were to proceed with mitochondrial donation, particular consideration should be given to the following issues:

- Equity of access—which may include financial considerations for ensuring equity of access to the technology.
- Consequences for the child born after mitochondrial donation—this includes how health tracking would be managed for those born through mitochondrial donation and how the balance would be maintained between personal autonomy and the need to gauge long-term safety for existing and future patients.

It was noted that some of these issues have been resolved previously for the introduction of other technologies, and that the approaches taken in other areas and jurisdictions could be considered.

## 5.2 Considerations specific for Aboriginal and Torres Strait Islander peoples

There is currently little information about whether mitochondrial DNA diseases or mitochondrial DNA mutations occur more or less frequently in Aboriginal and Torres Strait Islander peoples compared to the general Australian population. One written submission noted that there are Aboriginal families with mitochondrial DNA mutations in Queensland.

It is also not known if the potential uptake of mitochondrial donation, if introduced into Australian clinical practice, would be less or greater among Aboriginal and Torres Strait Islander people than the rest of the population.

However, it is still important to consider whether there are social and ethical issues specific to Aboriginal and Torres Strait Islander peoples related to mitochondrial donation that may not have been adequately addressed in Section 4.

Initial consultation has suggested that equity of access is a key issue. Like many current assisted reproductive technologies, mitochondrial donation may be developed within the private sector and the costs could be prohibitive, which may deny access to many prospective parents wanting to use the technology. It is important that access to mitochondrial donation is equitable, including for Aboriginal and Torres Strait Islander people. Indeed, this is an issue applicable more broadly to all ARTs, and initial consultation has suggested that future work may need to incorporate the consideration of ethical and sociocultural issues related to all ARTs from the perspective of Aboriginal and Torres Strait Islander people, before consideration of specific technologies such as mitochondrial donation. This is in line with findings from the [Final Report of the Independent Review of Assisted Reproductive Treatment](#) (July 2019) from the Victorian Department of Health & Human Services.

Additional issues may include the following:

- For many Aboriginal and Torres Strait Islander people genomic and mitochondrial information is new; therefore, many people may be reluctant to engage because of mistrust in health and medical research and services.
- The relationship between the donor, child and parents needs to be viewed from an Aboriginal and Torres Strait Islander standpoint. The clinical view is that there is not enough biological material from mitochondrial donation for there to be a relationship between the donor and the child. However, for communities where kinship practice is central, there needs to be a better understanding of how the communities will view the donor's relationship to the child.
- Other family and community members may be involved in decisions about reproduction and raising the child.

These issues will need further exploration through consultation with a broader range of Aboriginal and Torres Strait Islander stakeholders before the possible introduction of mitochondrial donation into Australian clinical practice.

## 5.3 Considerations for other cultural or social groups

Some online submissions expressed views about specific social and ethical issues relevant to particular cultural or social groups. The issues raised suggest that any further consideration of the possible introduction of mitochondrial donation into Australian clinical practice must include consultation with stakeholders that represent the specific

interests of groups such as people with disabilities, LGBTIQ+ people with mitochondrial DNA disease, and culturally and linguistically diverse people with mitochondrial disease. This list is not exhaustive and careful consideration would be required to ensure inclusivity.

Several concerns were also raised about whether community attitudes towards people with mitochondrial disease, or with disabilities in general, would be impacted by the possible introduction of mitochondrial donation. In addition, there was concern about attitudes towards women and/or couples with mitochondrial DNA disease who choose not to use mitochondrial donation, if available. Some submissions expressed views about the need for society in general to value and support people with disease or disability, and how a change in attitude may influence thinking around the relative risks and benefits of introducing mitochondrial donation in Australia. For example:

“As the technology becomes more accessible, we should be vigilant not to demean or be condescending to those living with the disease and we should continue to provide a high-standard of care. I’m speaking more broadly to concerns of disability activism and understanding that those with the disease should not be considered ‘defective’ or in need of fixing, but supported to self-determine. The choices of prospective parents should be respected also, as there are many values other than a normative conception of health that may weigh more heavily in their reproductive choice. As medicine becomes increasingly powerful and accessible we should continue to examine our values and empathise with people of diverse abilities and physiologies.”

“At the same time, there is also the risk that women would feel obliged or pressured to use the technology of mitochondrial donation if it were available. It is often taken for granted that procreators should be free to make decisions about reproduction – including when, how, with whom – based on their own values. But this autonomy is typically limited to actions that do not cause significant harm to others, prompting questions about what constitutes harm, and what is significant enough as to place limits on liberty. Further, there is good evidence that women often feel encouraged and even coerced into using technologies to avoid potential disabilities once this is a possibility, and are seen as responsible for causing harm to their child (and to society) if they don’t use them. For instance, women with children with Down Syndrome often report negative responses in regards to prenatal testing, including from strangers, along the lines of “didn’t you test?”. We can anticipate a similar social pressure to use technologies to avoid disabling conditions in children where those technologies are available, regardless of the specific circumstances of the woman, her values, and the often significant health burdens of the technology itself.”

Consideration of uses of mitochondrial donation other than for preventing transmission of mitochondrial DNA disease were not within the scope of this consultation. However, some submissions referred to the potential use of mitochondrial donation by lesbian couples to conceive genetically related children (rather than for the purpose of preventing severe mitochondrial disease) and suggested that preventing this use raises ethical concerns

related to equity of access and discrimination. These issues may require further consultation and consideration.

## 5.4 Importance of education and community engagement in the future

The biology of mitochondria, the inheritance of mitochondrial disease and mitochondrial donation technologies are all complex. One objective of the consultation was to provide accurate and accessible information on these topics to assist the community to provide informed views on the potential introduction of mitochondrial donation in Australia. NHMRC sought to achieve this objective by developing the Mitochondrial Donation Issues Paper (Section 2.2.1), producing an eight-minute consultation video based on comments from experts, conducting public forums and webinars, employing a science communication company to promote scientifically accurate media activities and conducting a citizens' panel process.

It should be noted that a number of submissions expressed significant concerns about the implication of mitochondrial donation if introduced into Australian clinical practice, including potential future misuse of the technology. As such, future community engagement must take into account the serious nature of these concerns.

### 5.4.1 Misunderstandings in written submissions

Community engagement should also consider addressing the key factual misunderstandings evident in some of the written submissions. In some cases, support for or opposition to mitochondrial donation in these submissions appeared to be based on these misunderstandings.

Some of the key factual misunderstandings included the following:

- Mitochondrial donation was a well-established technology in the UK that has resulted in the birth of several healthy children. At this stage, it is not known whether this is true. It is known that clinics and families in the UK have been approved to use this technology, but to date no pregnancies or births have been reported. Further, rather than deeming mitochondrial donation as 'safe', the UK has deemed it to be 'safe enough' to use in a limited set of circumstances, specifically when a woman with sufficiently high loads of mitochondrial DNA mutations wishes to have a child who is genetically related.
- Assumptions about how legislation/regulation would change to legalise mitochondrial donation, including that Australian regulations would be the same as those in the UK. Some submissions have assumed that the child born would not have a relationship with the donor, or alternatively, that the donor and prospective parents would all have parental relationships with the child. Similarly, some submissions have assumed that the donor in the UK will always be unidentified, though this is not necessarily the case. It should be better emphasised that decisions about future legislative change will likely involve further consultation that would aim to resolve many of the social and ethical issues raised, with particular reference to the relationships between child, donor and prospective parents. These misunderstandings have been led in part (or have been caused) by use of the terms "three parent babies" and "three parent IVF" in our consultation or elsewhere.
- The contribution of mitochondrial DNA to the phenotype of a person: many submissions have referred correctly to the fact that mitochondrial DNA contains 37 genes, compared to the 20,000–30,000 genes found in nuclear DNA. However, some submissions have interpreted this to mean that mitochondrial DNA does not contribute



significantly to personal characteristics. This interpretation does not reflect that mitochondria support a wide range of functions, and that mitochondrial DNA disease has a significant impact on personal characteristics.

- Mitochondrial donation could result in the mitochondrial disease being 'cured' or being eliminated. Although mitochondrial donation will likely result in children being born without mitochondrial DNA disease, there are many reasons why mitochondrial disease will not be cured or eliminated, for example because of carry-over and reversion, because nuclear DNA mutations are responsible for some mitochondrial diseases and because spontaneous mutations can occur in mitochondrial DNA.
- The meaning of terms such as 'fetus', 'embryo' and 'zygote' in the context of current Australian legislation, the technical details of the different mitochondrial donation technologies (such as what parts of the donor egg are used and the involvement of embryos), what is currently permissible in assisted reproductive technologies and in relation to egg donation. Whilst noting these issues are highly complex and can be emotive, the community should be encouraged to have more informed and respectful discussions about these aspects of mitochondrial donation.
- Mitochondrial donation and organ transplantation are equivalent. Whilst there are certainly many similarities, there are also some important differences that may need to be better explained, in particular to emphasise that the current legislation and guidelines about organ and tissue donation would not automatically apply to mitochondrial donation, and that mitochondrial donation introduces genetic changes that are inherited whereas transplantation does not.

#### 5.4.2 Misunderstandings of the Citizens' Panel

Some of these misunderstandings were reflected during the deliberations of the Citizens' Panel. However, one of the key benefits of the Citizens' Panel process was that it allowed a group of ordinary Australians to hear balanced information about mitochondrial donation. Experts were available throughout the process to challenge the Panel's assumptions and to clarify misconceptions. This meant that many of the Panel's misconceptions had been resolved by the time the Statement was completed.

However, some misconceptions and assumptions remained. This could reflect beliefs that are tightly held for a variety of reasons, or the highly complex nature of this technology. For example, Citizens' Panel members maintained a high level of trust that all new technologies are rigorously tested and understood before being made clinically available. There was a lack of appreciation that, for some new technologies such as ART, it can be more challenging to conduct research and develop evidence for safety and efficacy, and that for some technologies the decision to implement is based on evidence about being 'safe enough' rather than 'safe'. As such, the Panel provided support for mitochondrial donation assuming that further research would be conducted prior to clinical implementation. These assumptions may indicate that ordinary Australians would also assume and feel assured that further research would be done before implementation of mitochondrial donation, and suggest the need for careful communication about any remaining risks and unknowns.

In addition, most of the Panel's considerations relating to egg donation are not unique to mitochondrial donation and have been addressed in existing frameworks that regulate ART. This may indicate a need for broader community information or consultation about the existing frameworks in this field.



### 5.4.3 Summary

In summary, it will be crucial for any work on the possible introduction of mitochondrial donation to keep these common misunderstandings in mind, and for future communication/education activities to focus on clarifying these areas for key stakeholders or the general community. Some stakeholder groups may require targeted communication activities; for example, statements about “relationships” and ideas about decision-making need to be presented in a way that aligns with the culture and thinking of Aboriginal and Torres Strait Islander people.

Finally, it should be noted that many submissions have expressed vehement views both for and against the introduction of mitochondrial donation into Australian clinical practice. As such, some submissions contain comments that may be offensive to some members of the community. Future discussions in the public arena must aim to support respectful conversations, and encourage people to be aware of the diverse views and experiences of community members.

It also should be noted that for controversial technologies such as mitochondrial donation, the views of community members will often be formed based on pre-existing values. Since this consultation aimed to obtain informed submissions rather than reactive responses based on pre-existing values, it may be valuable to conduct a large, quantitative survey to better understand what the initial response of community members may be when hearing for the first time about the possible introduction of mitochondrial donation into clinical practice, for example, in the media. The survey results could inform communication strategies to help manage these initial responses to ensure meaningful and accurate engagement by the Australian Government with the community.

## Appendix A – Mitochondrial Donation Expert Working Committee

### Terms of Reference

The Mitochondrial Donation Expert Working Committee ('the Committee') will provide advice to the NHMRC Chief Executive Officer on the legal, regulatory, scientific and ethical issues identified by the Senate Community Affairs References Committee Inquiry into: *The Science of Mitochondrial Donation and Related Matters* ('the Inquiry').

The Committee will:

- a. advise on key questions to underpin community-wide consultation and increase community literacy on issues raised by mitochondrial donation to be delivered by April 2019
- b. consider relevant literature and advise on questions posed within Recommendation 2 of the Inquiry Report, specifically:
  - i. whether mitochondrial donation is distinct from germline genetic modification
  - ii. is there any new information to indicate that research findings from the United Kingdom, that the science of mitochondrial donation is safe for introduction into controlled clinical practice, cannot be applied in an Australian context, and
  - iii. whether other approaches to inheriting mitochondrial disease should also be the focus of Australian research
- c. advise on any other relevant issues as requested by the NHMRC Chief Executive Officer.

The Committee will be established under section 39 of the *National Health and Medical Research Council Act 1992*. Its membership shall comprise a Chair, and members with expertise and experience in the following areas:

- The genetics of mitochondrial disease and/or genetic modification.
- The science of embryology and developmental biology.
- Consumer health issues relating to mitochondrial disease.
- The clinical application of assisted reproductive technologies or gene therapies.
- Ethical and theological considerations relating to mitochondrial donation.
- The legislative and regulatory framework relevant to mitochondrial donation.
- A representative from an NHMRC Principal Committee (e.g. Embryo Research Licensing Committee and/or Australian Health Ethics Committee).

## Membership

|  |  |
|--|--|
| <b>Associate Professor Bernadette Richards</b> | Chairperson  |
| <b>Professor Justin St. John</b>               | Member with expertise in the genetics of mitochondrial disease and/or genetic modification and assisted reproductive technologies. |
| <b>Professor David Thorburn</b>                | Member with expertise in the genetics of mitochondrial disease and/or genetic modification.  |
| <b>Professor Patrick Tam</b>                   | Member with expertise in the science of embryology and developmental biology.  |
| <b>The Hon Judi Moylan AO</b>                  | Member with expertise in consumer health issues relating to mitochondrial disease.   |
| <b>Mr Sean Murray</b>                          | Member with expertise in the consumer health issues relating to mitochondrial disease.   |
| <b>Dr Clare Boothroyd</b>                      | Member with expertise in the clinical application of assisted reproductive technologies or gene therapies.                         |
| <b>Professor John Rasko AO</b>                 | Member with expertise in the clinical application of assisted reproductive technologies or gene therapies.                         |
| <b>Reverend Kevin McGovern</b>                 | Member with expertise in the ethical and theological considerations relating to mitochondrial donation.                            |
| <b>Professor Sheryl de Lacey</b>               | Member with expertise in the ethical and theological considerations relating to mitochondrial donation.                            |
| <b>Professor Ainsley Newson</b>                | Member with expertise in the ethical and theological considerations relating to mitochondrial donation.                            |
| <b>Professor Dianne Nicol</b>                  | Member with expertise in legislative and regulatory framework relevant to mitochondrial donation.                                  |

## Appendix B – Summary of Media Coverage

| Type  | Date        | Publication/outlet      | Title (and link if available)   |
|-------|-------------|-------------------------|---|
| Print | 20 October  | Adelaide Advertiser     | New IVF debate aims for answers<br><a href="http://bit.ly/35KqgDM">http://bit.ly/35KqgDM</a>  |
| Print | 20 October  | Sunday Mail Adelaide    | New IVF debate aims for answers   |
| Print | 7 November  | Herald Sun (Melbourne)  | New Hope for new life (editorial)   |
| Print | 7 November  | Herald Sun (Melbourne)  | Exclusive: IVF lifesaver, three parent babies (front page)  |
| Print | 7 November  | Courier Mail (Brisbane) | Exclusive: Radical IVF lifesaver on way, 3-parent babies  |
| Print | 11 November | The Conversation        | 3-parent IVF could prevent illness in many children (but it's really more like 2.002-parent IVF)<br><a href="http://bit.ly/33CxcDf">http://bit.ly/33CxcDf</a>   |
| Print | 13 November | Catholic Weekly         | Three-person IVF poses grave concerns<br><a href="https://www.catholicweekly.com.au/three-person-ivf-poses-grave-concerns/">https://www.catholicweekly.com.au/three-person-ivf-poses-grave-concerns/</a>  |
| Print | 14 November | Catholic Weekly         | Fragmenting motherhood: 3-parent children, IVF and the future<br><a href="https://www.catholicweekly.com.au/fragmenting-motherhood-3-parent-children-ivf-and-the-future/">https://www.catholicweekly.com.au/fragmenting-motherhood-3-parent-children-ivf-and-the-future/</a>      |
| Print | 16 November | Herald Sun (Melbourne)  | Forum on IVF laws   |
| Print | 26 November | Mirage news             | Last chance to tell us what you think about mitochondrial donation<br><a href="https://www.miragenews.com/last-chance-to-tell-us-what-you-think-about-mitochondrial-donation/">https://www.miragenews.com/last-chance-to-tell-us-what-you-think-about-mitochondrial-donation/</a> |
| TV    | 19 October  | Channel Ten (national)  | Controversial IVF babies  |
| TV    | 19 October  | Channel 7 (Adelaide)    | Mitochondrial donation  |

| Type  | Date        | Publication/outlet   | Title (and link if available)  |
|-------|-------------|--|--|
| TV    | 6 November  | Sunrise  | Three parent IVF<br><a href="http://bit.ly/2CzT1aB">http://bit.ly/2CzT1aB</a>  |
| TV    | 9 November  | ABC Weekend breakfast  | Interview with Isobel Karpin   |
| TV    | 7 November  | Seven News and syndicated in Sydney, Brisbane, Melbourne, Perth. | Three parent IVF procedure<br><a href="http://bit.ly/33nWrco">http://bit.ly/33nWrco</a>  |
| TV    | 7 November  | Nine in Brisbane, Perth (and probably syndicated)                | Mitochondrial donation<br><a href="http://bit.ly/2Ci5mjQ">http://bit.ly/2Ci5mjQ</a>  |
| TV    | 17 November | Sky news   | Govt considering legalising 'three parent baby' IVF technique<br><a href="https://www.skynews.com.au/details/_6105020605001">https://www.skynews.com.au/details/_6105020605001</a> |
| Radio | 7 November  | ABC News Radio Melbourne   | Interview with Virginia Trioli   |
| Radio | 7 November  | ABC Perth Radio  | Interview with Russell Woolf and Nadia Mitsopoulos   |

## Appendix C – Online Submissions

A list of the names of individuals and organisations that provided an online written submission to the consultation is below. Respondents who indicated that they did not want their submission to be published are described as ‘name withheld’. There were 199 submission numbers in total, with four of these being duplicates of other submissions. The order of the submission numbering is based on the date and time of submission, from earliest through to latest submissions. Of the 195 unique submissions, representative quotes from 137 were included in Section 4.

| Submission         | Name of individual or organisation |    |                               |
|--------------------|------------------------------------|----|-------------------------------|
| <b>INDIVIDUALS</b> |                                    |    |                               |
| 1                  | Michele Watts                      | 24 | [name withheld]               |
| 2                  | Colin Westman                      | 25 | [name withheld]               |
| 3                  | Steven Calleja                     | 26 | [name withheld]               |
| 4                  | Gillian Dale Ray                   | 27 | Dr Hoomis Pahos               |
| 5                  | [name withheld]                    | 28 | Anna Wise                     |
| 6                  | Alexander J Anderson               | 29 | Charles Lewicki               |
| 7                  | Diane Frances Cass                 | 30 | Michael John Percy            |
| 8                  | Jacqui Allen                       | 31 | [name withheld]               |
| 9                  | Pam Hausler                        | 32 | [name withheld]               |
| 10                 | Lynnette Colquhoun                 | 33 | [name withheld]               |
| 11                 | Preeti Raghvani                    | 34 | [name withheld]               |
| 12                 | Gary Andrew CLARK                  | 35 | Conrad Newbery                |
| 13                 | [name withheld]                    | 36 | [name withheld]               |
| 14                 | Pam Maddock                        | 37 | Julie Lawson                  |
| 16                 | Annabel Drynan                     | 38 | Roel and Isabella Van de Paar |
| 17                 | Sarah Louise Borrie Schenscher     | 39 | Emma-Lea Yarrow               |
| 18                 | Mrs Jane Eyre                      | 40 | Pat Darcey                    |
| 19                 | Isabelle La Macchia                | 41 | noel francis keogh            |
| 20                 | Lauren Anderson                    | 42 | Luke Mangleson                |
| 21                 | Magnon Damant                      | 43 | Daniel Combridge              |
| 22                 | Bob Van Veen                       | 44 | [name withheld]               |
| 23                 | Alfie Sorbello                     | 45 | [name withheld]               |
|                    |                                    | 46 | [duplicate]                   |
|                    |                                    | 47 | Peter W Hallifax              |

|    |                             |
|----|-----------------------------|
| 48 | [name withheld]             |
| 49 | [name withheld]             |
| 50 | Kylie Taylor                |
| 51 | [name withheld]             |
| 52 | Jennifer Margaret James     |
| 53 | Rachel Kotterer             |
| 54 | Trevor Duffin               |
| 55 | [name withheld]             |
| 56 | [name withheld]             |
| 57 | [name withheld]             |
| 58 | Carmen Douglas              |
| 59 | Francis Leo Long            |
| 60 | Sue Erasmus                 |
| 61 | [name withheld]             |
| 62 | [name withheld]             |
| 63 | [duplicate]                 |
| 64 | Nigel Bertram Mario D'Souza |
| 65 | [name withheld]             |
| 66 | Doris Armstrong             |
| 67 | Tracey Thompson             |
| 68 | [name withheld]             |
| 69 | Laura McGillion             |
| 70 | [name withheld]             |
| 71 | [name withheld]             |
| 72 | Bernard Wright              |
| 73 | Marc Correia                |
| 74 | Samantha Bryan              |
| 75 | Joan Apthorp                |
| 76 | Michael Kevin Buck          |
| 77 | [name withheld]             |

|     |                                  |
|-----|----------------------------------|
| 78  | Michael Joseph Casanova          |
| 79  | Karen Ann Murphy                 |
| 80  | [name withheld]                  |
| 81  | [name withheld]                  |
| 82  | Sarah Jane Bown                  |
| 83  | Gordon Henry Smith               |
| 84  | Nuala Collins                    |
| 85  | Allan and Jacqueline CHOVEAUX    |
| 86  | [name withheld]                  |
| 87  | Lorraine Manteit                 |
| 88  | Susan Ann Christie-Taylor        |
| 89  | Elizabeth Eileen Timbery Tierney |
| 90  | [name withheld]                  |
| 91  | [name withheld]                  |
| 92  | Alex Sullivan                    |
| 93  | [name withheld]                  |
| 94  | [name withheld]                  |
| 95  | [name withheld]                  |
| 96  | Todd Beiswenger                  |
| 97  | [name withheld]                  |
| 98  | Rebecca Pitt                     |
| 99  | [name withheld]                  |
| 100 | [name withheld]                  |
| 101 | Lucy Charlesworth                |
| 102 | [name withheld]                  |
| 103 | William Bernard Larkin           |
| 104 | Shelley Beverley                 |
| 105 | Nicholas Morgan                  |
| 106 | Melinda Behrens-Macaulay         |



|     |                    |
|-----|--------------------|
| 107 | Julia Farrington   |
| 108 | Bethany Hodge      |
| 110 | Paul burt          |
| 111 | Sharyn Stock-Myer  |
| 112 | Geoff              |
| 113 | [name withheld]    |
| 114 | [duplicate]        |
| 115 | [name withheld]    |
| 116 | Margaret Kelly     |
| 117 | Monika Janinski    |
| 118 | Tessa Hood         |
| 119 | HELEN LEACH        |
| 120 | John Olsen         |
| 121 | Holly Hood         |
| 122 | [name withheld]    |
| 123 | Christopher Rule   |
| 124 | Craig Hood         |
| 125 | [name withheld]    |
| 126 | [name withheld]    |
| 127 | [name withheld]    |
| 128 | Philisha Riddell   |
| 129 | Rebecca Patterson  |
| 130 | Stefanie Lawton    |
| 131 | Mark northage      |
| 132 | Denis Strangman AM |
| 133 | [name withheld]    |
| 136 | Julian Savulescu   |
| 137 | [name withheld]    |
| 138 | Ian Andrew Trounce |
| 139 | Jessica Harrison   |
| 140 | [name withheld]    |

|     |                           |
|-----|---------------------------|
| 141 | James Granger             |
| 142 | Pacita Lorraine Wissell   |
| 143 | [name withheld]           |
| 144 | Joanne Mcfadyen           |
| 145 | Rosamria                  |
| 146 | Margaret Cuthbertson      |
| 148 | [name withheld]           |
| 149 | Allison Beagley           |
| 150 | Linds phillip             |
| 151 | [duplicate]               |
| 152 | Rosamund Stobie           |
| 154 | Megan Donnell             |
| 155 | Sherree Snoodyk           |
| 156 | James Crawford            |
| 157 | Robin Ross                |
| 158 | [name withheld]           |
| 159 | Catherine Prendergast     |
| 161 | Timothy Hughes            |
| 162 | [name withheld]           |
| 163 | Sean Murray               |
| 164 | Dr Jeannette Rosita Young |
| 166 | Fiona Glenn               |
| 167 | [name withheld]           |
| 168 | Jay Windross              |
| 169 | Isabel Lopez Sanchez      |
| 170 | Keith Edwin Windross      |
| 171 | [name withheld]           |
| 172 | Karen Crawley             |
| 173 | Ritchie Hollands          |
| 175 | [name withheld]           |

|     |                         |
|-----|-------------------------|
| 176 | Sally Catt              |
| 179 | Kristina Elvidge        |
| 180 | Kevin Joseph McGovern   |
| 181 | [name withheld]         |
| 182 | Catherine McGovern      |
| 183 | Paul Anderson           |
| 184 | [name withheld]         |
| 186 | Carolyn Mary Sue        |
| 187 | Doug and Margie Lingard |
| 188 | Jennifer Kellaway       |
| 189 | John Stanley ROBERT     |
| 190 | [name withheld]         |
| 191 | Shann Kellaway          |
| 192 | [name withheld]         |
| 194 | [name withheld]         |
| 197 | Catherine Mills         |
| 198 | [name withheld]         |

| ORGANISATIONS |   |
|---------------|---|
| 15            | Tasmanian Clinical Genetics Service   |
| 109           | Human Genetics Society of Australasia   |
| 134           | [name withheld]   |
| 135           | Australian and New Zealand Infertility Counsellors Association (ANZICA)             |
| 147           | [name withheld]   |
| 153           | Australian Genomics Health Alliance   |
| 160           | MCRI - Biomedical Ethics Research Group   |
| 165           | Mito Foundation   |
| 174           | Genetic Support Network of Victoria   |
| 177           | [name withheld]   |
| 178           | Rare Voices Australia   |
| 185           | Australian Christian Lobby  |
| 193           | Plunkett Centre   |
| 195           | Australian Academy of Health and Medical Sciences and Australian Academy of Science |
| 196           | Australian Catholic Bishops Conference  |
| 199           | [name withheld]   |

## Appendix D – Targeted Roundtable Participant Organisations

The targeted roundtable was attended by representatives from the following groups and organisations:

Australian Genomics Health Alliance

Fertility Society of Australia

Australian Academy of Health and Medical Sciences

Australian Academy of Science

Australian Council of Learned Academies

Department of Health – Commonwealth

State and Territory Chief Health Officers

Project Reference Group on Health Genomics Membership

## Appendix E – Citizens’ Panel Position Statement

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# **Mitochondrial Donation Community Consultation Citizens' Panel Position Statement**



For further information on NHMRC's  
work on Mitochondrial Donation,  
visit

**[www.nhmrc.gov.au](http://www.nhmrc.gov.au)**



# Foreword

In 2019, the National Health and Medical Research Council (NHMRC) was tasked by the Australian Government to undertake a public consultation seeking the community's views on the possible introduction of mitochondrial donation, to prevent the transmission of mitochondrial disease, into Australian clinical practice. This work was in response to the Senate Community Affairs References Committee report of its Inquiry into the Science of Mitochondrial Donation and Related Matters.

NHMRC developed a consultation process that aimed to obtain the views from across the community. An important part of this approach was the formation of the Citizens' Panel and this resultant statement.

The Citizens' Panel was established to provide an opportunity for a group of people to assist the Government in making decisions about whether to change the law to allow mitochondrial donation in Australia. It brought together a diverse group of Australians, with different backgrounds and experiences, but minimal knowledge about mitochondrial donation. As a group, they were provided with information and formulated a position statement in response to the overarching question:

***What are the views of the broader Australian community on the possible introduction of mitochondrial donation into clinical practice, once the scientific, ethical and social issues are generally understood?***

The Citizens' Panel met over two weekends. The first weekend (19–20 October 2019) was held in Adelaide and included presentations from several experts in the fields of science and medicine, law and ethics, as well as patient advocacy representatives. The focus was on participants learning about issues related to mitochondrial donation and engaging with the experts, and each other, to develop their understanding of the issues and formulate initial viewpoints. The second weekend (9–10 November 2019) was held in Brisbane and focused on answering the participants' questions, strengthening their understanding of mitochondrial donation and developing this statement from the participants that summarised the Panel's position on the overarching question. Participants were encouraged to discuss the overarching question with their communities and to incorporate their learnings from those discussions into the development of the statement.

Both weekends were managed by a neutral facilitator to enable participants to ask questions, learn and share their views – and their reasons for those views – in a safe and supportive environment.

This statement has been written by the members of the Citizens' Panel. It expresses their expectations, concerns and recommendations about mitochondrial donation, and outlines points of agreement and disagreement among the participants. It is designed to help inform policy makers and researchers on the views and attitudes likely to be held by members of the Australian community if these members were sufficiently informed about mitochondrial donation and able to explore the technology and issues at length. It demonstrates to the Australian public that a broad range of issues was canvassed during the Citizens' Panel process and that ordinary citizens drove the process and final outcomes.

NHMRC wishes to thank the Citizens' Panel and the experts who joined their meetings for their contribution to this important process.

# Statement of citizens' panel on mitochondrial donation

**This statement was written by the 2019 citizens' panel on mitochondrial donation.**

## 1. Having the option of mitochondrial donation

We see a number of reasons why it is important for people who are at risk of passing on mitochondrial disease to their children to have the option of mitochondrial donation. The main reasons are:

- It could help prevent children being born with mitochondrial disease, which is a horrible disease with no cure currently available. So mitochondrial donation would help prevent this suffering and untimely death, with the aim of improving quality of life.
- In addition, it could give people at risk of passing on mitochondrial disease an opportunity to have healthy children who are genetically related to both parents.
- Potentially, it could help break the cycle of mitochondrial disease in families, reduce their emotional trauma and improve their mental health and wellbeing.
- Economically, it would reduce costs to the community of providing healthcare and disability support to people affected by mitochondrial disease and their families.

**We are aware of the unknowns related to mitochondrial donation, but the majority have the view that mitochondrial donation should be permitted.**

In coming to this view, we took into account the following:

- Any negative impacts on the child are likely to be less than if child was born to their parents without mitochondrial donation being used.
- Risks to the child can be minimised by gathering more information:
  - More data about outcomes for children born of mitochondrial donation in other countries will become available by the time any changes in Australian law were passed and an Australian clinic was ready to accept its first prospective parents, and

- o This period of time would also allow for more studies on large animals to be conducted.
- The unknown impact on future generations can be also minimised with further research.

**A small minority of us feel that mitochondrial donation should not be permitted,** because of unresolved concerns. These are:

- Too many unknowns about the process and outcomes.
- Impacts on the life of the child to be born, both health and privacy implications.
- Impact on future generations.

## 2. Who needs to be considered in making mitochondrial donation legally permissible

We agree that the following people need to be taken into account when deciding how to change the law, and put mitochondrial donation into clinical practice.

### The child

We recognise that there could be negative effects on the child born of mitochondrial donation, particularly:

- That the child could still develop mitochondrial disease – there is not a guarantee of success.
- The unknown level of risk that mitochondrial disease might re-appear in the next generation (by a healthy female born from mitochondrial donation going on to have a child who then gets mitochondrial disease).
- Medicalisation of the child, because of follow-up testing.
- Risk to the child's privacy from media and social scrutiny.
- Follow up of children should be actively encouraged, especially as part of regular health checks, but not mandatory.

We feel that people wanting to use mitochondrial donation should be made of aware of the risks to the child, and also that attention should be given to finding ways to reduce the risks.

### **The donor**

We think there would need to be safeguards to protect egg donors from various harms or risks, including exploitation, coercion, and loss of privacy. Specifically, we agree that attention should be given to the following aspects of the process of egg donation:

- Egg donors should come under existing frameworks that protect the rights of egg donors in Assisted Reproductive Technologies (ART) (including privacy, free choice, counselling and informed consent).
- Donors should be screened to ensure healthy viable eggs.
- Egg donors should have the right to withdraw up until their eggs have been collected.
- Women should not be excluded from being egg donors just because they have not had children of their own yet.
- Women should be compensated for all costs of being an egg donor, including loss of income.

We are also concerned to make sure potential egg donors are not put off by the process. We have mixed views on payment to donors and whether donors should have the option to remain anonymous to the child if they want to.

### **The prospective parents**

We feel that the following issues about prospective parents should be taken into account:

- Affordability – mitochondrial donation should be available to everyone who needs it, not just to those who can afford to pay. Various forms of financial subsidy should be considered.
- Methods for increasing availability of egg donors, such as egg sharing schemes, should be considered.
- Counselling for prospective parents, which they could have on-going access to, would be very important.

### 3. Considerations in changing the law

We agree that these considerations should be taken into account when designing the change in law:

- Oversight by an independent body with scientific expertise.
- Protection against possible misuses of the science, including cloning and creation of designer babies. This needs to be kept in mind when changing law about cloning.
- Mitochondrial donation should only be available for the avoidance of mitochondrial disease, not for other purposes.
- Regular review of outcomes to promote progress in research and clinical practice.
- Protection for everyone involved if something goes wrong.
- Potential positive impact including possibility of more research and funding leading to new medical discoveries.
- Importance of long-term monitoring of outcomes for the next generation.

We also discussed whether mitochondrial donation should be accessible to Australian residents only in the initial stages. We have mixed views on this.

We appreciate being involved in this process and would like to come to Canberra if this issue is debated in Parliament.









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