Monash IVF Group Limited
Pelaco Building 1
Level 1, 21-31 Goodwood Street
Richmond VIC 3121 Australia
+61 3 9420 8235
groupenquiries@monashivf.com
monashivfgroup.com.au
ABN 90 169 302 309

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The Senate
Parliament of Australia
Standing Committee on Community Affairs
Legislation Committee
E: community.affairs.sen@aph.gov.au

Submission to Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021

The Monash IVF Group (MVF) is in support of the Mitochondrial Donation Law Reform Bill. Severe mitochondrial disease can have a devastating effect on families, including the premature death of children, painful debilitating and disabling suffering, long-term disease, and poor quality of life. Mitochondrial donation is a pathway to prevent this life-threatening disease and reduce the burden of mitochondrial disease into the future and therefore the introduction of this treatment modality into Australia is a very positive step. Given the nature of this technology, however, it is imperative this introduction is done carefully and is closely monitored to ensure no adverse outcomes on the future generations who are born from this technology.

We have the following queries regarding the bill that we believe require further clarification:

Section 28C(3)(a): Does this mean that that culture of embryos up to 14 days is allowed in this setting?

Section 28D(1)(b) and 28J(5)(ii): How is the technical competence of the embryologist performing the tasks determined and assessed against those standards and does this happen through a pre-clinical research and training licence pathway first? Will this be determined by NHMRC Licencing Committee or will RTAC play a role in assessing this?

Section 28D(1)(c): Who will be responsible for determining that the licence holder's facilities, equipment, processes, and protocols for using the technique are suitable for using the technique in a trial setting?

Section 28J(3)(a): How will the number of excess ART embryos, eggs, or zygotes necessary to achieve the goals of the activity be determined?

Section 28K(1)(c): Will the licencing committee also notify RTAC, in addition to the HREC and relevant state body, regarding the issuing of any licence for mitochondrial donation so RTAC are able to factor this into annual assessments as they do embryo research licences?

Section 28P(1)(a): Will each individual patient be required to be registered with their own specific licence or will a general licence be issued to cover any patient at the clinic that fits the criteria of requiring mitochondrial donation as per 28P(4)(a) where the NHMRC needs to be satisfied that there is a risk to each particular woman's offspring (which would be determined through a different pathway). The way this section is written implies that each patient would need to be assessed and determined to be suitable to the NHMRC licencing committee but it is unclear whether they need their own licence or just approval that they meet inclusion criteria?

28P(8): If a patient creates embryos from the ART cycle where mitochondrial donation is used and wishes to use them >5 years after they are created does a further licence need to be created for future use of cryopreserved material or once they are created and cryopreserved is the licence to use no longer required?

28Q(1)(d)(ii): Does this clause prohibit the transfer of any female embryos to patients that have used this technique or does this mean that male embryos should be selected preferentially and therefore all patients MUST have PGT-A to prioritise embryo selection based on gender? What if embryos are not suitable quality for embryo biopsy, can patients opt for transfer of untested embryos? Also, in the rare situation the patient also carried a X linked disorder is this an acceptable reason to select female embryo instead of male embryos.

28S(1)(a): What aspects of pregnancy monitoring are required? Is it just whether the pregnancy is ongoing or are there other aspects of maternal/fetal health such as ultrasound data that is required?

28S(1)(a): For how many years is the health and ongoing development of the child born from mitochondrial donation to be monitored by the ART unit (which holds the clinical trial licence or clinical practice licence)? Will the collection of specific information be required each year to standardise health and development monitoring if multiple ART units are proving this technology?

Provision of licences: Will there be a restriction on the number of clinics in Australia that can undertake these procedures? Given the highly skilled nature of this work and the risk associated with the procedures and the high emphasis on scientist technical competence it would be advisable that the number of ART clinics that introduce this new technology is very carefully determined with respect to the clinical need and to ensure that the best possible outcomes are provided to patients.

Licencing committee: We would recommend that if RTAC is not going to play a role in oversight of technical competence or facility suitability that this committee includes a CREI subspecialist and a Scientific Director (as defined in the RTAC-COP) to ensure that the right expertise is available for monitoring and of program outcomes.

Kind regards

Prof Luk Rombauts
Monash IVF Group Medical Director

A/Prof Deidre Zander-Fox
Monash IVF Group Regional Scientific Director