

## MEP on ART and Surrogacy – Government Response to MEP Report Recommendations

Ministerial Expert Panel Recommendation		Government Response
<b>Part A:</b>	<b>Proposed legislation for regulation of ART practice</b>	
1.	<p>That the <i>Human Reproductive Technology Act 1991</i> (HRT Act), the <i>Surrogacy Act 2008</i> (Surrogacy Act) and the <i>Artificial Conception Act 1985</i> (AC Act) be repealed and replaced with a single Act combining the treatment and practice of ART and surrogacy. The title of the proposed legislation should be the Assisted Reproductive Technology and Surrogacy (ARTS) Act.</p>	<p><b>Supported.</b></p> <ul style="list-style-type: none"> <li>• Repeal of the three acts and combination into a single piece of legislation is supported and will recognise the intrinsic link between surrogacy and wider ART procedures and establish a cohesive and focused framework for subsequent regulation.</li> <li>• ART is a contemporary, familiar and recognisable term for assisted reproductive technology including surrogacy.</li> </ul>
2.	<p>That a second, separate Act is required to regulate research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA, and the continued prohibition of human cloning for reproduction and other prohibited practices.</p>	<p><b>Supported.</b></p> <ul style="list-style-type: none"> <li>• WA must have legislation that prohibits certain practices, including human cloning. A separate Act for research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA; and prohibition of human cloning for reproduction would: <ul style="list-style-type: none"> <li>○ support WA’s commitment at the national level to enact uniform legislation for these matters</li> <li>○ align WA with other Australian states and territories.</li> </ul> </li> </ul>
3.	<p>That proposed legislation:</p> <ol style="list-style-type: none"> <li>a) regulate the WA ART industry and reflect the changing context of medical, ethical, social and commercial challenges, to protect the best interests of persons born as a result of ART, individuals and their partners (if any) accessing ART, and those donating reproductive material or capabilities</li> <li>b) outline the roles and responsibilities of regulators and licensed ART providers, including reporting requirements</li> <li>c) establish an advisory and review board for specific ART matters.</li> </ol>	<p><b>Supported.</b></p>

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<p>4. That proposed legislation includes objectives to inform the intent and purpose of the legislation. The following objectives be adopted in the proposed legislation to:</p> <ul style="list-style-type: none"> <li>a) regulate the use of ART by licensed ART providers to deliver best clinical practice and decision-making that meet industry standards and safety and quality outcomes defined by the regulator</li> <li>b) regulate collection of participant and treatment data, and access to information about ART treatments and procedures carried out under the Act</li> <li>c) provide for the keeping of the Reproductive Technology Registers (RT Registers), and any other data collections related to the Act</li> <li>d) enable participant information relating to donor conception and surrogacy to be recorded for the purpose of sharing this with persons entitled to access the information under the legislation</li> <li>e) facilitate research into the incidence, causes and prevention of infertility, and the impact of treatments on the health outcomes of ART participants</li> <li>f) establish the ART Advisory and Review Board (AARB) to provide advice and support governance and oversight of ART in WA.</li> </ul>	<p><b>Supported.</b></p> <p>New legislation will ensure that the purposes for data collection, use and disclosure are achieved without limiting processes or sources for collection, or disclosure.</p>
<p>5. That proposed legislation contain principles developed by the MEP to guide the interpretation and administration of the Act and how activities to be regulated by the Act are conducted. Principles to be included in the proposed legislation:</p> <ul style="list-style-type: none"> <li>a) the best interests (including health, safety, welfare and rights) of persons to be born as a result of ART are paramount</li> <li>b) the health, safety and wellbeing, including physical, emotional and mental health, of persons accessing ART, their partner (if any), donors and surrogates must be protected</li> <li>c) all persons accessing ART must provide informed consent prior to a treatment or procedure being performed</li> <li>d) persons accessing ART must not be unlawfully discriminated against on grounds which include but are not limited to their sexual orientation, relationship status, gender identity, disability, race or religion</li> <li>e) trade in the reproductive capabilities of persons and the exploitation of people including children for commercial ends raise health and ethical concerns</li> <li>f) persons born as the result of the use of donated gametes have a right to information about their genetic heritage and biological parents</li> <li>g) the provision of ART must be transparent and open to scrutiny, while ensuring the protection of the privacy of</li> </ul>	<p><b>Supported.</b></p> <p>The proposed legislation will contain these Principles to help guide the actions of providers and regulators carrying out their activities under the Act.</p>

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	<p>all persons and their partner (if any) involved in ART, and persons born, to the degree that is protected by law</p> <p>h) licensed ART providers must provide safe, person-centred services and foster continuous improvement in the safety and quality of treatment procedures they provide</p> <p>i) the provision of ART must be underpinned by policies that support effective and efficient practices that minimise interventions not supported by evidence of successful clinical outcomes.</p>	
6.	<p>That the sections of the proposed legislation which address eligibility criteria and other associated matters involving access to ART and surrogacy be made effective as soon as possible after commencement of the proposed legislation.</p> <p>That there be a minimum 6-month period between commencement of the ARTS Act and implementation of the proposed legislation for other aspects of the legislation.</p>	<b>Supported.</b>
7.	That proposed legislation be reviewed 3 years after the date the Act (or review provision) comes into operation and every 5 years thereafter.	<b>Supported.</b>
<b>Part B:</b>	<b>Legislation for research involving excess ART embryos and prohibition of cloning for human reproduction</b>	
8.	<p>That there be a single piece of WA legislation to align with the 2 Commonwealth Acts, namely the <i>Research Involving Human Embryos Act 2002</i> (Cth) (Research Involving Human Embryos Act) and the <i>Prohibition of Human Cloning for Reproduction Act 2002</i> (Cth) (Prohibition of Human Cloning for Reproduction Act). This legislation would be separate to the proposed legislation addressing ART treatment and practice in WA.</p> <p>Legislation regulating research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence in WA, and prohibition of human cloning for reproduction and other prohibited practices, would commence at the same time as the proposed legislation for ART practice.</p>	<p><b>Supported.</b></p> <p>Proposed WA legislation regulating research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence; and prohibited practices is required to reflect the Objectives of the two Commonwealth Acts.</p>
9.	That proposed legislation regarding research involving excess ART embryos and embryos formed by means other than fertilisation under a NHMRC licence should be constructed in a manner that allows for flexibility, responsiveness, and regular review in anticipation of further advances in science, medicine and emerging technologies in ART treatment and practice.	<b>Supported.</b>

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<b>Part C:</b>	<b>Access to ART</b>	
10.	<p>That proposed legislation enable access to ART, including surrogacy and reciprocal IVF for any person and partner (if any) who meets the following eligibility criteria:</p> <ul style="list-style-type: none"> <li>a) the person and partner (if any) are unlikely to conceive other than by an ART procedure</li> <li>b) the person and partner (if any) are unlikely to be able to carry a pregnancy to term or give birth to a healthy child without an ART procedure</li> <li>c) the person and partner (if any) is at risk of transmitting a genetic condition or genetic disease to a child born as a result of a pregnancy conceived other than by an ART procedure, including a genetic abnormality or genetic disease when the person or their partner (if any) is the carrier</li> <li>d) where the treating clinician has assessed the person and believes that ART is appropriate having regard to all current and future physical, psychological and social circumstances.</li> </ul>	<p><b>Supported.</b></p> <p>These eligibility criteria will expand options for Western Australians to become a parent(s) using ART irrespective of marital status and gender.</p>
11.	<p>That proposed legislation use gender-inclusive language and refer to ‘person’ and ‘they/them’ instead of ‘woman/man’ and ‘he/she’, and use anatomical language where this is appropriate.</p>	<p><b>Supported.</b></p>
12.	<p>That proposed legislation exclusively use the term partner in reference to members of a couple who are seeking access to ART, with the term defined in the legislation as either:</p> <ul style="list-style-type: none"> <li>a) the person’s legal spouse irrespective of gender (other than a spouse from whom the person has separated)</li> <li>b) the person’s de facto partner irrespective of gender, who has lived with the first person on a genuine domestic basis for a minimum of 3 months</li> <li>c) a person not currently married or living in a de facto relationship, but where there is an established relationship.</li> </ul>	<p><b>Supported.</b></p>
13.	<p>That proposed legislation will require:</p> <ul style="list-style-type: none"> <li>a) implications counselling for the donor and recipient(s) by an Australian and New Zealand Infertility Counsellors Association (ANZICA) eligible counsellor (or overseas equivalent) prior to the donor and recipient(s) providing written valid consent to proceed</li> <li>b) the gamete and medical screening period run concurrently with the implications counselling for known donors and recipients</li> <li>c) at any stage during the period for gamete screening or implications counselling, any party to the ART arrangement may choose not to proceed with the process.</li> </ul>	<p><b>Supported.</b></p>

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14.	<p>That proposed legislation maintains the existing worldwide five-family limit for using donor gametes or embryos from the same donor to create or extend a family, with penalties or conditions on a licence introduced for exceeding the limit. In circumstances where exceptions are sought, these should be considered by the AARB. Exceptions will not be considered unless there are extraordinary circumstances that will affect the wellbeing of the child(ren). No exception will be considered unless donor information is available.</p>	<p><b>Supported.</b></p>
15.	<p>That licensed ART providers in WA be permitted to request or conduct genetic testing of embryos as follows:</p> <ol style="list-style-type: none"> <li>testing for monogenic and single gene disorders and testing for structural chromosomal arrangements using a list of approved conditions for which genetic testing can be conducted without the need for further approval</li> <li>genetic testing for aneuploidy when genetic testing for monogenic and single gene disorders or genetic testing for structural chromosomal arrangements is requested by a treating ART clinician</li> <li>other use of genetic testing for aneuploidy will be at the discretion of the treating fertility specialist who can use testing when they deem it clinically appropriate</li> <li>genetic testing of embryos for non-medical reasons (including sex-selection for family balancing) is prohibited</li> <li>use of genetic testing should align with the NHMRC Ethical Guidelines on the use of ART.</li> </ol> <p>For conditions not included on the list of approved conditions, licensed ART providers must apply to the AARB for the condition to be added to the list. In making its decision, the AARB can refer the application to a gene review panel who will advise the AARB.</p> <p>All patients receiving genetic testing for monogenic and single gene disorders, and genetic testing for structural chromosomal arrangements will need to receive counselling from a clinical geneticist and/or genetic counsellor prior to testing being performed.</p>	<p><b>Supported.</b></p> <p>The use of the word <i>should</i> in point e) will allow flexibility for WA regulators if there are changes to NHMRC Guidelines in the future that are not consistent with WA legislation or the intent of WA legislation.</p>
16.	<p>That proposed legislation permits genetic testing for the purpose of tissue typing an embryo (human leukocyte antigen (HLA) typing) for subsequent stem cell therapy for a parent, sibling or other relative who requires tissue or organ donation due to illness. Use of genetic testing for HLA tissue typing should align with the NHMRC Ethical Guidelines on the use of ART.</p> <p>Genetic testing of embryos for the purpose of supporting approved mitochondrial donation techniques for the treatment of mitochondrial disease will be permitted,</p>	<p><b>Supported.</b></p>

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	<p>following any introduction of mitochondrial donation in WA.</p> <p>All applications for genetic testing of embryos for the purpose of tissue typing or to support mitochondrial donation techniques must be approved by the AARB. In making its decision the AARB can seek the advice of a gene review panel.</p>	
17.	<p>That proposed legislation be drafted in a manner allowing flexibility in response to emerging scientific and medical evidence, advances in technology and clinical practice relating to genetic testing of embryos.</p>	<b>Supported.</b>
18.	<p>That proposed legislation permits reciprocal IVF. Reciprocal IVF enables one person to contribute their oocyte (egg) in order to create an embryo that will be carried to term by their partner.</p> <p>The partner's oocyte(s) used in reciprocal IVF will not be considered as donor material in the proposed ART legislation.</p> <p>Consent for embryo creation for the purpose of reciprocal IVF must include written direction regarding the use, on-donation or removal from storage of the embryos, including in the event of the death of either partner or separation of the partners.</p>	<b>Supported.</b>
19.	<p>That proposed legislation continues to permit the collection of gametes and reproductive tissue from a person who is deceased, and also permit collection from a person who is near death (dying) and unable to provide consent. This is to preserve the option for intended future reproductive purposes by the person's surviving partner. Collection must be consistent with the elements outlined in s 22 of the <i>Human Tissue and Transplant Act 1982</i> (HTT Act) being met and alignment with the NHMRC Ethical Guidelines for the use of ART using the following criteria:</p> <ol style="list-style-type: none"> <li>a) the dying person left clearly expressed oral or written directions consenting to the collection (retrieval) of their gametes or reproductive tissue in the event they are near death or following their death, or there is some evidence that the person would have supported the collection of their gametes or tissue for use by their partner</li> <li>b) where the deceased person left no instructions, the designated officer shall consider any information that supports the intention of the deceased person to have a child following their death, or determine there is no evidence that the deceased person would have objected to the use of their gametes, reproductive tissue or embryos by their surviving partner</li> </ol>	<b>Supported.</b>

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<p>c) if a person expressly objected to the collection of their gametes or reproductive tissue, then collection is prohibited</p> <p>d) the person was an adult at the time of their death</p> <p>e) the request for collection has come from the partner of the person who is near death, unless the partner is temporarily incapacitated, then the senior available next of kin may make this request on the surviving partner’s behalf</p> <p>f) the gametes or tissue collected are only for use by the partner, using a surrogate if required, for the purposes of bearing a child(ren) who will be cared for by the partner.</p>	
<p>20. That proposed legislation permits the posthumous use of:</p> <ul style="list-style-type: none"> <li>• embryos created from the gametes of a person who subsequently dies</li> <li>• gametes and reproductive tissue collected prior to, or after a person’s death.</li> </ul> <p>Use is subject to meeting the below criteria:</p> <p>a) the best interests of the person(s) to be born will be a primary consideration for any posthumous use of gametes, reproductive tissue or embryos</p> <p>b) the deceased person left clearly expressed oral or written directions consenting to the use of their gametes, reproductive tissue or embryos following their death, or there is some evidence that the deceased person would have supported the posthumous use of their gametes, tissue or embryos by their surviving partner. If a person has expressly objected to the posthumous use of their stored gametes, reproductive tissue or embryos, use to achieve pregnancy is prohibited</p> <p>c) where the deceased person left no instructions, the AARB shall consider any information that supports the intention of the deceased person to have a child following their death, or determine there is no evidence that the deceased person would have objected to the use of their gametes, reproductive tissue or embryos by their surviving partner</p> <p>d) the deceased was an adult at the time of their death</p> <p>e) the request to use the gametes, reproductive tissue or embryos will only be by the person’s surviving partner, including use of a surrogate, for the purposes of bearing a child(ren) who will be cared for by the surviving partner</p>	<p><b>Supported.</b></p>



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	<p>f) the surviving partner has undergone appropriate implications counselling and has been provided with sufficient information to facilitate an accurate understanding of the potential social, psychological and health implications for the person who may be born</p> <p>g) sufficient assessment has been made that the surviving partner’s grief and related emotions have been addressed to ensure their effective decision-making</p> <p>h) use will require approval by the proposed AARB and will align with the requirements of the NHMRC Ethical Guidelines on the use of ART, unless otherwise specified in the proposed legislation.</p> <p>The MEP recommends that the collection, storage and use of all reproductive material to be used for intended reproductive purposes is regulated under the proposed ART legislation. This would include posthumous collection of gametes and reproductive tissue. The MEP notes this will require amendment to the HTT Act.</p>	
21.	<p>Where a child is born as the result of the posthumous use of a deceased partner’s gametes or an embryo created with such gametes in an artificial conception procedure, that provision in the <i>Births, Deaths and Marriages Registration Act 1998</i> be made to enable the deceased person to be listed on the child’s birth certificate as a parent of that child.</p>	<p><b>Supported.</b></p>
22.	<p>That, consistent with the principles for the proposed legislation outlined in recommendation 5, prerequisites for a valid surrogacy arrangement include:</p> <p>a) the intended parent(s), and the surrogate and partner (if any) are all 18 years of age or older</p> <p>b) the intended parent(s) be ordinarily resident in WA at the time an application for parentage is made and the Family Court have the discretion to dispense with the residency requirements</p> <p>c) the intended parent(s) and the surrogate receive separate legal advice from separate lawyers, not in the same practice</p> <p>d) the parties’ intentions and agreement be documented and executed in a written agreement</p> <p>e) in determining eligibility, the treating ART clinician should have regard to medical and psychosocial suitability of all participants and undertake an appropriate risk assessment regarding these factors</p> <p>f) the intended parent(s) and the surrogate must undertake implications counselling at the following</p>	<p><b>Supported.</b></p> <ul style="list-style-type: none"> <li>• In all Australian legislation, all persons aged from 18 years are recognised as adults with sufficient maturity to responsibly comply with Australian legislation.</li> <li>• The requirement for all parties to have participated in implications counselling, and to have received independent legal advice from separate lawyers, is intended to ensure all persons are sufficiently informed and prepared to effectively consent prior to ART treatment.</li> <li>• Intended parent(s) should be ordinarily resident in WA at the point the surrogacy arrangement was entered into (written agreement). This is to provide</li> </ul>



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	<p>times as a minimum:</p> <ul style="list-style-type: none"> <li>• separate implications counselling prior to ART treatment</li> <li>• joint implications counselling prior to ART treatment</li> </ul> <p>g) known donors receive joint implications counselling with the intended parent(s) prior to donation, and separate implications counselling as required for any gamete or embryo donation</p> <p>h) unknown donors will have advice/consent provided/obtained at the time of donation and are therefore not required to undertake counselling or provide consent to the use of their gametes/embryos in a surrogacy arrangement.</p>	<p>assurance of residency at the start of the surrogacy arrangement prior to ART treatment.</p>
23.	<p>That the proposed legislation include provision for licensed ART providers to seek advice from the AARB in relation to concerns the licensed ART provider may have about a potential surrogacy arrangement.</p>	<p><b>Supported.</b></p>
24.	<p>That surrogacy arrangements remain unenforceable except for the current exceptions for agreed reimbursement of expenses detailed in the surrogacy arrangement and the Family Court's discretion to dispense with the consent of the surrogate.</p>	<p><b>Supported.</b></p>
25.	<p>That the parentage of a person already born via an overseas surrogacy arrangement where that child has been granted citizenship by descent, has their parentage recognised by operation of law and reflected on their WA birth certificate.</p> <p>That parentage can include the person who provided their gametes and their partner (if any).</p> <p>This arrangement should only apply to persons born via an overseas surrogacy arrangement prior to the commencement and up to 2 years after the commencement of the new legislation.</p>	<p><b>Supported in principle.</b></p> <p>Noting limitations on the Department of Justice in existing legislation and international best practice that will need to be considered.</p>
26.	<p>That surrogates continue to be eligible for reimbursement for actual incurred costs due to the surrogacy arrangement. Reimbursement be expanded to include reasonable travel, accommodation and childcare expenses, with particulars detailed in ART regulations. Penalties to remain where a surrogate has received money for reward or other material benefit due to the surrogacy arrangement.</p>	<p><b>Supported.</b></p>
27.	<p>That proposed legislation permits licensed ART providers in WA to advertise for, and recruit, potential altruistic surrogates. Prospective intended parents and</p>	<p><b>Supported.</b></p>

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	<p>surrogates continue to be allowed to advertise their willingness to enter an altruistic surrogacy arrangement. Formal introduction through a licensed ART provider should be permitted, as should introduction of parties via informal channels, so long as the process remains altruistic and not for reward.</p>	
<b>Part D:</b>	<b>Regulation</b>	
28.	<p>That proposed legislation establishes a framework for regulating and governing ART in WA. The regulatory system will:</p> <ul style="list-style-type: none"> <li>a) set the parameters for access and eligibility to ART</li> <li>b) address safety and quality in delivery of services providing ART, including reporting of adverse events</li> <li>c) establish the requirements for licensing and monitoring of licensed ART providers in WA</li> <li>d) establish the requirements for reporting of data and information by licensed ART providers or the RT Registers</li> <li>e) allow flexibility to address regulatory stewardship and risk-based regulation</li> <li>f) allow the CEO to investigate and respond to complaints related to ART</li> <li>g) establish an ART Advisory and Review Board to support the Minister for Health and the CEO with their responsibilities to administer the legislation.</li> </ul> <p>Under proposed legislation:</p> <ul style="list-style-type: none"> <li>a) licensing functions will remain with the CEO, who will have the ability to delegate some responsibilities to appropriate officers within the department</li> <li>b) the CEO will retain powers to investigate a breach of the legislation or participant complaints</li> <li>c) the CEO will retain powers to impose conditions on licensing of WA ART providers, and may impose penalties for non-compliance and determine disciplinary action with the ability for the licensed ART provider to seek review in the</li> </ul>	<p><b>Supported.</b></p>

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<p>State Administrative Tribunal</p> <p>d) ART clinical practitioners in WA must be registered with the Australian Health Practitioner Regulation Agency (AHPRA) or be eligible for membership of their relevant professional body</p> <p>e) licensing of ART providers will require that they comply with:</p> <ul style="list-style-type: none"> <li>• relevant WA and Commonwealth legislation</li> <li>• applicable standards and guidelines as defined in regulations and directions under proposed legislation, including relevant standards set by national regulators, industry codes of practice, national ethical guidelines for ART, and standards developed by the WA regulator</li> </ul> <p>f) the Minister for Health and CEO may issue directives from time to time, as required.</p>	
<p>29. That proposed legislation establishes a WA ART Advisory and Review Board (AARB) that will:</p> <p>a) provide information on its own initiative or upon request to the Minister for Health and/or CEO regarding regulation and governance of ART in WA</p> <p>b) provide advice on its own initiative or upon request to the Minister for Health and/or CEO regarding trends and issues relating to the medical, social, scientific, legal and ethical/moral issues arising from ART</p> <p>c) provide guidance (but not legal advice) where requested, to licensed ART providers for matters relating to a potential surrogacy arrangement, noting that under proposed legislation the AARB does not approve surrogacy arrangements and decision-making lies with the clinician(s)</p> <p>d) provide guidance (but not legal advice) where licensed ART providers seek further assistance or where a clinician has concerns regarding issues beyond the eligibility criteria</p> <p>e) approve applications for:</p>	<p><b>Supported.</b></p>

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<ul style="list-style-type: none"> <li>• genetic testing of embryos for conditions outside of the list of approved conditions for genetic testing</li> <li>• addition of a condition to the list of approved conditions for genetic testing</li> <li>• genetic testing of an embryo for tissue typing or to support mitochondrial donation techniques</li> <li>• use of posthumously collected gametes or reproductive tissue for intended reproductive purposes where conditions of use are met</li> <li>• posthumous use of previously stored gametes, reproductive tissue or embryos for intended reproductive purposes in the absence of written consent from a now deceased person for such posthumous use</li> <li>• exceptions to the five-family limit.</li> </ul> <p>For matters where approval decisions are made by the AARB, there will be a review process enabling AARB decisions to be referred to the State Administrative Tribunal.</p> <p>The AARB will have the capacity to seek further specialist input for specific matters, as required. For matters relating to genetic testing of embryos, the AARB will be supported by a gene review panel that will function as an ad-hoc committee to inform the AARB on applications and matters related to genetic testing.</p>	
<p>30. That the Minister for Health appoint membership of the AARB for terms of 3 years with the option of one additional term. The AARB to comprise 8 members, including the Chair, being:</p> <ul style="list-style-type: none"> <li>a) 2 suitably qualified specialist medical practitioners, at least one with significant experience in ART such as RANZCOG certification in reproductive endocrinology and infertility (CREI) or similar</li> <li>b) a legal practitioner with extensive experience in family law, infertility law and surrogacy matters</li> <li>c) a representative from the WA State Solicitor’s Office</li> </ul>	<p><b>Supported in principle.</b></p> <p>Noting that it is important in considering membership to ensure separation of regulatory functions from the role of the ART Advisory Board.</p>

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<p>d) a person who has accessed ART or a person born of ART</p> <p>e) an ethicist with experience in medical and social ethics</p> <p>f) a counsellor eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA)</p> <p>g) a WA ART regulator from the department (ex officio member).</p> <p>Membership terms and operational matters for the AARB will comply with directives and instructions and policies for WA Government boards and committees.</p>	
<p>31. That proposed legislation allows the time for storage of gametes and embryos to be determined by a written agreement between the licensed ART provider and the person or persons for whom the gametes or embryos will be stored.</p> <p>Under WA licensing requirements:</p> <p>a) the storage of gametes and embryos by licensed ART providers will align with the NHMRC Ethical Guidelines on the use of ART</p> <p>b) storage of gametes and embryos must be with the valid, written consent of the parties</p> <p>c) consent for storage must capture decisions regarding the management and plan for:</p> <ul style="list-style-type: none"> <li>• embryos no longer needed by a person or persons for their own reproductive purposes</li> <li>• disputes between members of a couple for whom an embryo is stored</li> <li>• stored gametes or embryos in the event of the death of a gamete provider, including that gametes or embryos should not be stored beyond the death of the gamete provider unless there is valid, written consent for the posthumous use of the gametes or embryos by the surviving partner</li> <li>• the removal of gametes and embryos from storage.</li> </ul> <p>d) licensed ART providers will be required to have clear policies relating to storage of gametes and</p>	<p><b>Supported.</b></p>

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	<p>embryos that comply with requirements of the legislation and align with the NHMRC Ethical Guidelines on the use of ART</p> <p>e) should ownership of the licensed ART provider transfer to another entity, the original contract for storage must be upheld until an alternative contract is in place</p> <p>f) at the end of the storage period specified in the consent form, if the person(s) responsible for the stored gametes or embryos cannot be contacted to provide further direction and consent, a licensed ART provider may after a further 2 year period (in which further attempts to contact the person(s) are made) remove the gametes or embryos from storage in accordance with the provider’s policy.</p>	
32.	<p>That proposed legislation requires licensed ART providers to ensure compliance with all regulatory requirements before accepting imported donor gametes and embryos into WA. Licensed ART providers must confirm that:</p> <p>a) the gametes and/or embryos will be used only in an ART procedure, or for approved research</p> <p>b) the donation is altruistic and complies with State and Commonwealth legislation which prohibits commercial trade in human gametes and embryos</p> <p>c) there is compliance with the five-family limit</p> <p>d) all information required for submission to the RT Registers is available as would be required had the gametes and/or embryos been donated in WA</p> <p>e) the donor has received counselling to a standard equivalent to counselling provided to donors in WA</p> <p>f) the donor has given informed consent prior to the donation being made.</p> <p>Before exporting donated gametes and/or embryos from WA, the licensed ART provider must obtain confirmation in writing from the receiving fertility provider that:</p> <p>a) information required for the RT Registers about the ART treatment(s) using the exported gametes and/or embryos will be provided to</p>	<p><b>Supported in principle.</b></p> <ul style="list-style-type: none"> <li>• It is intended that the current criteria for the import and export of gametes and embryos reflect the Principles of proposed legislation including that the best interest of the person born as a result of ART is paramount.</li> <li>• This recommendation is supported in principle as it is intended that the AARB should receive for approval applications for the import and export of gametes or embryos for the following situations: <ul style="list-style-type: none"> <li>a) for the importation of donor gametes where the request is specifically to exceed the world-wide five-family limit, that will continue to apply in WA. Such requests will require demonstration of exceptional circumstances</li> <li>b) to import embryos created using donor gametes where there are other children already born using the same donor, or existing embryos in storage with no further opportunity to create more embryos</li> <li>c) when there is a significant health risk to a person and</li> </ul> </li> </ul>

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<p>the exporting ART provider for submission to the RT Registers</p> <p>b) identifying information about the recipient(s) of the gametes and/or embryos to be exported, will be provided to the exporting ART provider in order that the required information may be submitted to the RT Registers</p> <p>c) the recipient(s) consent will be recorded, and the recipient(s) will be advised that their identifying information will be submitted to the RT Registers.</p> <p>AARB approval is required in exceptional circumstances where the above criteria are not met. The decision of the AARB will reflect the legislative principles. Exceptions will not be considered unless there are extraordinary circumstances that will affect the wellbeing of the child(ren). Penalties will apply if licensed ART providers do not comply with all regulatory requirements.</p>	<p>HLA tissue typing is necessary</p> <ul style="list-style-type: none"> <li>• All other criteria for the import or export of gametes and embryos would remain a requirement of legislation which will not require approval by the AARB.</li> <li>• This recommendation preserves the elements of the current HRT Act to prohibit commercial trade of gametes and embryos, and to ensure informed consent prior to donation of gametes and embryos, and that donor-conceived persons have a right to information about their genetic heritage.</li> </ul>
<p>33. That proposed legislation will outline the conditions of licensing and registration requiring that:</p> <p>a) licensed ART providers do not engage in false or misleading advertising or practices in relation to treatments or practices that may be considered experimental, do not have a sound evidence-base, or are not supported by research to improve birth outcomes</p> <p>b) all participants in an ART treatment procedure must provide informed consent prior to the treatment procedure being performed and must receive appropriate written information including the rationale for any treatments offered to the person undergoing ART or to the gametes/embryos that will be used in the person’s treatment</p> <p>c) licensed ART providers do not provide treatments that are of unknown efficacy unless it is part of a clinical trial where ethics approval and informed consent has been granted</p> <p>d) licensed ART providers do not provide treatments that are unnecessary or motivated by interests that are non-therapeutic.</p> <p>If the regulator has concerns about the practice of a licensed ART provider, the CEO may commission an</p>	<p><b>Supported.</b></p>



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<p>investigation which may involve experts within or outside of WA.</p>	
<p><b>Part E:</b></p> <p><b>Data collection and registers</b></p>	
<p>34. That proposed legislation be drafted with flexible, but clearly defined provisions around the collection, access and use of reproductive technology data. The ability to link with other datasets, including but not limited to the WA Midwives Notification System (MNS), should be enabled. Licensed ART providers should ensure that all birth outcomes are shared with the department for inclusion on the RT Registers.</p> <p>Opportunities for collecting and linking data about ART participants and children born of ART should be identified to meet the following important objectives:</p> <ul style="list-style-type: none"> <li>a) to monitor health outcomes, including long-term health outcomes, for ART participants and persons born of ART</li> <li>b) for safety, quality and assurance purposes including monitoring and compliance undertaken by the department as a regulator of ART, including the monitoring of adverse events</li> <li>c) for approved research purposes.</li> </ul> <p>A statutory duty will remain to record information between parties to donor conception or surrogacy to enable future matching.</p>	<p><b>Supported in principle.</b></p> <p>That proposed legislation be drafted to enable flexibility, but with defined provisions that will continue to address the collection, access, disclosure, and use of reproductive technology data, and the protection of an individual’s health information. This is supported in principle as future legislation must support achievement of desired objectives without limiting the operational methods used for data preparation and disclosure.</p>
<p>35.</p> <p>That proposed legislation should enable donor-conceived persons to have access to identifying information about their donor(s) when they reach 16 years of age regardless of when they were born, subject to a contact preference system and availability of records. Until the donor-conceived child has reached 16 years of age, their parent(s) should be able to access identifying information about their donor(s). To support this, the MEP recommends a broad public education and information campaign.</p>	<p><b>Supported.</b></p> <p>Donor-conceived persons will be supported to access identifying information about their donor(s), regardless of when they were born, subject to the availability of records.</p> <p>Prior to April 1993, the Department of Health had no statutory duty to record information regarding treatments using donations that occurred. Records of births for this time period are therefore limited.</p> <p>Some records are held for the period between April 1993 and 1 December 2004. At the time, it was not mandatory for donors to</p>

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		<p>consent to identifying information being released to donor-conceived people.</p> <p>Since 1 December 2004, donors are required to consent to their identifying information being released to their donor-conceived offspring after the person has attained 16 years of age. The proposed legislation will continue to mandate this practice.</p> <p>Due to advances in technology, including the availability of low-cost DNA tests and social media, anonymity is no longer guaranteed for people who donated gametes prior to 1 December 2004.</p> <p>The removal of donor anonymity for donations made prior to 1 December 2004, where information is available, is supported.</p> <p>Legislative changes will be accompanied by an education campaign for parties to donor conception. All parties will be encouraged to lodge their contact preference, which may include a preference for no contact.</p> <p>Contact between parties will only be facilitated with the consent of all parties.</p>
36.	That proposed legislation requires licensed ART providers to notify all donors whose gametes are used following commencement of the legislation, of any births resulting from their donation and provide information about the sex assigned at birth and year of birth.	<b>Supported.</b>
37.	That proposed legislation requires licensed ART providers to keep all existing records about ART, including historical records that predate the HRT Act. Penalties should be introduced should a licensed ART provider intentionally destroy any records, particularly those relating to donor conception.	<b>Supported.</b>

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<p>38. That the Donor Conception Information Service (DCIS) should be expanded to support donor-conceived persons 16 years of age and over to obtain identifying information about their donor(s), regardless of when they were conceived, where information is available.</p> <p>That donors will have access to identifying information regarding their donor-conceived offspring, only with the consent of that person, and where information is held. Donor-conceived persons would be supported by the service to lodge a contact preference should a donor request information about them. The DCIS should offer appropriate intermediary support and counselling when successful matching of parties has occurred. All parties to a donation should be encouraged to lodge their contact details and contact preferences with the DCIS. This will facilitate information sharing between parties, and where contact is desired by the parties and information is available, the DCIS will facilitate contact that is informed by the preferences lodged by all parties.</p>	<p><b>Supported.</b></p> <p>A donor-conceived person’s consent will be required prior to any identifying information being provided to a donor.</p> <p>In limited circumstances, a donor seeking information about a donor-conceived person may result in donor-conceived persons becoming aware of their status. The DCIS will offer implications counselling and support in these instances.</p> <p>Contact between parties will only be facilitated with consent of all parties.</p>
<p>39. That resources be provided to the DCIS to deliver services and introduce a public information campaign to advise all parties to donation of the proposed changes to the legislation.</p>	<p><b>Supported.</b></p>
<p>40. That the department works with the Registry of Births, Deaths and Marriages (BDM) to adapt the birth registration form to enable the recording of donor conception or surrogacy. That legislation should enable BDM to verify the details of children born from donor conception or surrogacy once the birth registration form is submitted by the parents recording the use of donor conception or surrogacy.</p>	<p><b>Supported.</b></p>
<p>41. That the <i>Births, Deaths and Marriages Registration Act 1998</i> should be amended, and the department should work with BDM, to permit addendums to be added to birth certificates for all future children born from donor conception or surrogacy once they reach 16 years of age, in the event a donor-conceived person contacts BDM for a copy of their birth certificate. Licensed ART providers should advise recipient(s) or intended parents of this approach at the time of treatment to ensure they understand that information may be disclosed to their child from 16 years of age. The proposed legislation should expressly recognise that donor-conceived persons, and people born via surrogacy, have</p>	<p><b>Supported.</b></p>

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	the right to request replacement birth certificates that reflect accurate information about both their biological and legal parentage from 16 years of age. This should be retrospective where accurate information is held and would not confer any legal obligations on the donor.	
<b>Part F:</b>	<b>Other matters</b>	
42.	That the Minister for Health consider a request to the Commonwealth Government to explore ways to expand the Medicare Benefits Schedule (MBS) to include IVF in surrogacy arrangements. Medicare rebates should be accessible for anyone who meets the eligibility criteria for ART.	<b>Noted.</b>
43.	That the Minister for Health and/or the CEO of the department explore further options for promoting the advantages and benefits of using a licensed ART provider when persons access donated reproductive material or services.	<b>Noted.</b>
44.	That the Minister for Health and/or the CEO of the department explore options for increasing provision for ART services in WA, including expansion of resources for public ART treatment, and opportunities to support travel and accommodation to access ART.	<b>Noted.</b>
45.	That proposed ART legislation allows for the provision of 'delegated practitioners', who are clinicians who can undertake some limited ART procedures in regional WA with the support, approval and supervision of a licensed ART provider, with the list of delegated practitioners expanded to include registered nurses and midwives.	<b>Supported.</b>
46.	That the Minister for Health and/or the CEO of the department explore options to: <ul style="list-style-type: none"> <li>• provide information to Aboriginal people about fertility preservation through gender specific education campaigns aimed at protecting fertility and identifying potential infertility</li> <li>• expand access to ART services for Aboriginal people</li> <li>• require licensed ART providers to report the number of Aboriginal clients treated</li> <li>• monitor licensed ART providers to ensure delivery of culturally safe care.</li> </ul>	<b>Noted.</b>