

LEGISLATIVE ASSEMBLY

INFERTILITY TREATMENT AMENDMENT BILL 2007

(Amendments to be moved by Ms Campbell)

1. Clause 6, page 4, lines 23 to 31 and page 5, lines 1 to 15, omit all words and expressions on those lines and insert the following—
 - "(a) each person who produced a gamete that was used to form the embryo has agreed, in writing, is unsuitable for implantation; and
 - (b) is one of the following—
 - (i) a human embryo that is diagnosed by pre-implantation genetic diagnosis as unsuitable for implantation, in accordance with the Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004), issued by the Chief Executive Officer of the NHMRC;
 - (ii) a human embryo that is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the Chief Executive Officer of the NHMRC under the National Health and Medical Research Council Act 1992 of the Commonwealth and prescribed by the regulations under the Commonwealth Act for the purposes of paragraph (b) of the definition of unsuitable for implantation in section 7(1) of that Act;"
2. Clause 7, page 6, lines 18 to 25, omit all words and expressions on those lines and insert the following—
 - "(1) A person commits an offence if the person undertakes research or training involving the fertilisation of a human egg by a sperm, outside the body of a woman, for the purposes of research or training in ART and—
 - (a) the research is not in accordance with relevant NHMRC guidelines; or"
3. Clause 9, line 14, omit "section 21EA" and insert "sections 21EA and 21EB".
4. Clause 9, page 8, line 2, omit 'licence.'" and insert "licence.".
5. Clause 9, page 8, after line 2, insert—

'21EB Person may be civilly liable for conduct authorised under this Act

- (1) A person is not relieved from liability for negligence in relation to anything done or omitted to be done by the person, including for loss of life, medical impairment, loss of fertility or any adverse medical effects, merely because the conduct or failure was purportedly authorised under this Act or a provision of a licence.
 - (2) For the purposes of subsection (1), a licensee of a licensed centre must have a risk management strategy in place for research conducted at the licensed centre, including a comprehensive insurance policy to cover liability arising out of anything done or omitted to be done in the course of the research.".'.
6. Clause 10, lines 29 to 33 and page 9, lines 1 to 5, omit all words and expressions on those lines and insert—
- "(f) the obtaining of a human egg from another person for research, but only if—
 - (i) the applicant does not hold a licence under this Act to conduct treatment procedures; and
 - (ii) the place at which the applicant will obtain the egg is not a place at which treatment procedures are conducted.
 - (1A) A person cannot apply under subsection (1) for a licence authorising the person to do anything mentioned in subsection (1)(a) to (d) in an accredited ART centre (within the meaning of section 21A).".
7. Clause 10, page 9, line 6, omit "(1A)" and insert "(1B)".
8. Clause 10, page 9, after line 12, insert—
- '(2) After section 21H(2) of the Principal Act **insert**—
 - "(3) Also, an application under subsection (1) must be accompanied by evidence—
 - (a) that the person applying for the licence has established an ethics committee, accredited by the NHMRC; and
 - (b) that the ethics committee has regular meetings and assesses research projects; and
 - (c) that the person has submitted the application to the person's ethics committee; and
 - (d) that the research the subject of the application has been tested in non-human research; and
 - (e) of any other matter required by the NHMRC in accordance with the Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004), issued by the Chief Executive Officer of the NHMRC.".'.
9. Clause 12, page 10, lines 15 to 33, omit all words and expressions on these lines.

10. Clause 13, line 5, omit "creations" and insert "creation".
11. Clause 14, omit this clause.
12. Clause 15, omit this clause.
13. Clause 30, omit this clause.
14. Clause 33, line 17, after "**chimeric**" insert "**or hybrid**".
15. Clause 33, lines 18 to 23, omit all words and expressions on these lines and insert—
 'In section 38L(3) of the Principal Act for "10 years" **substitute** "15 years".'.
16. Clause 34, omit this clause.
17. Clause 38, page 20, lines 13 to 34 and page 21, lines 1 to 19, omit all words and expressions on these lines.

NEW CLAUSE

18. Insert the following New Clause to follow clause 38—

'A Adverse events register

After section 62 of the Principal Act insert the following—

"62A Adverse Events Register

- (1) The designated officer of a licensed centre must keep an Adverse Events Register for that centre at the centre or at another place that is specified in the licence for the centre.
Penalty: 50 penalty units.
- (2) The designated officer must ensure that there is recorded in the Adverse Events Register information, as required by subsection (3), about adverse events arising from the donation of gametes and embryos for research including data about, and a description of the outcomes of, the donation of gametes and embryos and the procedures involved in the donation.
Penalty: 50 penalty units.
- (3) The information must be recorded in the Adverse Events Register in a way that will allow it to be used—
 - (a) by the licensed centre to provide information to persons who are donors or prospective donors of gametes and embryos to assist the persons in making decisions about consenting to donations and inform the persons about the possible side-effects of making donations; and

- (b) to facilitate long term studies by the licensed centre of donors of gametes or embryos, including long term adverse outcomes and subsequent effects on fertility; and
 - (c) to facilitate long term studies by the Authority and the NHMRC of the health of donors and persons who have undergone treatment procedures.
- (4) The designated officer must, by 31 July in each year, forward a copy of the Adverse Events Register for the previous year to the Authority for inclusion in the Authority's report to the Minister under section 137."