Australian Government
National Health and Medical Research Council
NHMRC

INVESTING IN AUSTRALIA'S HEALTH
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Senator Gary Humphries
Chair, Community Affairs Committee
Australian Senate
CANBERRA

Via email to: community.affairs@aph.gov.au

# Legislative responses to recommendations of the reports of the Legislation Review Committee on the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* – Supplementary Information

Dear Senator Humphries

Thank you for the opportunity to appear before the Committee last Friday (20 October 2006). At that time I undertook to provide the Committee with some supplementary material and answers to questions taken on notice. I have pleasure in providing that information.

## *1. Numbers of embryos used for treatment of disease*

The only licence issued for the generation of human embryonic stem cell lines aimed at treating a specific condition is to IVF Australia. The inner cell mass is extracted by the licence holder and then transferred to the Diabetes Transplant Unit at the Prince of Wales Hospital with the aim of producing stem cell lines that will be used in the study and treatment of type I diabetes.

This licence authorises the use of no more than 100 excess ART embryos for the derivation of up to six stem cell lines. To date, 30 of these excess ART embryos have been used, resulting in the production of the stem cell line Endeavour-1, which is the second human embryonic stem cell line to be produced without exposure of the cells to animal products.

The other three licences to derive human embryonic stem cell lines are not aimed at a specific disease, though the licence holder has indicated some diseases as examples for downstream applications of these cell lines.

GPO Box 1421, Canberra ACT 2601
Level 5, 20 Allara Street, Canberra City ACT
T. 13 000 NHMRC (13 000 64672) or +61 2 6217 9000 F. +61 2 6217 9100 E. nhmrc@nhmrc.gov.au
ABN 88 601 010 284

## 2. IVF clinics doing research work on diseases under licence

The Diabetes Transplant Unit is an example of collaboration between an IVF clinic and researchers for work not directly related to IVF treatment. Other collaborations are between Monash IVF and Monash University and Melbourne IVF and Stem Cell Sciences. The provisions of the current legislation are that only "a person" may apply for a licence so it is not possible to issue licences to licences to more than one person.

## 3. Embryos in storage

Earlier this year, the Australian Institute of Health and Welfare reported that there were 104,830 embryos in frozen storage in 2003. I can not speculate on how this number may develop in future.

Only a small proportion of the embryos in storage may have been declared to be excess to ART requirements, as most embryos in storage are for use in IVF treatment programs. The NHMRC, together with the Australian Institute of Health and Welfare's National Perinatal Statistical Unit (NPSU) is currently ascertaining exactly how many excess ART embryos are in storage. The feasibility of collecting the required data is the subject of a consultancy between the NHMRC and the NPSU which is due to report in mid 2007. If the outcomes of the feasibility study are supportive, the NHMRC will commission further work to collect these data.

The numbers of embryos authorised for each licence issued by the NHMRC and the number used under each licence is tabulated at Attachment 1.

## 4. Information on application process and other information from NHMRC regarding the embryo research legislation

Eighteen copies of the information package the NHMRC has prepared to explain the embryo research and prohibition of human cloning legislation, including the process for making an application to the Licensing Committee were delivered to the Senate last Friday (20 October 2006).

## 5. Process for appointing members of the Australian Health Ethics Committee (AHEC)

Amendments to the *National Health and Medical Research Council Act 1992* passed this year require that before making appointments to AHEC, the Minister must consult "appropriately". The requirements before that time are set out in Attachment 2.

Yours sincerely

Professor Warwick Anderson
Chief Executive Officer

25 October 2006

**Attachment 1**

| *Licence Number* | *Licence Holder* | *Activity* | *Start date* | *Expiry date* | *Number of Embryos that are Authorised to be:* | | | *Number of Embryos used as at 31 March 2006* **(last reporting period)** |
|---|---|---|---|---|---|---|---|---|
| | | | | | *Thawed specifically for licence* | *Transferred from other licences* | *Used under this licence* | |
| 309700 | Monash IVF | Training | 11 March 2005 | 11 March 2008 | 175* | NA | 105* | 0 |
| 309701 | Sydney IVF | Improvement of embryo culture | 16 April 2004 | 16 April 2007 | 670* | NA | 512* | 0 |
| 309702A | Sydney IVF | Improvement of embryo culture | 16 April 2004 | 16 April 2007 | 170* | NA | 128* | 0 |
| 309702B | Sydney IVF | Development of pre-implantation diagnostic tests | 16 April 2004 | 16 April 2007 | 50 | 170 from 309701 | 220 | 9 |
| 309703 | Sydney IVF | Stem cell derivation | 16 April 2004 | 16 April 2007 | 50 | NA | 50 | 21 |
| 309704 | Melbourne IVF | Development of pre-implantation diagnostic tests | 16 April 2004 | 16 April 2007 | 120 | NA | 120 | 47 |
| 309707 | Monash University | Stem cell derivation | 21 December 2004 | 21 December 2007 | 200 | NA | 200 | 26 |
| 309708 | IVF Australia | Stem cell derivation | 5 November 2004 | 5 November 2007 | 100 | NA | 100 | 30 |
| 309709 | Melbourne IVF | Stem cell derivation | 11 June 2004 | 11 June 2007 | 200 | NA | 200 | 45 |
| | | | | | **TOTAL: 1735** | | | **TOTAL: 178** |

* Under Licences 309700, 309701 and 309702A the number of excess ART embryos permitted to be thawed is greater than the maximum number of embryos permitted to be used. This difference reflects the predicted freeze-thaw survival rate, ie. not all embryos will survive the freeze-thaw cycle. The survival rate differs between IVF clinics.

**Process for making appointments to the Australian Health Ethics Committee before the amendments to the *National Health and Medical Research Council Act 1992* (NHMRC Act) contained in the *National Health and Medical Research Council Amendment Act 2006*.**

The following provisions were repealed from section 36 of the NHMRC Act

(4) The Minister must not appoint a person as Chairperson unless:
  (a) the Minister has consulted with the Health Minister of each State or Territory; and
  (b) the Minister is satisfied that the person has expertise relevant to the functions of the Committee.

(5) The Minister must not appoint the member referred to in paragraph 36(1)(b)[1] unless:
  (a) the Minister has consulted with the Health Minister of each State or Territory; and
  (b) the Minister is satisfied that the person has expertise relevant to the functions of the Committee.

(6) The Minister must:
  (a) before appointing the member referred to in paragraph 36(1)(c), seek nominations from such bodies representing the legal profession as are prescribed for the purpose; and
  (b) before appointing the members referred to in paragraphs 36(1)(d), (f) and (h), seek nominations from such learned academies as are prescribed for the purpose; and
  (c) before appointing the member referred to in paragraph 36(1)(e), seek nominations from such peak religious bodies as are prescribed for the purpose; and
  (d) before appointing the member referred to in paragraph 36(1)(g), seek nominations from such peak public health bodies as are prescribed for the purpose; and
  (e) before appointing the member referred to in paragraph 36(1)(i), seek nominations from such bodies representing the medical profession as are prescribed for the purpose; and
  (f) before appointing the member referred to in paragraph 36(1)(j), seek nominations from such bodies representing the nursing and allied health professions as are prescribed for the purpose; and
  (g) before appointing the member referred to in paragraph 36(1)(k), seek nominations from such bodies responsible for maintaining professional medical standards as are prescribed for the purpose; and
  (h) before appointing the member referred to in paragraph 36(1)(l), seek nominations from such peak consumer organisations as are prescribed for the purpose; and
  (i) before appointing the member referred to in paragraph 36(1)(m), seek nominations from such peak bodies representing people with a disability as are prescribed for the purpose.

Regulations to the NHMRC Act prescribed the bodies to be consulted for the purposes of the above paragraphs.

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[1] a person with knowledge of the ethics of medical research