APPENDIX 3

COUNCIL OF AUSTRALIAN GOVERNMENTS COMMUNIQUE – 5 APRIL 2002

The following extract relating to human cloning, assisted reproductive technology (ART) and related matters is from the COAG communique dated 5 April 2002.

INTRODUCTION

The Council of Australian Governments (COAG) today held its 11th meeting in Canberra. The Council, comprising the Prime Minister, Premiers and Chief Ministers and the President of the Australian Local Government Association (ALGA), had wide ranging discussions on important areas of national interest.

This Communique sets out the agreed outcomes of the discussions.

HUMAN CLONING, ASSISTED REPRODUCTIVE TECHNOLOGY (ART) AND RELATED MATTERS

The Council agreed that the Commonwealth, States and Territories would introduce nationally-consistent legislation to ban human cloning and other unacceptable practices. The Council noted the Commonwealth intends to introduce legislation by June 2002.

The Council agreed that research involving the use of excess assisted reproductive technology (ART) embryos that would otherwise have been destroyed is a difficult area of public policy, involving complex and sensitive ethical and scientific issues. Having noted the range of views across the community, including concerns that such research could lead to embryos being created specifically for research purposes, the Council agreed that research be allowed only on existing excess ART embryos, that would otherwise have been destroyed, under a strict regulatory regime, including requirements for the consent of donors and that the embryos were in existence at 5 April 2002. Donors will be able to specify restrictions, if they wish, on the research uses of such embryos.

The regulation restricting the use of embryos created after 5 April 2002 will cease to have effect in three years, unless an earlier time is agreed by the Council. The Council also agreed to establish an Ethics Committee with membership jointly agreed by the Council to report to the Council within 12 months on protocols to preclude the creation of embryos specifically for research purposes, with a view to reviewing the necessity for retaining the restriction on embryos created on or after 5 April 2002. The Council also agreed to request the National Health and Medical Research Council (NHMRC) to report within 12 months on the adequacy of supply and distribution for research of excess ART embryos which would otherwise have been destroyed.

The Council agreed that research involving the destruction of existing excess ART embryos be permitted under a strict regulatory regime to enable Australia to remain at the forefront of research which may lead to medical breakthroughs in the treatment of

disease. It was further agreed that the regulatory regime governing the use of excess ART embryos that would otherwise have been destroyed will be reviewed within three years. Research would need to have approval from an ethics committee and be in accordance with NHMRC and Australian Health Ethics Committee guidelines. This arrangement will be administered by the NHMRC as the national regulatory and licensing body.

Details of the agreed arrangements on the bans on human cloning and other unacceptable practices and the regulatory regime governing research involving the destructive use of existing excess ART embryos are attached.

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Council of Australian Governments
5 April 2002

ATTACHMENT

ARRANGEMENTS FOR NATIONALLY-CONSISTENT BANS ON HUMAN CLONING AND OTHER UNACCEPTABLE PRACTICES, AND USE OF EXCESS ASSISTED REPRODUCTIVE TECHNOLOGY (ART) EMBRYOS

The Council agreed that the Commonwealth, States and Territories would introduce nationally-consistent legislation to ban human cloning and other unacceptable practices. The Council noted the Commonwealth intends to introduce legislation by June 2002.

It is also intended that this legislation establish a national regulatory regime in relation to the use of excess ART embryos. Given the pace of scientific developments in this area, the Council also agreed that arrangements for research using excess ART embryos will be reviewed within three years.

The arrangements agreed by the Council are as follows.

A nationally-consistent ban on the cloning of a human being

1. The following wording is to be used as the basis for a nationally-consistent ban on the cloning of a human being:

1.1 A person must not:

a) create, or attempt to create, a human clone by means of a technological or other artificial process; or

b) cause a human embryo clone to be placed in the body of a human or animal for any period of gestation.

1.2 For the purposes of establishing that a human clone or human embryo clone is a genetic copy:

a) it is sufficient to establish that the set of genes in the nucleus of the human cell has been copied; and

b) it is not necessary to establish that the copy is an identical genetic copy.

1.3 It is not a defence that the human clone or human embryo clone did not or could not survive.

“Human clone” means a human that is a genetic copy of another living or dead human.

“Human embryo clone” means a human embryo that is a genetic copy of a living or dead human.

“Embryo” is a developing organism from the completion of fertilisation, or initiation of development by any other means, until eight weeks when the organism becomes known as a foetus.

Nationally-consistent regulation of certain unacceptable practices

2. The following practices are unacceptable and should be prohibited in Australia.

2.1 A person must not create or develop an embryo outside the body of a woman:

a) for purposes other than assisted reproduction; or

b) by a process other than the fertilisation of a human ovum by human sperm.

2.2 A person must not create or develop an embryo for assisted reproduction that contains genetic material from more than two people.

2.3 A person must not create or develop an embryo for assisted reproduction that uses any precursor cells of eggs or sperm from an embryo or foetus.

2.4 A person must not maintain an embryo outside the body of a woman after the 14th day of its development excluding any time in which its development has been suspended.

2.5 A person must not alter the genome of a cell of a human being or in vitro embryo such that the alteration is inheritable.

2.6 A person must not conduct embryo flushing.

3. A person must not:

a) create or develop a hybrid embryo; or

b) place a hybrid embryo in the body of a human or animal for any period of gestation.

“Hybrid embryo” means a single living organism which has a mixed genetic origin as a consequence of combining cells derived from humans and other species.

3.2 A person must not:

a) place a human embryo in an animal or in any human body cavity other than the female human reproductive tract; or

b) place an animal embryo in a human for any period of gestation.

3.3 A person must not give or offer valuable consideration to any person for donation of gametes or embryos of that person or of any other person.

“Valuable consideration” includes a discount or priority in the provision of a service but does not include the disbursement of any reasonable expense incurred by a person in connection with a donation of his or her reproductive material.

4. The prohibited practices will be comprehensively reviewed within three years of nationally consistent legislation taking effect, taking into account changes in technology, the potential therapeutic uses for such technology and any changes in community standards.

A nationally-consistent approach to research involving human embryos

5. Research involving human embryos should be regulated through nationally-consistent legislation.

6. The following principles should underpin nationally-consistent legislation:

6.1 legislation should ensure appropriate ethical oversight of research involving embryos based on nationally-consistent standards;

6.2 the nationally-consistent standards should be clear, detailed and describe the ethical issues to be taken into account, research which may be permitted and the conditions upon which it may be permitted (that is, the "rules" to be observed by researchers undertaking work with embryos) and should be based on National Health and Medical Research Council (NHMRC) guidelines as devised by the Australian Health Ethics Committee (AHEC);

6.3 these national standards should be applied consistently throughout Australia, recognising that jurisdictions may use different mechanisms to establish that proposals comply with the national standards;

6.4 the system should provide for public reporting of research involving embryos so as to improve transparency and accountability to the public; and

6.5 the system should enable appropriate monitoring of compliance with the national standards and provide legislated penalties for non-compliance.

7. There is a range of legislative options that could meet these principles including systems of accreditation, licensing or mandating of compliance with the revised AHEC guidelines.

A nationally-consistent approach to the development and/or use of embryos for the derivation of stem cells

8. Research with existing stem cell lines will be permitted to continue in Australia subject to observance of conditions set by NHMRC/AHEC.

9. Research and possible therapeutic applications which involve the destruction of existing excess ART embryos (or which may otherwise not leave the embryo in an implantable condition) will be permitted in accordance with the regulatory regime at Appendix 1.

10. The ban on the development of embryos for purposes other than for assisted reproduction will be maintained and reviewed within three years taking into account the implications for therapeutic use of embryonic stem cells (as detailed in the Health Ministers' report, Chapter 4).

A nationally-consistent approach to ART

11. Accreditation by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia should provide the basis for a nationally-consistent

approach to the oversight of ART clinical practice in Australia, noting that compliance with the NHMRC/AHEC Ethical Guidelines on ART is a key requirement of RTAC accreditation.

12. Individual jurisdictions may choose to mandate RTAC accreditation in legislation or supplement requirements for RTAC accreditation with an additional layer of oversight (for example, through a system of licensing or accreditation of ART service providers).

13. Non-legislative measures should be implemented to improve clarity regarding the role of Human Research Ethics Committees in relation to innovative practice and to increase public reporting of research and innovative practice (as detailed in the Health Ministers' report, Chapter 5).

APPENDIX 1

REGULATORY REGIME CRITERIA FOR RESEARCH USES OF EXCESS ASSISTED REPRODUCTIVE TECHNOLOGY (ART) EMBRYOS

Governments agree to put in place a strict regulatory regime under nationally-consistent legislation and administered by the National Health and Medical Research Council (NHMRC) as the national regulatory and licensing body. The NHMRC would issue a licence for a person to use an excess embryo from an ART programme for research or therapy that damages or destroys the embryo. A licence would only be issued where that project has the approval of an ethics committee established, composed and conducted in accordance with NHMRC guidelines, and that the approval is given on a case by case basis that:

- there is a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed procedure;
- the significant advance in knowledge or improvement in technologies could not reasonably be achieved by other means;
- the procedure involves a restricted number of embryos and a separate account of the use of each embryo is provided to the ethics committee and the national licensing body;
- all tissue and gamete providers involved and their spouses or domestic partners, if any, have consented to research for each embryo used, including by specifying restrictions, if they wish, on the research uses of such embryos; and
- the embryo had been created prior 5 April 2002.

These regulations will be reviewed within three years.

The regulation restricting the use of embryos created after 5 April 2002 will cease to have effect in three years, unless an earlier time is agreed by the Council.

- The Council also agreed to establish an Ethics Committee with membership jointly agreed by the Council to report to the Council within 12 months on protocols to preclude the creation of embryos specifically for research purposes, with a view to reviewing the necessity for retaining the restriction on embryos created on or after 5 April 2002.

- The Council also agreed to request the NHMRC to report within 12 months on the adequacy of supply and distribution for research of excess ART embryos which would otherwise have been destroyed.

5 April 2002