F

Appendix F—NHMRC

Ethical guidelines on assisted reproductive technology (1996) 6 & 11

6 Research on embryos

Research involving early human embryos raises profound moral and ethical concerns. There are differences of opinion amongst Australians regarding the moral status of the human embryo, particularly in its early stages of development.

Some believe that there is the same obligation to refrain from harming an embryo as that which is recognised in relation to human subjects in general. If so, then any destructive or other harmful experimentation would be morally unacceptable to researchers or gamete donors with this belief. Others believe that research which may potentially harm the embryo may be justified where it is undertaken for the direct benefit of other embryos. Still others believe that research which is harmful to embryos may be justified on the basis of advancing knowledge or improving technologies for treatment.

These differences of opinion were understood and reflected in the discussions which led to the development of these guidelines. At the present time these differences cannot be resolved.

6.1 Research on human embryos must take place within the limits prescribed by law. In those States and Territories where there is no relevant legislation such research may only take place according to these guidelines (see also guidelines 11.2).

6.2 Embryo experimentation should normally be limited to therapeutic implantation and development. procedures which leave the embryo, or embryos, with an expectation of

6.3 Non-therapeutic research which does not harm the embryo may be approved by an IEC.

6.4 Non-therapeutic research which involves the destruction of the embryo, or which may otherwise not leave it in an implantable condition, should only be approved by an IEC in exceptional circumstances. Approval requires:

- A likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research;
- That the research involves a restricted number of embryos; and
- The gamete providers, and their spouses or partners, to have consented to the specific form of research (see guideline 3.2.5).

6.5 Protocols for ART in any clinic should take account of the success rates of fertilisation typically achieved in that clinic and, on that basis, seek to avoid the likelihood of production of embryos in excess of the needs of the couple. Techniques and procedures which create embryos surplus to the needs of the infertility treatment should be discouraged.

11 Prohibited/unacceptable practices

The following practices are ethically unacceptable and should be prohibited:

11.1 Developing embryos for purposes other than for their use in an approved ART treatment program.

11.2 Culturing of an embryo in vitro for more than 14 days.

11.3 Experimentation with the intent to produce two or more genetically identical individuals, including development of human embryonal stem cell lines with the aim of producing a clone of individuals.

11.4 Using fetal gametes for fertilisation.

11.5 Mixing of human and animal gametes to produce hybrid embryos.

11.6 Mixing of gametes or embryos of different parental origin so as to confuse the biological parentage of the conceptus.

11.7 Placing an embryo in a body cavity other than in the human female reproductive tract.

11.8 Embryo flushing.

11.9 Commercial trading in gametes or embryos.

11.10 Paying donors of gametes or embryos beyond reasonable expenses.

11.11 The use in ART treatment programs of gametes or embryos harvested from cadavers.