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- For the purposes of the Research Involving Human Embryos Act 2002 these guidelines remain in force in the context of prescribed guidelines under Sections 8 and 21(4)(c) relating to a) obtaining proper consent and b) those to be considered by the NHMRC Licensing Committee when deciding whether to issue a licence authorising use of excess ART embryos.

It is anticipated that regulations giving effect to new guidelines will be made in the near future by the Governor-General and, to that extent, these guidelines may now be regarded as the interim guidelines.

In all other respects the new Ethical Guidelines on the Use of Reproductive Technology in Clinical Practice and Research are those that users should refer to.

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Ethical guidelines on assisted reproductive technology
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Background

1. In October 1982 the National Health and Medical Research Council (NHMRC) issued guidelines on the ethical aspects of research related to the use of assisted reproductive technology (ART) as Supplementary Note 4 (SN4) to the *NHMRC Statement on Human Experimentation*. When the NHMRC Act was passed in 1992 by the Commonwealth Parliament, all guidelines with the specific exception of SN4 remained in force. SN4 was not saved and the NHMRC was required to issue revised guidelines in this area.

2. The Australian Health Ethics Committee (AHEC) commenced the revision of SN4, titled “*In vitro fertilisation and embryo transfer*”, in October 1993 with a call for public submissions. Sixty two submissions were received. In 1994 AHEC established the Reproductive Technology Working Group (RTWG) with a brief to review the submissions and redraft guidelines covering research and reproductive technology. Based on this group's recommendations AHEC released “Draft guidelines on assisted reproductive technology” for second stage public consultation in June 1996. Eighty seven submissions were received from a wide range of individuals, both within and outside the field of ART, and a number of professional and consumer groups.

3. Since 1982, the regulation of assisted reproductive technologies has become complex. In addition to guidelines, ART is regulated by specific legislation in three States, the Victorian Infertility Treatment Act (1995), South Australian Reproductive Technology Act (1988) and the Western Australian Human Reproductive Technology Act (1993). There is a system of self-regulation and accreditation comprising the Reproductive Technology Accreditation Committee (RTAC) and its Code of Practice for units using IVF and related reproductive technologies, with RTAC setting professional and laboratory standards for clinical practice under this system of accreditation.

4. It has been argued that research into ART should be subject to more stringent ethical constraints, and stricter control mechanisms, than those which apply to routine clinical practice in this field. Some of the submissions called for such a clear distinction between research and clinical practice. However, in many areas of clinical practice this distinction is difficult to make. In the area of ART there is a broad overlap between research and clinical practice. These guidelines address innovations in clinical practice as well as research.

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5. The practice of ART involves social issues of eligibility, surrogacy, consent for posthumous use, genetic diagnosis and selection and gene therapy, and storage of gametes and embryos. These are issues which are beyond the remit of AHEC in relation to medical research. The need for all States and Territories to introduce comprehensive ART legislation was recommended in a number of submissions. In revising the guidelines AHEC resolved that these social issues should be addressed by complementary ART legislation in all States and Territories. In particular, AHEC considers that without uniform legislation, regulation of national data collection and maintenance of a centralised data base and monitoring of research in this area cannot be achieved.

AHEC has referred the proposal for legislation to the Commonwealth Minister for Health and Family Services, recommending unanimously and strongly that ART legislation be enacted in those States and Territories which have not yet introduced such legislation.
Glossary of working definitions

Embryo experimentation — interventions/manipulation

- **Therapeutic**: interventions directed towards the wellbeing of the individual embryo involved.
- **Non-therapeutic**: intervention that is not directed towards the benefit of the individual embryo but rather towards improving scientific knowledge or technical application. Non-therapeutic experimentation includes both non-destructive procedures (which include observation) and destructive procedures.

Procedures

- **IVF procedure**: any in vitro fertilisation procedure, regardless of the timing or location of any subsequent embryo transfer (including frozen embryo transfer) (for the purposes of this document), and gamete intrafallopian transfer (GIFT).
- **Artificial insemination** (AI): any procedure in which human sperm are introduced into the reproductive tract of a woman by a non-coital method other than as part of an IVF procedure (as defined above) including artificial insemination by husband (AIH) and donor insemination (DI).
- **Assisted Reproductive Technology** (ART): includes a range of methods used to circumvent human infertility, including in vitro fertilisation (IVF), embryo transfer (ET), gamete intrafallopian transfer (GIFT), artificial insemination (AI), all manipulative procedures involving gametes and embryos and treatment to induce ovulation or spermatogenesis when used in conjunction with the above methods. It may be inaccurate to use the term “assisted” when referring to some medical procedures involved in reproductive technology.
- **Donation**: a process by which a person who has the responsibility to make decisions about the keeping or use of any gametes or embryo gives consent for their use by another person or persons.

**Institutional Ethics Committee** (IEC): a committee which is composed in accordance with Supplementary Note 1 of the *NHMRC Statement on Human Experimentation*, and which otherwise complies with its provisions.

*Ethical guidelines on assisted reproductive technology*
Introduction

Assisted reproductive technology (ART) includes a range of methods used to circumvent human infertility, including in vitro fertilisation (IVF), embryo transfer (ET), gamete intrafallopian transfer (GIFT), artificial insemination (AI), and treatment to induce ovulation or spermatogenesis when used in conjunction with the above mentioned methods.

Since several ethical and social values are engaged by contemporary reproductive technologies, these guidelines attempt to address the practical requirements of these values including:

- a serious regard for the long-term welfare of any fetuses brought into existence, and any children who may be born, as a result of the application of these technologies;
- a corresponding regard for the long-term welfare of the individuals, both women and men, who have recourse to these technologies;
- the recognition that any experimentation and research involved in these technologies should be limited in ways which reflect the human nature of the embryo, acknowledging that there is a diversity of views on what constitutes the moral status of a human embryo, particularly in its early stages of development; and
- a concern that the whole of society be well-served by the development and application of the technologies.

The application of ART raises a wide range of ethical issues which apply not only to research but also to those aspects which have become established clinical practice.

The guidelines which follow apply to all clinical and research activities in the area of ART. In particular, the guidelines require that any innovations in clinical practice be notified to an Institutional Ethics Committee (IEC) irrespective of the number of patients or subjects involved. The IEC must approve any major changes to existing practice, based on the same standards as research in the area.
1 Relationship of these guidelines to legislation

1.1 In those States where there is specific legislation regulating assisted reproductive technology (ART), compliance with provisions of the statutes must be observed. Where both the State law and the guidelines apply, the State law prevails.

1.2 Access to ART programs may be restricted by legislation in some States\(^1\) or by codes of practice. Such restrictions may be in conflict with provisions in the *Commonwealth Sex Discrimination Act (SDA, 1984)*. ART programs which may be in breach of the SDA may seek exemption from this Act by application to the Human Rights and Equal Opportunity Commission.

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\(^1\) Victoria, South Australia and Western Australia have legislation dealing with ART. The Australian Health Ethics Committee has strongly and unanimously recommended to the Commonwealth Minister for Health and Family Services that complementary legislation in the area of assisted reproductive technology be introduced in all States (see Background paragraph 5).
2 Accreditation and approval processes

2.1 Whether or not required by State law, Reproductive Medicine Units (RMUs) offering ART must obtain accreditation by a recognised accreditation body\(^2\). Such accreditation must include consideration of:

2.1.1 Compliance with National Health and Medical Research Council (NHMRC) Guidelines.

2.1.2 Compliance with the Code of Practice of the accreditation or licensing body.

2.1.3 Certification and maintenance of appropriate professional standards for all personnel involved in relevant clinical and laboratory work.

2.1.4 Maintenance of quality assurance programs for both laboratory and clinical work.

2.2 A specific research project including the use of gametes and/or embryos in an ART procedure must comply with the specific legislation of the particular State and must be approved by an Institutional Ethics Committee (IEC) constituted in accordance with the NHMRC Statement on Human Experimentation. In providing ethical approval an IEC will consider whether all procedures in the project satisfy the Code of Practice of the accreditation body and these guidelines and are subject to satisfactory monitoring arrangements.

2.3 Improvements in existing treatment methods and innovative developments in ART should not be introduced into routine clinical practice without prior evaluation of safety and efficacy, where it is possible to obtain relevant data, and consideration of legal and ethical issues.

When major changes to existing procedures/practices or significant innovations in therapy are proposed, formal IEC approval must be obtained even where only one person or couple is involved. This requires consideration by the IEC of a written protocol, patient information sheet and consent form.

\(^2\) Currently the Reproductive Technology Accreditation Committee (RTAC)

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However, in the earliest stages of developing improvements or innovations in therapy, before systematic evaluation is carried out or when the changes proposed are minor, IEC notification may be more appropriate than formal approval.

2.4 IEC notification

The IEC notification procedure may be used when the changes to existing procedures or practices are determined by the IEC to be minor, and involve only one or a small number of subjects.

IEC notification must be made in advance, should include a description of the nature of the changes, and the clinician/investigator should give the following undertakings:

• that appropriate informed consent will be obtained;
• that the couple have been informed and are aware of any additional cost involved; and
• that the IEC will be notified of the outcome(s), including any adverse events.

2.5 Research protocols approved by an IEC, involving gametes and embryos in ART procedures, post-treatment follow-up and data linkage studies should be notified to a national body, such as the National Perinatal Statistics Unit, in order that a national data base, listing all research involving this type of material in Australia, may be maintained (refer to guideline 5.1).
3 Informed decision-making

3.1 Information giving

3.1.1 Prior to any ART procedure, a participant must be given all information which may be of significance to the participant in a way that is appropriate to, and sufficient for, informed decision-making.

Full information given should include accurate and objective information about the procedures; relevant success and failure rates; potential benefits; treatment options; details of costs involved (including a detailed breakdown of all component costs in each treatment cycle); short and long-term potential physical and psychosocial risks, including any risk of adverse outcome for the child to be born, and any risks associated with multiple births, ectopic pregnancies and spontaneous abortion; information on counselling services available; details of what records will be kept; and, whether procedures for which consent is being sought are established or experimental.

3.1.2 All those who are to give their consent should be given an oral explanation, supported by written information in plain language that is provided to them in sufficient time for it to be taken away, read and considered, prior to the giving of consent to any ART procedure, or any significant step in the procedure that requires consent.

This explanation should be given with sensitivity to cultural diversity and accessibility to those with low literacy, disability, and/or those whose first language is not English.

3.1.3 Informed decision-making is required for all participants, including the donors of gametes and embryos. This requires personal preparation that includes exploration of the short and long-term personal and social implications of ART for the couple or the individual. Clinics should incorporate processes which facilitate this preparation into clinic routines and encourage participation.

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3 Rogers v Whitaker (1992) 175 CLR 497 states that “a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment: a risk is material if, in the circumstances of the particular case, a reasonable person in the patient’s position, if warned of the risk, would likely to attach significance to it or if the medical practitioner is or should be reasonably aware that the particular patient, if warned of the risk, would be likely to attach significance to it” (at 502).
3.1.4 Participants should be informed about the importance of follow-up and the need to evaluate long-term effects of treatments. They should also be informed of the possibility of later contact as part of their participation in any treatment program (see also guideline 5.3.3).

3.1.5 Children born from the use of ART procedures are entitled to knowledge of their biological parents. Any person, and his or her spouse or partner, donating gametes and consenting to their use in an ART procedure where the intention is that a child may be born must, in addition to the information specified in this section, be informed that children may receive identifying information about them.

3.2 Consent

3.2.1 Consent to an ART procedure should be given in accordance with existing State legislation, where applicable, and with the Code of Practice of the accreditation body (as defined in guideline 2.1).

3.2.2 Consent should be given in writing, following the provision of information and adequate opportunities for personal preparation (as set out in guidelines 3.1.1 and 3.1.3).

3.2.3 It is the responsibility of the medical practitioner to ensure that participants are aware of the implications of proposed treatments and that they have consented in a free and informed way (see also guideline 3.1.2).

3.2.4 An ART procedure, including one where donor gametes or embryos are used, may only be carried out after obtaining the consent of the person to be treated and any spouse or partner of that person.

3.2.5 The gamete provider, and any spouse or partner of that person, must give consent to the keeping or use of any gametes, and if the intention is to create an embryo or embryos outside the body, this consent must specify the purpose or purposes for which that embryo or embryos may be used, namely:

- to provide treatment for the provider or the provider and a named partner;
- to provide treatment for others; or
- for specified research (in which the outcome for the embryo or embryos is explained)(see guideline 6.4 and the glossary).
3.2.6 Consent to the storage and use of gametes should:

- specify the maximum period of storage (if this is to be less than the permitted maximum); and
- give an advance directive as to what should be done with the gametes if the gamete provider dies, becomes incapable of varying or revoking the consent, or fail to give further instructions at the expiry of the maximum period of storage.

3.2.7 The couple who are consenting to the storage and use of their embryos should:

- specify the maximum period of storage (if this is to be less than the permitted maximum); and
- give an advance directive as to what should be done with the embryos if either member of the couple, or both, should die, become incapable of varying or revoking the consent, or fail to give further instructions at the expiry of the maximum period of storage.

3.2.8 Where disputes arise between couples about storage of embryos, those embryos shall be kept and not be allowed to succumb until the dispute has been resolved and a decision taken about the embryos.

3.2.9 Should one member of a couple with the responsibility to make decisions about an embryo die, the surviving member has the responsibility to make the relevant decisions about the keeping or use of the embryo, taking into consideration any advance directive from the deceased partner.

Should both members of the couple die, where possible any advance directive from the couple should be complied with or, if there is no such directive or it cannot be complied with, the embryo should be allowed to succumb.
4 Counselling

4.1 Counselling of a supportive or therapeutic nature should be available as an integral part of any ART program.

4.2 Counselling may be provided within, or independently of, the clinic. It should be incorporated into the routines of the clinic and be available as part of long-term follow-up.
5 Research, dissemination of results and the role of IECs

5.1 Having regard to State law, in order to obtain the information required for decision making as provided for in guideline 3.1.3, research programs should investigate and document the outcomes, short and long-term health status and psycho-social effects of ART for participants, donors and offspring (see also guideline 2.5).

5.2 RMUs, and practitioners who later care for participants and offspring, should disseminate knowledge, together with State Health Authorities, the national data collection body and the accreditation body, about the long-term effects of ART.

5.3 Role of Institutional Ethics Committees

5.3.1 An IEC shall receive notification of changes in treatment methods and innovative procedures as spelt out in guidelines 2.3 and 2.4.

5.3.2 Any research undertaken using records maintained by RMUs should follow the guidelines set by the NHMRC, including approval and monitoring by an IEC.

5.3.3 In order to evaluate long-term effects of treatment and the importance of follow-up, IEC approval must be obtained before studies involving contact with participants of an ART procedure are undertaken (see guideline 3.1.4).

5.3.4 The national data collection body, in addition to the accreditation body, must receive notification when long-term follow-up studies receive IEC approval (see also guideline 2.5).
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 guideline 11.2).

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

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.
7 Storage of gametes and embryos

7.1 Storage of gametes and embryos should be in accordance with relevant State legislation and the Code of Practice of the accreditation body. Consent procedures dealing with consent for storage, as provided for in guidelines 3.2.6 and 3.2.7, must be followed.

7.2 Embryos may be kept for a period not exceeding 10 years, following which, if not used by the couple, they may be donated or allowed to succumb. These arrangements may be varied on compassionate grounds with approval by an IEC.

7.3 The identity and location of any gametes, and the identity, number and location of any embryos, in storage should be recorded in detail. In the case of donated gametes and embryos, the identity of the donor(s) should be accurately recorded. Labelling methods should be used which are not susceptible to unauthorised, undetectable, or accidental alteration.

7.4 Embryos may be allowed to succumb by withdrawal of support. Each clinic is to have protocols in place for this purpose. If indicated in their consent, the preferences of a couple who generate an embryo are to be respected in this matter.

7.5 Where no consent exists for storage of embryos, or for withdrawal of support (see also guidelines 3.2.6 and 3.2.7), the embryo should remain in storage until the expiry of the maximum period of storage and may then be allowed to succumb.
8 Record keeping

8.1 Records should enable staff in an RMU to trace what happens to an individual embryo, egg or sperm sample from the date of collection so as to facilitate appropriate access, where permitted, to relevant medical, social and demographic information.

8.2 Detailed clinical and laboratory records should be kept appropriate to the unique nature of reproductive medicine. Records should be adequate to:

8.2.1 facilitate both short and long-term follow-up of the effects of treatments undertaken including psychosocial effects;

8.2.2 enable linkage studies with other health data e.g. registers such as cancer and congenital abnormalities; and

8.2.3 facilitate the study of the short-term and long-term outcomes of any ART procedure that is commenced, including the occurrence of singleton and multiple pregnancies, preterm births and multiple births; and the health of the women and offspring.

8.3 RMUs must keep records which enable compliance with any reporting requirements in State legislation, and should contribute data to any relevant national body collating statistical information about treatments and their outcomes. The reporting of data should be standardised. In particular the reporting of treatment cycles should employ the definition of a treatment cycle found in the explanatory notes to the Medicare Schedule4.

8.4 Each RMU should have a code of conduct to maximise the security, integrity and effectiveness with which information about persons, treatments and outcomes is collected, recorded and reported.

8.5 Arrangements should be made by clinics for ART and donor records to be maintained indefinitely and any practitioner who ceases to practice should make arrangements to transfer these records to another suitable person or location, and should leave instructions on how this is to be carried out in the event that he or she dies or is otherwise unable to make the arrangements.

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4 "A treatment cycle is a series of treatment for the purposes of in vitro fertilisation, gamete intrafallopian transfer or similar procedures and is defined as beginning either on the day on which treatment by superovulatory drugs is commenced or on the first day of the patient’s menstrual cycle, and ending nor more than 30 days later”.

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9 Complaints and appeals

9.1 Complaints about clinic practices

9.1.1 The institution should ensure that procedures are in place for investigating and resolving complaints.

9.1.2 All participants should be given information about the relevant routes for complaint, including statutory routes.

9.2 The avenues of appeal open to persons aggrieved by decisions made in the area of ART will vary depending on the State or Territory involved. They could include making a complaint through special provisions in the relevant ART legislation, through a statutory or administrative body with responsibility for dealing with health services complaints, through State or Territory equal opportunity legislation or to the Human Rights and Equal Opportunity Commission.
10 Conscientious objection

10.1 Those staff who conscientiously object to research projects or therapeutic programs conducted by institutions that employ them should not be obliged to participate in those projects or programs to which they object and they should not be put at a disadvantage because of their objection.
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.
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