

Guidelines for Research on Gametes and Non-viable Embryos

The following clauses are taken from the National Health and Medical Research Council, *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*, 2004.

15.4 Minimise risks

Researchers must ensure that any risks of involvement in the research are appropriate for the type of research.

15.4.1 Where clinical care is combined with research, the risks of research should be balanced by the possibility of intended benefits from the research (see paragraph 1.6 of the National Statement).

15.4.2 For research undertaken solely to develop new knowledge, any risks (particularly any long-term risks to persons born) should be minimal.

16.4 Minimise risks

Researchers must ensure that any risks of adverse effects to any subsequently created embryo (or to the long-term health of any person born as a result of use of the embryo to achieve a pregnancy) are minimal.

15.5 Offer separate decision-making processes for clinical care and research

It is unethical to coerce potential research participants in any way into taking part in the research. Consent must be freely given and be explicit for the proposed research. Any concealment of the purposes of a study from the persons responsible is unethical and excludes informed and voluntary consent.

Proposals for research must include procedures to ensure that the process of providing information and obtaining consent for involvement in the research is clearly separated from clinical care.

Information sheets for research projects must be completely separate from, and capable of being read independently of, written information provided to a patient in the course of routine clinical care.

15.6 Provide information

Participants in research are often vulnerable and can easily misunderstand the purpose and nature of the research. Researchers must provide information to

participants, at their level of comprehension, about the purpose, methods, demands, risks, inconveniences, discomforts and possible consequences of the research (including the likelihood and form of publication of the research results). Section 9 provides guidelines on information giving and counselling for clinical practice; and the same principles must be applied for research.

16.5 Provide information

Researchers must give gamete providers (and their spouses or partners, if any), and any persons for whom an embryo may be created, all relevant information about the research.

16.5.1 The information provided should include a full explanation of any consequences and risks involved for any embryo created and any person born after implantation of the embryo, and how they are balanced by potential benefits.

15.8 Keep detailed records

Good record keeping is an essential component of research. Researchers must keep accurate records of their research, including records of all gametes and embryos in their care, and the outcomes of the research.

Section 10 provides guidelines on record keeping for clinical practice. The same principles must be applied for research.

15.10 Assess and monitor outcomes for all participants (present and future)

All clinical research requires evaluation. For research involving participants in reproductive treatment, researchers must assess, evaluate and monitor outcomes for all participants (including any persons conceived using reproductive procedures, their siblings, where relevant, and the gamete or embryo donors).

15.11 Disclose financial interests

The participants in research are entitled to know about any financial benefits that the researcher or clinic may gain from the research. Researchers must disclose in the project proposal to be submitted to the HREC, any financial interests they have in the research. The HREC must consider the extent to which disclosure of relevant financial aspects of research should be made known to the participants. For example, where researchers plan to request donation of embryos with the intention of undertaking research that may ultimately yield commercial profit, this must be clear to the donors before consent is obtained.

15.12 Respect conscientious objections

Conscientious objectors are not obliged to be involved in the procedures or programs to which they object. If any member of staff or student expresses a conscientious objection to the research involving ART procedures conducted by the clinic, the clinic must allow him or her to withdraw from involvement in the research to which he or she objects. Clinics must also ensure that staff and students are not disadvantaged because of a conscientious objection.

16.3 Use valid scientific protocols

Research must be justified in terms of its potential contribution to knowledge or technical application.

16.5 Obtain consent

Researchers must obtain consent from the gamete providers (and their spouses or partners, if any), and from any persons for whom an embryo may be created, that the gametes will be the subject of research, following which fertilisation may be attempted to create an embryo for transfer to the uterus of the recipient to achieve a pregnancy.