FINRRAGE

Feminist International Network of Resistance to Reproductive and Genetic Engineering

***FINRRAGE* SUBMISSION**:

Comments on Revised draft of *Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research*.

Introductory Comments

FINRRAGE has strongly argued against the introduction of Research Cloning in the 2006 Commonwealth Patterson Bill and in the 2007 State of Victoria Infertility Treatment Amendment Bill. We do not wish to re-iterate our arguments here, they can be accessed in our Submissions to both the Commonwealth and State of Victoria (see also Submissions by the international pressure group for a moratorium on egg harvesting for research Hands Off Our Ovaries and Women's Forum Australia).

We share with these groups our great concern that allowing research cloning - the production of SCNT embryos in particular - will put a significant group of (young) women at risk because of well known short- and long-term drug related health effects of egg harvesting as well as risks of the harvesting procedure itself (for an excellent review of these issues see Diane Beeson and Abby Lippman (2006). Egg harvesting for stem cell research: medical risks and ethical problems. *RBM Online* vol. 13, No. 4 October 2006).

In addition, we worry greatly that in particular young women from families in which degenerative diseases manifest themselves will be approached to do an 'altruistic' act of providing eggs for research into a disease from which they see a family member suffer. We are frustrated by Australia's 'catch-up' development with research cloning which has already been severely discredited through the Hwang Woo-suk fraud in South Korea in 2005. Moreover, the UK should serve as an example of the failure of egg harvesting for research: although allowed since 2004, women did not come forward in sufficient numbers to provide eggs and so in 2006 the UK allowed half-price IVF (thus exploiting poorer women). When even this move did not yield the necessary quantities of eggs, in February 2007 they introduced a payment of up to £ 250 for 'expenses' in relation to egg harvesting. It is important to state that none of these measures have produced sufficient numbers of human eggs nor, importantly, have they led anywhere in the world to the development of embryonic stem cells from SCNT embryos (not even in California where SCNT research is also already practiced). Meanwhile stem cells are discovered rapidly in many of the body's organs, in amniotic fluid and cord blood and furthermore adult stem cell researchers are reporting some encouraging results. We thus believe that this line of research will soon be superseded by newer 'promising' research avenues and we are deeply frustrated that hundreds of women will have risked their health, perhaps even lives, for failed research.

However be this as it may, both the Commonwealth and State of Victoria Bills have been accepted which means that the NHMRC Guidelines hold an important place to safeguard women donating eggs for research cloning. Given this importance we are disappointed that the Draft Guidelines for *research cloning* have been merged with those for ART treatment or research. This makes for many unclear passages, best exemplified in 16.4 (in Part C):

> 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. This condition may be modified for licensed procedures involving embryos that are not to be used to achieve a pregnancy (my italics).

The last sentence supposedly serves to deal with SCNT cloning or excess embryos from IVF but it is confusing. A cynical reader could also infer that these Guidelines are already preparing for the not too distant future when 'reproductive cloning' will quietly enter the clinical practice of ART programs, e.g. when a husband/male partner who can not produce sperm, will have a nucleus of one of his somatic cells injected into one of his female partner's egg cells and thus produce a 'cloned' embryo. That this is not a far fetched scenario is already exemplified by the practice of cytoplasm transfer between the eggs of a younger and older woman which has

led to the birth of babies that now contain the DNA of three people (see Sections 4.1 and 4.2 in the Guidelines).

We suggest that if the AHEC/NHMRC want to protect the public who was reassured that the recent Bills did *no*t endorse human cloning, it must separate the Guidelines into those for ART treatment and those for ART research and 'therapeutic' cloning (which we call research cloning: a more honest description).

A further general comment we wish to make relates to the many safeguards spelt out in the Guidelines (not only the Revisions but the existing Guidelines). We applaud those sections where the health of women whether as ART participants or experimental subjects in cloning research is to be safeguarded. But the many 'should's' instead of 'must's' in the Guidelines reveal a fundamental weakness: it leaves the regulation to individual ART clinics and ART/cloning researchers. For instance, reporting to the Perinatal Statistics Unit is still not mandatory. Moreover, it does not cover the overwhelming majority of women who leave ART clinics without a child - conservatively estimated to be at least 70%! - they/their health are lost to any follow-up.

This, we think is scandalous. In 1995, after long deliberations, the NHMRC published a report *Long-term effects on women from assisted conception* with recommendations for studies to be undertaken into the long-term health of women who had undergone ART treatments as well as children born from these techniques (*FINRRAGE* member Dr Renate Klein was on the Committee). Twelve years later, to our knowledge no such studies have been undertaken which we find unacceptable. *FINRRAGE* takes this opportunity to urge the NHMRC to finally follow up on its promises and begin research into women's health after ART treatment - especially those who left without a child.

Given the new group of women who stands to be harmed by ART drugs and procedures for cloning research which is of no benefit to them (i.e. it does not even hold the promise of a baby), such research is especially timely. *FINRRAGE* was perplexed by the absence of any Clause in both the Federal of State of Victoria Bills to accompany the cloning research with research on the egg providing women and saddened that Amendments put forward to that end at the Victoria State level were not accepted. The health and lives of women really still seem to count for nothing when research glory and gold in state coffers are on the horizon (elusive as these promises may be). That in 2007 both the Commonwealth and the State of Victoria explicitly endorse such human rights abuses is great cause for concern. Even the Scrutiny of Acts and Regulations Committee of the State of Victoria found that the Infertility Treatment Amendment Bill 2007 had human rights implications.

We urge the AHEC/NHMRC to do its best to at least put some Guidelines in place that reduce the great potential of harm to (young) women research subjects *if* such research were indeed to proceed. Again we reiterate that *FINRRAGE* believes that the 2002 laws which allowed the use of excess IVF embryos for stem cell research allow plenty of research opportunities. The fact that hardly any Australian researchers availed themselves of the 2002 opportunity makes us wonder even more why the new Bills were deemed so crucial.

We now move to some specific comments on the Revised Draft Guidelines. Our comments are in italics.

PART A
Structure and use of the guidelines 2.10
• Part C provides ethical guidelines for research involving ART and other practices.

Change Part C to independent Guidelines for research involving ART and research cloning practices

3.5 Human research ethics committees Activities that require a licence (see 4.2) and all proposals for human research must be approved by an HREC. Other activities, such as some quality assurance and innovative practices, may also need to be considered and approved by an HREC.

We suggest some feed back mechanisms from HRECs to AHEC/NHMRC be explicitly mentioned as we do not have too much faith in HRECs. For example we are reminiscent of the 1995 incident when a Melbourne HREC gave its green light to clinical research on RU 486 despite the fact that the consent forms for the women participants were misleading through the omission of adverse effects. The then Minister for Health, Dr Carmen Lawrence, intervened and closed the research down.
On the other hand we acknowledge that many HRECs will act with great integrity and may be able to safeguard research participants from harm.

Given that HRECs have an important role in providing licenses, such feedback seems crucial (see 4 and 4.1.)

4. Introduction
Although exceptions to prohibited activities may be licensable, institutions and their HRECs have a responsibility to consider all ethical concerns of a proposal, including that *embryos should only be formed to achieve pregnancy and should not be treated as mere tissue* (our italics).

Clearly SCNT embryos are formed for research? - this is one of the many places where the mixture of ART clinical practice and research (ART and cloning) is confusing. Needs to be amended.

As above: Sections 4.1 and 4.2 should be differentiated into ART clinical practice and research (ART and cloning). These are crucial parts of the Guidelines and need to be separated.

Part B
9 Information giving, counselling and consent

We suggest that the whole Section 9 should also appear in Part C and be adjusted for women 'donating' eggs for SCNT research and/or for providing spare IVF embryos for stem cell research. Leaving the detailed information in Part B only is confusing.

9.8 Obtain consent for retrieval and storage of gonadal tissue or gametes for a child or young person The retrieval of gonadal tissue or gametes from a child or young person for storage in anticipation of their future need is associated with a range of difficult ethical, social and legal considerations. Decisions to permit the retrieval and storage of gonadal tissue or gametes for a child or young person are ethically acceptable only when: • The risks and discomfort to the child or young person are minimal • Storage is the only means of maintaining the benefit of the reproductive capacity of the child or young person. • There is an independent judgement that the storage is in the child's or young person's overall best interests.

FINRRAGE objects to 9.8. The retrieval of gonadal tissue or gametes from a child or young person is a most difficult ethical problem that we believe has not had any discussion in public fora. We find the caveat that 'There is an independent judgement…' not convincing to prevent serious irreversible harm to a child/young person.
We suggest deletion of 9.8.

10 Record keeping and data reporting
We note with surprise that Section 10 has not been amended to take account of the need to keep records in relation to procedures that involve women who provide eggs. Similarly, record keeping and data reporting must be extended to embryos formed for research (rather than implantation in a woman's womb). We suggest Section 10 be amended so that all details to do with the procedure of a woman providing eggs (drugs used, number of eggs retrieved etc) as well as her long-term health afterwards be recorded.

[12 Preimplantation genetic diagnosis
FINRRAGE holds strong critical views on PGD. We are very saddened that PGD is permitted in Australia. We commend Germany, amongst other countries, for continuing to prohibit this technology which, plainly, reinforces eugenics. We are aware that PGD is not under discussion now but wish to state our strong and long-held objection to it.]

[13 Surrogacy
FINRRAGE is also strongly opposed to any form of surrogacy.]

PART C
Before we comment on the Ethical Guidelines for Research covered in Part C we want to state again the point we made in the Introductory Comments that we are categorically opposed to any woman providing eggs for research only on the grounds that such research jeopardises her health and psychological well being.

For research undertaken solely to develop new knowledge, any risks (particularly any long-term risks to persons born) should be minimal.
Here is another instance where research as part of an ART treatment and SCNT research (or on excess IVF embryos) should be distinguished so as not to have sentences such as '(particularly any long-term risks to persons born)' included in research situations only - unless of course as stated earlier, such passages are already geared towards future research on reproductive cloning!

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. This condition may be modified for licensed procedures involving embryos that are not to be used to achieve a pregnancy.

The above is another passage that reflects great confusion because of the mixing of ART research and cloning research. We reiterate our strong suggestion that there should be separate Guidelines.

17.13 Ensure that the embryo has been declared an excess ART embryo The decision to allow an embryo to be used for research is a difficult one for many people. Researchers must not approach persons responsible for the embryos for consent to use their embryo in a specified research project until after a decision has been made, and confirmed in writing, by all persons responsible for the embryo is no longer needed for reproductive treatment and that it is therefore an excess ART embryo (as defined by the RIHE Act; see Explanation of key terms).

FINRRAGE welcomes Section 17.13. We hope that the AHEC/ NHMRC and HRECs will be able to strictly monitor researchers adhering to it.

Apply objective criteria

• is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the CEO of the NHMRC. The objective criteria for determining that an embryo is unsuitable for implantation are to be based on whether the embryo is incapable of successful implantation if transferred to the body of a woman. These criteria will be developed by the Licensing Committee.

The onus on the CEO of the NHMRC and the Licensing Committee to develop criteria is substantial. FINRRAGE believes this is one of the instances where the Guidelines are not precise enough and leave too much room for judgment in favour of researchers.

If the objective criteria are met in relation to an embryo, the woman and her spouse (if any) may still decide that the embryo is not an excess ART embryo.

We approve of this section.

17.16 Specify the purpose of the research

The consent form must be specific for the purpose, nature and scope of, and rationale for, the research. In the case of destructive embryo research, it must be made clear to the persons responsible for the embryo that it may not be possible to report the fate of individual embryos. For example, if stem cells were to be harvested from a given embryo, the persons responsible would be consulted about that use of the embryo, but, for the purpose of giving the proper consent required under the RIHE Act, would not need to be consulted about the subsequent use of those stem cells.

The difference in consultation seems illogical. If a woman were told that stem cells derived from the SCNT embryo would be used for drug testing, she might not consent!

Where proper consent has been given by persons responsible for an excess ART embryo that has been deemed unsuitable by the objective criteria to a use that will damage or destroy the embryo, consideration may be given by the Licensing Committee to reducing the length of the cooling-off period to no less than 48 hours.

FINRRAGE believes that the reduction of this cooling-off period should not be allowed. It is biased towards the researchers' wishes to use the excess embryo as soon as possible and does not allow sufficient time for the woman to consider the fate of her embryo.

Research on embryos created by means other than by fertilisation of a human egg and human sperm

Accordingly, women are able to donate excess eggs from ART treatment to research. Further, women and men who are not involved in an ART program for the purpose of reproduction may choose to donate gametes for purposes unrelated to reproduction, or to the treatment of infertility.

Again we wish to state our total disapproval of this section. The AHEC/NHMRC should seriously consider the consequences for their reputation if a woman who is not involved in an ART program develops ovarian

hyperstimulation syndrome and becomes seriously sick needing emergency treatment - possibly even dies. This would surely spell disaster for research cloning. However, for the women's sake we would prefer such a possibility not to arise in the first place: don't allow women not already in an ART program to 'donate' eggs.

When obtaining gametes or cells from a donor involves the donor receiving treatment, there must be separation of clinical and research roles. • The clinician treating the donor should not be an investigator in the intended research, and • Whenever possible, persons other than members of the research team should obtain consent to research from the potential donor. When the involvement of researchers is unavoidable, their role in the research must be made known to a donor.

FINRRAGE would like to exclude the researcher(s) EVER having to be involved in obtaining consent from the 'donor.'

• Members of the research team should be available to discuss the involvement of the gamete or gonadal tissue donor in the research protocol. In doing so, researchers should use appropriate language and graphics to convey accurate, clear information.

We believe the above puts far too much pressure on a woman to agree to the use of her eggs or tissue. It should be deleted.

There should be no payment for gametes, gonadal tissue or cells donated for research that is subject to these guidelines. The reimbursement of reasonable out-of-pocket expenses associated with the procedures is acceptable. In research to which these guidelines apply, reimbursement does not cover compensation, including compensation for time.

Imprecise wording. What are 'reasonable out-of-pocket expenses'? Would they amount to the £250 (ca $ 410) - or more - allowed in the UK? We do not believe any monetary compensation should exist so as not to entice poor women and students to enter the business of egg provision.

If genetic screening and disease testing related to gamete or cell donation is to be done, there must be an ethically defensible plan for how such information will be handled. (See sections on human genetics in the National Statement 2007)

This is a dangerous passage – no such screening and 'disease testing' should be envisaged.

Protocols for recruitment must ensure that donation of gametes, gonadal tissue or cells is voluntary and free from exploitation or coercion. Where participation involves non-therapeutic interventions of more than low risk, recruitment should exclude potential participants who are in dependent relationships. Such dependent relationships include those between researchers and students or those working within the research institution, and between clinician researchers and patients. For explanation of 'low risk' and 'dependent relationship', see the National Statement 2007.

We welcome these intentions. We doubt though that they are strong enough. Terms such as 'voluntary and free from exploitation or coercion' are very subjective. This is one of the reasons why we are against any inclusion of 'volunteers' as egg providers.

For the purpose of consent, the potential donor should be provided with the following information in written and oral form:

• A description of the retrieval process for gametes, gonadal tissue or cells, including what will be done, where the procedures will be done and by whom

• A statement of the potential risks of retrieving and donating gametes, gonadal tissue or cells

We suggest that Section 9 Information giving, counselling and consent from Part B be repeated here and adjusted for egg providers (should this practice be allowed at all…). The dot points under 17.21.6 are not specific enough.

The possible risks of long-term consequences for fertility of hormonal stimulation of the ovaries and surgical collection of eggs must be disclosed to potential donors.

Given the mention of possible impairment of fertility how can the AHEC/NHMRC safeguard the fertility of

young egg provider women? Our answer is that this is not possible - as a consequence no young women should be allowed to provide eggs before they have had at least two children of their own.

17.21.13 In deciding whether to approve research involving donation of eggs by a woman, who is not on an ART program to achieve pregnancy, an HREC and the Licensing Committee **must be satisfied that the risks associated with the donation process are justified by the direct benefits of the research to the donor or others.** In reaching those decisions, HRECs and the Licensing Committee must apply the section on risk and benefit in the National Statement 2007.

If the wording in this section is to be followed no woman would ever be able to 'donate eggs! (see sections in bold: there will not be any direct benefit to the DONOR). See also 17.21.14.

17.21.17 Given the risks to donors, clinicians and clinical centres engaged in gamete or gonadal tissue retrieval should encourage studies on the medical and psychological effects of gametes or gonadal tissue donation on the donors with a view to achieving a more accurate evaluation of risks and benefits

*FINRRAGE suggests changing '...should encourage studies…' **to 'must engage in studies on … Otherwise no permission for obtaining eggs will be given'**. (See our Introductory Comments regarding the 1995 NHMRC report on Long-term effects on women from assisted conception – and the non- implemention of its recommendation for research in this area.)*

Respect persons who have died
We agree with these provisions.

Research on gametes or gonadal tissue from the human foetus, or foetal tissue, after separation
17.23 Respect the human foetus
FINRRAGE is thoroughly opposed to any research that may derive stem cells from human foetuses which then might be grown into eggs cells (and sperm). Such research is far too closely associated with reproductive cloning. We also believe this section to contain disrespect for pregnant women especially if they are considering a termination or are experiencing a miscarriage, They should be left alone by researchers – we find this whole section disrespectful and unethical and strongly recommend deletion of 17.23 and all subsections.