FINRRAGE (Australia)

Feminist International Network of Resistance to Reproductive and Genetic Engineering

Submission
On Review of NHMRC Guidelines on the Ethical Conduct of Research Involving Human Subjects

General Comment

FINRRAGE (Australia) welcomes the opportunity to contribute this submission to the revising of Guidelines on the Ethical Conduct of Research Involving Human Subjects to replace the NHMRC Statement on Human Experimentation and Supplementary Notes.

As a general comment we wish to express our disappointment with the subjective nature of many of the assumptions behind definitions of 'disease,' 'health,' 'risk' etc throughout these Guidelines. Given that the NHMRC is considered a 'scientific body', the subjective value judgments upon which these Guidelines are based, are unacceptable. They reflect elitist either/or thinking and reaffirm the view that medical bodies consider themselves to have the right to express views as if they were based on 'objective facts' when, in reality, they reflect socio-political views of the dominant group that are heavily influenced by - unacknowledged - economic, race, gender and age variables (eg one may experiment on 'bad' foetuses but must save 'good' foetuses; 'unconscious' patients or 'the mentally ill' are distinguished from 'normal' humans; see supplementary note 2).

NHMRC Statement on Human Experimentation

Point 4: The research protocol should *always* be based on prior laboratory and animal experiments.

Point 6: Qualifications and experience that demonstrates competence should be more specific. Dealing with any contingencies that may arise is quite inappropriate to include here as medical doctors do not necessarily hold professional counselling skills. This should be a separate clause - the researcher should be obliged to provide counsellors, totally independent of the project if required.

Point 7: It should be in writing prior to undertaking any new therapeutic or experimental procedure that monetary compensation, including access to medical followup be essential.

Point 8: The words 'at his or her level' should be removed as it is ambiguous and provides the researcher with an excuse not to give the full details about the purpose, methods, demands, risks, inconveniences and discomforts of the study.

Point 10: Special care should be taken in relation to consent and to safeguarding the welfare of *all human subjects* .

Supplementary note 1 (1992) - Institutional ethics committees (IECs)

There is too much evidence to suggest that IEC's often act as like-minded gatherings of people who uphold and confirm the research imperatives of the given institution. That private ethics committees are connected to research bodies does not allow for the impartiality and distance necessary to determine the desirability or otherwise of certain research.

FINRRAGE (Australia) believes a major flaw in the NHMRC guidelines is that they are unenforceable: there are no powers of investigation for suspected breaches and no sanctions for non-compliance.

FINRRAGE (Australia) believes all responsibility should not be devolved to IEC's.

FINRRAGE (Australia) believes the NHMRC should enforce stringent requirements to ensure that IEC's become genuine agencies for questioning, examining, and scrutinising research.

The work of Paul McNeill warrants scrutiny in this regard.

In his chapter Research Ethics Committees: Is the Tail Wagging the Dog? McNeill raises the concern that research interests may predominate on review committees, while the subject of research is not represented.

> I am particularly concerned with the adequacy of the representation of the subjects and the adequacy of the representation of research...there is a need to change the basis of membership of research ethics committees to more adequately represent the interest of subjects.

McNeill points out that the interests of research and the research institution have the majority numerically on research ethics committees as presently constituted. He points out that research representatives "can expect to be challenged outside of committee when colleagues disagree with a decision taken by the committee."

> The members with research expertise, by their training and investment in the scientific process, have a unique commitment to research. Their priorities and values are not necessarily shared by the rest of the community or by subjects of experiments. Even with the best intentions, therefore, committees with a majority of members who are staff members of the institution have an inherent bias toward supporting research. Although the NHMRC statement requires that priority be given to protecting human subjects of experiments, the system may operate as if the priority is on getting research approved. It is my view that the 'non-research' members of the committee are not easily able to overcome this bias. They are in the minority. Secondly, they do not have the same pre-established working relationships and they do not have the same opportunities for consulting with each other outside of meetings. More importantly, they depend on the 'expert' members of the committee to help them understand research proposals and to grasp clearly the implications for human subjects.

The Report of the Review of the Role and Functioning of Institutional Ethics Committees reinforces that this is a problem.

Particular concerns were also raised about power differentials between the members of the IEC particularly whether the biomedically trained members may dominate the lay members. This concern was raised in a number of submissions and ...quote one submission which stated "...the failure of the [Supplementary] Note to specify a maximum number of members for an IEC, combined with conscientious efforts...to obtain sufficient medical and clinical expertise on an IEC inevitably leads to the lay/religious/legal members being in a significant numerical minority.

FINRRAGE (Australia) would like to know why there are no representatives of the research participants on IEC's. We see it as a major flaw that those most at risk by the experiments are without representation on these committees. As the above report observes, the fundamental role of an IEC is to protect research subjects from unethical research.

The lay members of IEC's are supposed to represent the subjects of research, as well as society in general. However a Bulletin article has also questioned this. It quotes one commentator: "Community representatives sometimes become enthralled with the importance of the research and at times become more pro-research than the scientists." One lay person quoted in the article says: "The main problem in the meetings is thinking how to say what I want to say and make it sound important."

The NHMRC should investigate claims that the go-ahead for research sometimes is given after the fact. McNeill, for example, claimed in the same Bulletin article that approval by an in-house ethics review committee sometimes is given after the research is done. He was quoted:

> One person told us off the record that he normally does the whole research project, gets the results and then applies for funding to the committee for approvals...I was amazed, but a friend told me it happens all the time. It's so hard to get funding that funding agencies virtually want you to tell them the results before you've got them, so you might as well do the experiment and then apply for the funding. In the meantime, they'll fund it from a previous project. It means you can present a better protocol and the project looks very sound. You can iron out all the problems and anticipate the results.

FINRRAGE (Australia) is extremely concerned that IEC's go membership shopping to find those most in agreement with the research aims of the institution. This is backed up by McNeill who states: "People have told me privately that they weren't going to have someone who was likely to object to the research. For instance, they wouldn't have a Roman Catholic priest if they were doing research on embryos, obviously."

The inadequate system of ethical evaluation and trial monitoring in Australia, the unacceptable means by which hazardous drugs are allowed to be trialed on Australian subjects and the inadequacy of the functioning and membership of Institutional Ethics Committees has been evidenced in a number of clinical trials in the past few years involving women research subjects in trials of contraceptive/abortifacient drugs.

This inadequacy was especially highlighted during the RU-486 trials in Victoria and New South Wales, during which it was revealed that the mandatory religious member of the Victorian Family Planning Ethics Committee had no involvement with the approval process and the Department of Health was forced to admit that there was no need for any of the people compulsorily on the board to actually do anything or even turn up.

FINRRAGE (Australia) led the call for an investigation of the consent forms used in the trials. These consent forms were inadequate. They did not give full information on the short and long term health risks. The consent form was judged inadequate by the then Health Minister Carmen Lawrence and FPV was forced to rewrite it.

The approving committee for the trial in Melbourne was the Victorian Family Planning Ethics Committee and in Sydney, the NSW Family Planning Association Ethics Committee. The membership of the Sydney committee included Dr. Edith Weisberg, who is Medical Director of the NSW FPA and the State Manager of the Sydney Centre for Reproductive Health - the bodies conducting the NSW trials. FINRRAGE (Australia) would suggest that there is a serious conflict of interest where those approving the trials are actually running the trials.

The attitude of these committees and the researchers involved in the trials when asked for information about the trials and the process whereby approval was given, illustrated the contempt in which they held public accountability and freedom of information. The committees and the RU-486 researchers demonstrated reluctance in submitting themselves and their work to public scrutiny, complaining to the NHMRC that parliament's demands for trial details and consent forms were a threat to academic freedom.

Questions were raised about whether the trials breached criminal law. There has been no independent assessment of legality. It was likely the trials were in violation of NHMRC Statement of Human Experimentation: Supplementary Note 5. In a 1987 opinion on the possibility of trials of abortifacient drugs, Dr Robert Jansen, an advocate for human embryo experimentation and former member of the Medical Research Ethics Committee of the NHMRC, stated: "...the NH&MRC's current statement and supplementary notes on human experimentation do not obviously permit such trials". The Therapeutic Goods Agency acknowledged that it left scrutiny of the legal and ethical implications of the trial to the IEC's involved and that it merely sends out a receipt after payment of the application fee for the trial to proceed.

FINRRAGE (Australia) accepts a number of the recommendations of the Report of the Review of the Role and Functioning of Institutional Ethics Committees: A Report to the Minister for Health and Family Services, March 1996. The executive summary states:

> (the report) recommends alteration to the current membership of IECs, that they are better resourced with improved record keeping, improved monitoring mechanisms and more defined accountability. The importance of fostering an ethical culture in research through education of ethics committee members (including ongoing training and skills development and researchers) is also emphasised.

FINRRAGE (Australia) endorses a number of the report's Recommendations, especially 5, section 4.9 stating: "The annual IEC compliance report to AHEC should require details of monitoring arrangements." However we believe that it should be mandatory that such details be provided.

We also agree with Recommendation 21, section 9.3 that:

AHEC should revise its current IEC Compliance Form and require annually the following information from IECs:

membership/membership changes;
numbers of meetings;
confirmation of full participation by minimum required members;
confirmation of due procedures
    -numbers of rejections and reasons for rejections

-monitoring procedures in place and any problems encountered;
complaint procedures;
number of complaints handled.

FINRRAGE (Australia) especially supports recommendation 7, section 5.2 that an IEC must not approve a research project unless it is satisfied that appropriate procedures providing for information to potential subjects and obtaining their voluntary consent are in place. However we also refer to Allars observation that: "The consent which is envisaged (in the Statement) is one which is "free" and given "after comprehending the nature of the study" at the subject's "level of comprehension". There is no suggestion in the Statement that less detailed or comprehensive information is to be provided to subjects with a lower level of comprehension."

FINRRAGE (Australia) also supports Recommendation 6 re working procedures listed in section 5.1 of report:

> Participation in research entitles the research subjects to all relevant information relating to the project, including the objectives and consequences of involvement and details of any identifiable (known or potential) risks and inconvenience. Potential research subjects, having received this information, are then entitled to decide whether they wish to participate in the research. For a research subject to give a valid, informed and voluntary consent, it is essential that the information is given in a comprehensible form and that there is an absence of any form of coercion during the process. This process will be accompanied by the distribution of an Information Sheet, written in plain and accessible language, to the potential research subjects. Time should be made available to the research subject to consider participation in the project and there should be an opportunity to obtain further advice or counselling in relation to involvement. (Report p36-37)

We would argue that definition of so called "innovative therapy" is poor and in many cases this "therapy" has actually been of an experimental nature. In her very significant investigation into the prescribing of human pituitary hormones to women in the 1970's and 1980's and their subsequent implication in the incurable brain infection Creutzfelt-Jakob Disease, Margaret Allars points out that the Human Pituitary Hormones program was not considered experimental. Yet this treatment for infertility and growth abnormalities was experimentation. A broader definition of research is required. As the Report into the Review of IEC's states: "The distinction between research, innovative clinical practice, psychological assessment, clinical treatment, quality assurance programs, evaluation of new procedures and surgical therapies is often unclear."

We endorse Allars recommendation that the NHMRC review the Statement on Human Experimentation to ensure that
- it provides guidance with regard to decisions as to whether treatment in a therapeutic setting constitutes an experiment;
- a procedure is developed by which such decisions are scrutinised and not left entirely to the treating medical practitioner.

FINRRAGE (Australia) supports Rec 1 p17 of the report (1b):

Where any innovative therapy/intervention is trialed on more than one patient, or undergoes some other form of systematic investigation it should be presented for similar ethical assessment to any other research protocol.

FINRRAGE (Australia) supports Recommendation 12 and 13 that each IEC should have an independent complaints handling officer. Again, we believe this should be a mandatory requirement.

We especially agree with the Report that "Institutions conducting research should have in place transparent systems of accountability to enable public scrutiny of their activities." This should be mandatory.

The institution should not appoint members of IEC's. An independent body should be given this task. Those with a direct interest in the proposal due to their involvement in the proposed research must be excluded.

FINRRAGE (Australia) believes IEC's should be open to community review. Their decisions should be on the public record and they should be required to demonstrate why they have approved or rejected a certain project. This may go some way to easing concern that IEC's are more focussed on facilitating research rather than scrutinising it in the public interest.

Supplementary note 2 - Research on children, the mentally ill, those in dependent relationships or

comparable situations (including unconscious patients)

There seems to be no recognition of the social, political or moral significance of different types of dependencies and vulnerabilities experienced by human beings at various stages in their lives. Eg The difficulty of making a decision because a woman is experiencing post-natal depression or the early confusions of Alzheimer's does not warrant the decision by the researcher/physician that she is 'incompetent' or 'like a child'. Unfortunately, social assumptions such as these are not left on the doorstep outside the researcher's study.
- The guidelines do not seem to acknowledge the environment or relational setting of a disabled subject is living in can have a profound impact on their ability to make judgements about their treatment or their lives. Nor does it meaningfully discuss the different degrees of disability and the corresponding recognition of 'competence'. In addition to the bald record of 'consent' there is in many instances of disability the need to attempt to communicate with the subject in ways that are perceived as unconventional or energy consuming. It is easy to rationalise the process as unnecessary, too much trouble or 'a waste of time'.
-Competence, for instance, is often judged by the verbal or reading skills of the subject, and this may bias the treatment of those who for related or unrelated reasons have experienced educational or social impediments to such skills.
-Giving consent for research involves, for even for the 'unimpaired' subject, a number of quite reflective but important considerations. '...it is not sufficient that participants understand the risk, benefits, and alternatives to the research, they must also "appreciate" that they are research subjects and what that implies'
p63 ('Senile dementia and informed consent' Barbara Stanley in *Behavioural Sciences and the Law* 1:4 1983)
- There is little mention of the impact of recent legal judgements upon matters relating to competence and the nature of therapy (Department of Health and Community Services v JWB [Marion case 1992]), or to obligations of medical professionals in accessing the consent of would be patients or certain disabled subjects are the target subjects for politically remunerative and popular studies: Alzheimer's, alcoholism, suicide. (cf Fletcher et al Consent to Research with Impaired Human Subjects', IRB:Review Nov/Dec 1985). These subjects are doubly disadvantaged, since they are often perceived to have no 'interests' for themselves (being cognitively or physically diminished in the eyes of the researchers), and because the momentum to discern 'scientific importance' for a project is fired by the popular acclaim and kudos also waiting at the finishing line for researchers who are working to eliminate a 'dreaded' disability.

Unconscious and critically ill patients
The fact remains that unconscious or critically ill patients are unable to gain informed consent, nor can they agree to any so-called 'experimental intervention intended or expected to benefit' them and therefore the ethics in doing research on them is questionable. Women are often seen in intensive care units as second class citizens and suitable for trials as though their life is not of any value. It is also inappropriate to ask permission of next of kin who will grasp at anything in the wake of such a stressful event. FINRRAGE (Australia) is opposed to any trials being carried out on unconscious or critically ill patients in intensive care units.

Supplementary note 3 - Clinical trials
FINRRAGE (Australia) commends the inclusion of a pharmacologist or clinical pharmacologist being involved in preparing the protocol on clinical trials involving humans. This should be mandatory.

Adverse drug effects should not only be observed and reported but action should be taken to prevent any harm to the humans being experimented on.

Supplementary note 5 - The human fetus and the use of human fetal tissue
The most important criteria for FINRRAGE (Australia) in commenting on this supplementary note is the indivisible nature of foetus and woman. Put differently, as we see the foetus *as part of* a woman's body, we reject any notion of having fetus and woman assessed individually. Therefore, we strongly reject any experiments on the foetus in utero.

The same applies to the question of the use of foetal tissue. Apart from our basic objection that, again, foetal tissue has grown from within a woman's body and is therefore part of her body, we see the potential for serious misuse of using foetal tissue. For instance, in the US there have already been cases of 'coercing' women to become pregnant to then use the foetal tissue after an abortion for a relative's brain disease (Parkinsons). A woman's body is not a machine that can be made pregnant and then aborted for the benefit of a third party - especially when she is asked to do this 'for love'.

We also reject the so-called benefits from 'screening' embryos. This is nothing but eugenics and the power for

some to select the perfect child. This idea is based on individualistic notions that take no account that such decisions have huge implications for society at large, specifically women as a social group.

With regard to 5. whilst we agree not to intend harm to the fetus, we point out that the same needs to apply to the woman. In other words, fetal surgery or drugs administered to the fetus that could harm the woman must be equally prohibited.

6. We object to the arbitrary nature of deciding what is 'viable' and 'pre-viable'. Referring to the point made above - that a fetus is part of a woman and *not* an entity in itself - such a distinction is meaningless. Therefore we reject ANY experimentation on foetuses, whatever their gestational age.

7. Apart, again, from our basic objection, there is something fundamentally wrong with giving someone (the NHMRC as opposed to the woman???) the right to decide which abortion is 'lawful' and which is not. We strongly support legalisation of abortion so that women alone can decide whether to have children or not.

As to ii, iii, and iv, we are dismayed that such scenarios are even mentioned. It goes without saying that they would violate a woman's bodily integrity and dignity.

9. We are strongly opposed to even consider obtaining consent from the future 'father.' This amounts to nothing less than patriarchal control of the woman and again is based on the premise that she and the foetus are two separate entities that might be in an adversarial relationship.

10. We find it shocking that decisions regarding the use of foetal tissue is to be made by the doctor rather than the 'research worker'. For us, the only person who can make decisions regarding her own pregnant body is the woman.

11 (i-iii) We agree with these points but suggest including altruism after 'commerce'. As we know from so called altruistic surrogacy this is a different word for familiar coercion.

Supplementary note 6 - Epidemiological research

The guidelines adopt a short-sighted, liberal and highly individualised notion of consent throughout this note. While recognising that research data can carry with it emotional or social impact for the individual, there is little acknowledgment that research protocols and the data they seek to collect may disadvantage relatives or associates of a research subject or the subject's class or social group as a whole.
The notes do not indicate any recognition of alternative cultural perceptions of permission giving.

-This is particularly well illustrated by the research involving genetic information.
Women identified as 'carriers' of the BRAC1 allele, may be mothers of women for whom this positive association with 'disease' is equally traumatic and life-shattering. Women fearful of the 'force of destiny' implied by such genetic association have been known to consider double mastectomies rather than live with the pain of not knowing' how their mother's test results will impact on them.

Likewise genetic research is being proposed for conditions and behaviours that are massively stigmatised in various societies.
Para 4: Since epidemiological research is the study of populations - what mention is there of the written protocols being made available in plain language versions or indeed in any form which the target group may have access to or indeed have any chance of understanding?

Para 6: Is the reassurance that 'records' should normally be restricted to medically qualified investigators and research associates reassurance enough? What principle appears in these notes which would prevent the employed health officer of a large corporation gaining access to genetic information about a prospective employee?
Should not the NHMRC also acknowledge the implications of the computer and internet revolution on questions relating to information ethics?
Para 7: Seems to abandon the nicety of consent seeking (either group or individual) if in the particular perception of scientist or ethics committee, the discussion might cause 'unnecessary anxiety'. Is there in the drafter's mind a virtuous and 'necessary' type of anxiety? Or does this imply that researchers may override subjects' consent if time is wasted (and 'scientific value' lost) while mere subjects 'worry their little heads' over

matters they cannot hope to understand. There is a suspiciously patronising tone to this paragraph.

Para 15 : What particular notion of 'health' do the guidelines envisage. There is a blandly apolitical discussion of decisions about health and perceptions of health throughout this section.
Eg Were experiments into the anti-fertility 'vaccines' on Indian women considered 'healthy' by the subjects because they were assured that the vaccines were designed to be a reversible, safe form of birth control which they reasonably saw as being in their immediate interest (though evidence is mounting that they are neither) and because 'vaccines' have about them the odour of efficient Western medicine? By contrast, do the researchers perceive 'health' as any hook or by crook reduction in women's fertility, simply because they are residents of what is perceived to be a population pressure cooker?

The guidelines do not adequately define the terms 'therapy' or 'experimental' nor do they define other terms dependent on these.

Likewise the particular ethical problems associated with obtaining or discerning consent among babies as opposed to older children deserves special treatment.
For instance the Council of 'Europe's Draft convention on Human Rights and Biomedicine' (June 1996) notes in Article 6.2 'The opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity'. While this itself is not satisfactory (eg is 'maturity' judged by willingness to give oneself to the 'greater good of science'? -
it does indicate that more careful consideration should be given to this area.

The vernacular use of 'brain dead', 'vegetative' etc. indicates that unconscious patients are greatly at risk of being treated as research objects rather than as disabled subjects. This is a fiction invented by the medical profession so that they may procure organs for transplantation.

The research guidelines fail to acknowledge that in consent or the choice to be involved in research is not the expression of powerful self-determination but its reverse.

> Women make choices about what they judge to be in their own self
> interest or survival, often in a desperate attempt to find safety or security
> and often to give meaning to their existence...Like most women, they make survival choices in a context of restricted options...'
> (J. Raymond 242. 'Connecting Reproductive and Sexual Liberals', 1996)

Supplementary note 7 - Somatic cell gene therapy and other forms of experimental introduction of DNA and RNA into human subjects

1. FINRRAGE (Australia) is of the opinion that somatic cell gene therapy is a paradigmatic example of a 'slippery slope' argument. For instance, who decides what is a 'grave' inherited disease? Furthermore, the consequences of DNA piece insertions is uncontrollable and may lead to a host of unforeseeable health problems.

Obviously we welcome the prohibition of germ cell therapy.

3. (a) We query the arbitrary nature of 'good reason': who decides what constitutes 'improvement' or not (eg prolonging life for 3 days??).

(c) (i) 'No effective treatment' could be a self-fulfilling prophesy: An example is cystic fibrosis. If all hope is seen in prevention through gene therapy then no effective treatment will be development. Also, how can 'a lesser burden' be predicted?

4. In addition to our comments on Institutional Ethics Committees earlier in this Submission we suggest that national independent Ethics Committees - which include independent lay people - not only consumers where it is in their best interest to gain from the research - be the ultimate arbiters in all research proposals.

Paul M. McNeill in *Ethical Intersections: Health research, methods and researcher responsibility*, ed, 1996 Allen & Unwin, p.16,17

Report of the Review of the Role and Functioning of Institutional Ethics Committees, A Report to Health and Family Services, March 1996, p.43.

Report of the Review of the Role and Functioning of Institutional Ethics Committees, A Report to Health and Family Services, March 1996, p.15.

. Science Sadism and Silence, *The Bulletin* with *Newsweek*, V115 (5870), May 18, 1993, p44-46

Bulletin,p.46

See Margo Kingston "Bungling all round on RU486 trials", *The Canberra Times*, August 10, 199

See Melinda Tankard Reist, "RU486 Trials - Controversy in Australia, *Bioethics Research Note* 1994, p.25-26, Margo Kingston, "Trial & terror", *Sydney Morning Herald*, October 27, 1994.

See Margo Kingston "Fearing light, forgetting purpose," *The Canberra Times,* August 17, 1994.

"Ethical Consequences of Developments in Induced Abortion", background paper, April 14-15, 1

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