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Te Kaunihera Wahine O Aotearoa

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Submission to the Ministry of Health on Guidelines on Using Cells from Established Human Embryonic Stem Cell Lines for Research

The National Council of Women of New Zealand (NCWNZ) is an umbrella organisation representing 38 nationally organised societies. It has 32 branches throughout the country attended by representatives of those societies and many individual members. The Council's function is to serve women, the family and the community at local, national and international levels through research, study, discussion and action. NCWNZ has a longstanding history of encouraging the promotion of social and health issues, particularly as they affect women and children.

This document was distributed to Branches, members of the Health Standing Committee and interested parties. Responses were received from members of the Health Standing Committee, other interested individuals, Branches and other groups representing women e.g. Women-HortWide, Voice for Life and the Abortion Law Reform Association of New Zealand. This is a summary of their disparate opinions.

General Comments

Historically, NCWNZ has made a number of submissions dealing with aspects of the application of reproductive technologies. In general, NCWNZ has supported advancements in the application of these technologies with the strong proviso that such activities be regulated by processes and procedures that are robust, transparent and regularly reviewed.

Some individuals and groups commented on the difficulty they had in drafting a response to these proposed guidelines. As one group stated, "As lay people we found it hard to comment on this issue but realise the importance of having realistic guidelines for researchers and ethics committees to follow." The Convenor of the Health Standing Committee notes that it was clear that some respondents found it difficult to answer some questions, particularly those where more than one issue was stated or implied in the question.

Many responses acknowledged the possible benefits resulting from embryonic stem cell research, particularly in relation to a better understanding of some serious illnesses and the development of new or improved treatments. Areas in which benefits might be seen, include: regeneration of heart muscle, improved treatment of Type 1 diabetes, regeneration of neural tissue damaged by disease or acute injury, improved treatment of autoimmune diseases etc. In contrast, one response claimed that potential benefits from embryonic stem cell research were greatly overstated. Most respondents stressed that it was vital to have in place appropriate and robust guidelines to regulate such research. Opinions were varied as to how restrictive such guidelines should or should not be.

A few responses expressed a very strong and clear opposition to the use of human embryonic stem cells for any research. This opposition was based on the view that human life begins at conception and therefore obtaining stem cells from embryos meant the destruction of a human being. Use of embryonic stem cells was seen as unjustifiable, unethical and in breach of the Universal Declaration of Human Rights.

One respondent, while being in favour of using established embryonic stem cell lines, was concerned that women should not become commodified. NCWNZ has made similar comments in related submissions. For example, in the submission on "Guidelines for the Practice of Embryo Donation for Reproductive Purposes (2004)" it was stated "NCWNZ finds the idea of commercial embryo donation to be particularly abhorrent." NCWNZ strongly supports any steps to ensure that donors do not receive any inducement or valuable consideration for the supply of human embryos or gametes.

Some concerns were raised about the composition of ethics committees and the competency of committee members. NCWNZ has commented on this issue previously, for example, in the submission "Terms of Reference for Ministerial Committee and National Ethics Committee on Assisted Reproductive Technologies (2005)". In that submission comment was made about the need for training of committee members, a requirement for ethicists to be involved and the possibility of conflicts of interest. This last point is particularly important considering the size of the New Zealand research community.

NCWNZ believes that proposed guidelines must be flexible and reviewed on a regular basis with appropriate public consultation. Technological advances together with continuing moral and ethical debates result in ideas changing over time and the guidelines need to reflect those changes.

Part One

1. **Is it appropriate for guidelines to require ethics committees to review all research using established human embryonic stem cell lines, including basic biological research? If not, why not and should some other form of oversight be put in place?**

The majority of respondents agreed that it is appropriate for ethics committees to review all research.

It was acknowledged that ethics committees are generally experienced in reviewing research proposals. NCWNZ believes that the review process should be transparent and the public should have access to review outcomes. Some respondents expressed concerns about the composition of ethics committees, for example:

- Ensuring a good balance between experienced researchers from a variety of scientific disciplines and informed lay people.
- Ensuring that enough experienced researchers are available to serve on ethics committees. Members were concerned that the New Zealand research community is relatively small.
- In light of the above, ensuring that there are no conflicts of interest.

2. **If yes, do you agree that the health and disability ethics committees established under the New Zealand Public Health and Disability Act 2000 are the appropriate ethics committees to consider applications for such research?**

The majority of respondents agreed that it was appropriate that ethics committees set up under the New Zealand Public Health and Disability Act 2000 review all research applications.

Concern was expressed, however, that current ethics committees might become overloaded.

One dissenting respondent believed that the ethics committees should be established under the Human Assistance Reproductive Technologies (HART) Act 2004 rather than the New Zealand Public Health and Disability Act 2000.

Part Two

3. **Given that the Human Assisted Reproductive Technology (HART) Act 2004 advisory committee will produce guidance on the use of embryos for research in New Zealand, do you agree that it is appropriate for guidelines on the research use of established human embryonic stem cell lines to restrict researchers to only using lines derived from surplus *in vitro* fertilisation embryos?**

The majority of respondents did not support this proposal. They believed that the proposal was too restrictive and might prevent important research from proceeding, for example, the development of cell lines from other sources e.g. adult (somatic) cells, aborted foetuses, embryos created specifically for research, umbilical cord and cord blood, always presuming that informed consent had been properly obtained.

Most respondents expressed the view that surplus embryos arising from *in vitro* fertilisation (IVF) should be able to be used for research and the establishment of Human Embryo Stem Cell lines as long as informed consent was properly obtained. Comment was made that embryos surplus to the reproductive requirements of the donors would otherwise simply be destroyed. Surplus embryos could be seen as a valuable resource that should be able to be used for research to benefit mankind. Several respondents, however, took the view that surplus embryos produced by IVF should not be used in research under any circumstances.

4. **Are the proposed provisions around consent adequate to address the consent issues raised by human embryonic stem cell research? If not, why not?**

The majority of respondents agreed that the provisions for consent were adequate.

The following suggestions were made:

- Those seeking consent should ensure that the potential donor(s) understand the nature of the request, i.e. the terminology used must be clear and understood.
- Consideration should be given to enable a support person to be present to assist and support the donor(s).
- Consideration should be given to a 3 month cooling off period as per the French Bioethics Law 2004 which states that “After consent is given, the couple must be given three months in which to change their mind before research begins using their embryos.”

Some members felt that it was important that the consent process should not become so onerous as to hinder the research.

5. **Are the requirements on the evidence that researchers must provide around the level of consent obtained reasonable? Are there instances in which researchers may not be able to meet these requirements?**

The majority of respondents agreed that the requirements are reasonable.

Some respondents believed that there might be circumstances where adequate evidence of informed consent might not be available and that this should not of itself automatically preclude the research project from being approved. The circumstances, however, must be outlined in the application so that the ethics committee could make an informed decision. Reasons for the unavailability of adequate evidence of informed consent might include sudden death, donor(s) have moved overseas or are unable to be contacted, inadequate import records, etc. In such circumstances it is suggested that a risk analysis approach be adopted.

The above view was not universal. One respondent stated, "If researchers are unable to meet the requirements then the research should not go ahead."

The HART Act specifically bans the giving and receiving of valuable consideration for the supply of human embryos and gametes. NCWNZ strongly supports this position and would therefore expect that any consent form would include a signed declaration that no 'valuable consideration' has been given or received. Some members felt that this could still allow abuse of the system as donors may lie about having received a payment or 'valuable consideration'.

Some concerns were expressed about the importation of human embryonic stem cell lines. It is recognised that requirements concerning informed consent might not be the same in the country of origin as in New Zealand. Some respondents suggested that if the requirements or records of those requirements do not meet New Zealand standards this should not of itself preclude approval for importation and use. Again, it is suggested that in these circumstances a risk analysis approach be adopted. The ethics committee could, for example, consider the reputation and reliability of the source. In the event that they regard the source as unreliable then permission to import and use such stem cell lines should be declined. Other respondents believed that New Zealand requirements must be met and if this was not possible then permission to import and use such cell lines should be declined.

There was considerable disquiet about the possibility of the importation of embryos for the purpose of developing human stem cell lines. The few respondents who raised the issue expressed a strong view that such an activity should be prohibited.

Part Three

6. **Do you agree that human embryonic stem cell research should be limited to research that 'has the long-term goal of helping to increase human knowledge about either serious diseases and their treatment or the processes of human development'? If not, what boundaries should be placed on such research?**

The majority of respondents agreed with the proposal.

One group of respondents supported research to increase human knowledge about serious diseases and their treatment but did not support research into processes of human development.

Several respondents expressed a strong view that this research work must not be used to manipulate human intelligence, produce 'designer babies', or to promote a 'super race'.

Many respondents accept that the reasons why such research is being developed are worthy, e.g. research into regenerative medicine, replacement of heart muscles, the treatment of diabetes, neurological conditions, autoimmune diseases and other conditions; the understanding of cell growth, proliferation and differentiation and understanding the causes of developmental

abnormalities. Given that this area of research is still at a very early stage it would seem inappropriate to set boundaries beyond those already established by existing ethics committees, e.g. the banning of cloning for reproductive purposes. It is acknowledged that as research progresses knowledge will increase and given that public opinion about ethical issues may also change over time, this issue of limitation of research boundaries should be regularly reviewed.

7. Is the requirement for researchers to demonstrate that the research objective cannot be addressed through other types of research reasonable?

Although opinion on this question was fairly evenly divided the majority of those who provided an explanation for their view felt that the requirement was too restrictive. It was suggested that alternative methods might be more difficult to do, have reduced chances of success, be more expensive or even less safe.

Further, comment was made that this requirement would preclude serendipity, i.e. "the gift of making fortunate discoveries by accident" (Collins English Dictionary).

8. Does a requirement that research using human embryonic stem cell lines be peer reviewed in every instance by a suitable independent person or committee adequately address the need for such research to be soundly designed?

The majority of respondents agreed that all research proposals should be peer reviewed by a suitable independent person or committee to ensure that the proposal is soundly designed.
Such procedures are well accepted in other areas of research and the same principles for sound research should apply. NCWNZ supports the proposition that the principal researcher must provide the ethics committee with documentary evidence that the proposal has been peer reviewed by an appropriately qualified, independent person or committee and that the proposal has been judged to be soundly based, well designed and has reasonable likelihood of a satisfactory outcome.

9. Do the guidelines deal with the issue of leftover human embryonic stem cells adequately? Is it appropriate for researchers to store such leftover cells, or should they be disposed of once the approved research project has finished?

The majority of respondents agree that the guidelines adequately cover the issue of storage and disposal of surplus stem cells. It is acknowledged that established human stem cell lines are potentially valuable and currently are a limited resource.

Most respondents believe that the destruction of any unused stem cells should not be undertaken lightly. A minority believe that surplus stem cells should be destroyed at the end of any research projects or stored only for a limited time. There were some concerns about the possibility of deleterious effects on embryonic stem cells of long-term storage. NCWNZ has commented previously on a related matter, namely the storage of human gametes and embryos, in its submission on the Assisted Human Reproduction Bill (1999). In that submission, NCWNZ supported the notion of a maximum period of storage. It is suggested that a maximum period of storage should be set for embryonic stem cells.

Concern was expressed by some about the possibility of export from New Zealand of human embryonic stem cell lines or surplus stem cells. It was suggested that there should be a protocol or reference to a protocol governing such an activity.

Part Four

10. Do you agree that once a human embryonic stem cell line has been approved for use in a research project in New Zealand, that cell line should be considered as an 'approved human embryonic stem cell line' by ethics committees that consider later applications to use the cell line? If not, why not?

The majority of respondents agreed with the proposal in the interest of preventing unnecessary and costly delay in applying for consent and that the guidelines should include a section on the use of "approved human embryonic stem cell lines (4.3.1)."

11. Does establishing a publicly available register of approved human embryonic stem cell lines and approved research projects adequately address the transparency and accountability issues involved in this research?

The majority of respondents agreed with the establishment of a publicly available register of approved embryonic stem cell lines and approved research projects. There were some concerns about possible plagiarism and the potential for sabotage or undesirable publicity if the details of the research and its location were disclosed.

12. Is it appropriate for ethics committees to establish such a register? If not, who should be responsible for its establishment?

NCWNZ strongly supports the establishment of a register of approved human embryonic stem cell lines and approved research projects. Further, NCWNZ believes that the register should be a national register. Opinion was divided about who should be responsible for the establishment of such a register. Options suggested included the HART Act Advisory Committee, the ethics committees overseeing the research or the Ministry of Health.

Where and with whom such a register would be held needs clarification.

13. Are the details that the proposed guidelines specify should be available from the register reasonable? If not, why not?

In general respondents agreed that the details to be included in the register, as outlined in the guidelines, were appropriate.

Some respondents commented that the format and language used in a publicly available register should be readily understandable by lay people. Issues were also raised about the availability of such a register. It was suggested, for example, that it should be available or accessible in some form in public libraries.

General questions

14. Do the proposed guidelines identify all relevant ethical issues that are specific to human embryonic stem cell research?

The majority of respondents believed that the proposed guidelines identified all relevant ethical issues that were specific to human embryonic stem cell research.

15. If not, what extra issues should be identified?

The minority who disagreed with question 14 expressed concern about the following:

- The possibility that human embryonic stem cells might be exported.
- The possibility that human stem cells could be used in conjunction with other animal cells.
- The position of some medical/nursing/technical staff who may have strong ethical, religious or cultural objections to any involvement in such research or the application of research outcomes.

16. How should these issues be addressed in guidelines?

The concerns expressed in question 15 could be met by:

- The establishment of a protocol for dealing with the exportation of human embryonic stem cells. An alternative might be to specifically ban the export of human embryonic stem cells from New Zealand.
- The establishment of robust audit procedures to ensure that human stem cells are not used in conjunction with other animal cells.
- The guidelines could acknowledge possible ethical, religious or cultural difficulties that some employees might have with this technology. It is suggested that an 'opt out' clause should be included in employment contracts, with no penalty, for those staff who may be involved in any way with this technology, e.g. nursing a patient undergoing treatment if and when it becomes widely available.

NCWNZ thanks you for this opportunity to be able to comment on these proposed guidelines and looks forward with interest to the outcome of the consultation process.

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