GOVERNMENT RESPONSE

TO THE

REPORT OF THE STANDING COMMITTEE ON SOCIAL ISSUES OF THE LEGISLATIVE COUNCIL

CLINICAL TRIALS AND GUARDIANSHIP: MAXIMISING THE SAFEGUARDS

13 SEPTEMBER 1997

MARCH 1998

Government Response to the Report of the Standing Committee on Social Issues of the Legislative Council: *'Clinical Trials and Guardianship: Maximising the Safeguards'*. (Report No.13, September 1997)

Background

The Guardianship (Amendment) Bill 1997 was introduced into the Legislative Council, 7 May 1997. One of the aims of the Bill was to amend the provisions in relation to new treatments to ensure that those with decision-making disabilities could have access to new treatments for medical conditions that they had when those treatments were available only through clinical trials.

The Bill was debated in the Legislative Council, 28 May 1997. Although members of the Opposition and cross-benches spoke in favour of the provisions relating to access to new treatments, they voted to exclude those provisions from the Bill. They overlooked the consultation that had taken place on the discussion paper which provided the foundation for the Bill appreciating that if these provisions were not enacted, the matter would be referred to the Standing Committee on Social Issues of the Legislative Council.

These relevant provisions were deleted from the Bill which was enacted, in its reduced form, by both the Legislative Council and the Legislative Assembly. The Guardianship Amendment Act 1997 came into force, in the form in which it was enacted, 2 February 1998.

On 2 June 1997, the then Minister, the Hon Ron Dyer, MLC, referred the following terms of reference for an enquiry to the Standing Committee on Social Issues:

> "The appropriateness of the clauses of the Guardianship (Amendment) Bill 1997 that were deleted by amendments in the Legislative Council. Particular reference should be paid to the adequacy of safeguards for people unable to consent to themselves gaining access to new treatments available only through clinical trials."

The Standing Committee undertook a substantial public consultation. It advertised in the press calling for written submissions and received 58 of these. It also took oral evidence from 21 people.

The Standing Committee tabled its report in September 1997. It made 20 recommendations. The Standing Committee was unanimous in relation to all of those recommendations.

The Standing Committee concluded the introductory chapter of its report with the following:

> "The Committee supports the overall objective of the amendments relating to clinical trials that were excised from the Guardianship (Amendment) Bill 1997. The Committee considers that people with decision-making disabilities should not be denied an opportunity to participate in a trial that may alleviate or even cure their condition. At the same time, legislation which aims to enhance access to clinical trials must also protect the rights and welfare of people who are unable to consent to their own treatment.

> In order to satisfy these twin goals of access and safety, the Committee supports the re-introduction of the provisions relating to clinical trials in the Guardianship (Amendment) Bill, with certain modifications which aim to maximise the safeguards proposed in the Bill."

The Standing Committee then went on to make its first and central recommendation, namely:

> "that the Guardianship Act provide for the conduct of clinical trials through the re-introduction of the clinical trial provisions of the Guardianship (Amendment) Bill, with additional amendments as recommended in this report."

The Government's Response

In accordance with recommendation 1 of the Standing Committee's report, the Government will introduce the Guardianship (Amendment) Bill 1998. The Bill will give effect to recommendations 1,3,10,11 and 16 of the report.

The Government intends to deal with recommendations 7 and 8 by administrative action. They deal with the variation of the protocol in a clinical trial.

Occasionally the protocol for the administration of treatment in the clinical trial is varied during the course of the trial. When this is done, the investigator must inform the Institutional Ethics Committee and renegotiate consent with trial subjects. The Standing Committee on Social Issues stated:

> "that it considered it absolutely essential that any modifications to the trial protocol should be communicated to the Board (meaning the Guardianship Board which is now known as the Guardianship Tribunal) and that the Board must consider whether the changes require a review of the original consent to the trial. Recommendation 7 implies that the Guardianship Act be amended to provide for this."

The Standing Committee on Social Issues may not have appreciated that when consent is given for inclusion of people who cannot consent to their own treatment in a clinical trial, that consent applies to the clinical trial as at the time the consent was given. If the protocol changes so that the treatment changes, then the consent is no longer effective.

In order for the trial to continue to include those who cannot consent to their own treatment, a further application has to be made to the Guardianship Tribunal for consent for their participation in the clinical trial under the amended protocol.

It is appropriate that that fact be communicated to the relevant people. This would best be done by informing the Institutional Ethics Committees and in requesting them to make this matter clear when giving their approval to clinical trials which may involve people who cannot consent to their own treatment.

Recommendation 8 states:

> "that the Guardianship Act require the Guardianship Board, in the event of a variation to a trial protocol, to contact all 'persons responsible' who have given consent to the participation of the individual in a clinical trial and provide them with the option to reassess their approval."

This recommendation is impractical. The Tribunal will not know who the 'persons responsible' are who have given consent, let alone how to contact them. Those facts will be known to the clinical trial investigators.

The best way to give effect to the spirit of the recommendation is to do what is proposed in relation to recommendation 7, namely to inform the Institutional Ethics Committees of the situation when the treatment protocol is varied.

In this regard, recommendation 19 is relevant. That recommendation states:

> "that the Minister for Community Services instruct the Guardianship Board to conduct a series of briefings with Institutional Ethics Committees throughout New South Wales after the Amendment Act is passed to inform the Institutional Ethics Committees of their responsibilities under the Act."

Contact has already been made between the Guardianship Tribunal and the relevant officers of the New South Wales Department of Health working with the Institutional Ethics Committees in New South Wales. The President of the Tribunal has received an invitation to brief the Institutional Ethics Committees. He has undertaken to draw their attention to the effect on consent to treatment caused by a change to a protocol involving either variation of the treatment regime or some other material change. In those circumstances, the Tribunal will have to be informed and if the changes render the original consent ineffective, a new hearing will have to be held to consider the changed protocol.

The government will not be adopting recommendations 2, 9, 12 and 17. Its reasons for this position are set out below.

Recommendation 2 states:

> "that the Guardianship Act require the Guardianship Board to withhold consent for a clinical trial if it is not satisfied that adequate, independent monitoring arrangements are in place for the conduct of the trial."

Under the safeguards in clause 45AA(2)(e), as originally drafted, the Guardianship Tribunal must be satisfied that the clinical trial complies with any relevant guidelines issued by the National Health and Medical Research Council (NH & MRC). The NH & MRC's statement on human experimentation, supplementary note 1 states that the minimum monitoring responsibilities of an Institutional Ethics Committee are to:

i) at regular periods, and not less frequently than annually, require the principal investigators to provide reports on matters, including:

- security of records
- compliance with approved consent procedures and documentation
- compliance with other special conditions;

ii) as a condition of approval of the protocol, require that investigators report immediately anything which might affect ethical acceptance of the protocol, including:

- adverse effects on subjects
- proposed changes in the protocol
- unforeseen events that might affect continued ethical acceptability of the project; and

iii) establish confidential mechanisms for receiving complaints or reports on the conduct of the project (National Health and Medical Research Council, 1992b: 7).

The Standing Committee on Social Issues notes that very few, if any of the Institutional Ethics Committees engage an independent person or committee to monitor clinical trials primarily because they lack the resources to do so. This view is consistent with the evidence quoted in the Committee's report. The Committee considered that it was essential for the NH & MRC to consider current arrangements for the monitoring of clinical trials urgently and while acknowledging the lack of resources as a major constraint, then went on to make recommendation 2.

It is the present practice that the protocols for clinical trials require investigators to report on anything that might affect the ethical acceptance of the protocol including adverse effects on subjects, proposed changes in the protocol and unforseen events that might effect continued ethical acceptability of the project.

Whilst the Standing Committee on Social Issues referred to concerns raised by witnesses, it does not refer to any instance where there were adverse consequences as a result of the lack of independent monitoring. There is no evidence at present to indicate that independent monitoring, in addition to the reporting required of principal investigators, is necessary to ensure that clinical trials are properly and ethically carried out.

To require the Guardianship Tribunal to withhold consent from trials if it was not satisfied that adequate, independent monitoring arrangements were in place, would be to ensure that it could consent to almost no clinical trials. The consequence would be that people in New South Wales who had lost their capacity to consent to medical treatment would be denied access to new treatment for conditions they had which were available only through clinical trials.

It is inappropriate to use the guardianship legislation as a Trojan horse to force Institutional Ethics Committees to find the resources for independently monitoring clinical trials when this is an issue not within the State government's purview and about which there is no evidence to indicate that it is in fact a problem.

Recommendation 9 states:

> "that any reference to clinical trials in the Guardianship Act use the word 'person' in place of the terms 'patients' and 'participants'."

The amendments to the Guardianship Act dealing with clinical trials will be inserted in Part 5 of that Act. Part 5 deals with substitute consent to medical and dental treatment for people unable to give a valid consent to their own treatment. The term used throughout that Part for a person receiving treatment is 'patient'. The use of the term 'patient' helps emphasise one of the objects of Part 5, namely "that any medical or dental treatment that is carried out on such people is carried out for the purpose only of promoting and maintaining their health and well-being".

The use of the term 'patients' in proposed sections 45AA and 45AB relating to clinical trials helps emphasise the first safeguard in section 45AA(2), namely that people may participate in clinical trials only if they have the condition which the treatment being tested in the clinical trial is intended to alleviate or cure. In that sense, they can take part only if they are 'patients' and cannot take part if they are just 'persons' generally.

The term 'participants' is used to refer to those who participate in clinical trials and differentiates them from others referred to in the relevant provisions. This is done for drafting purposes. The term is in no way derogatory, discriminatory or pejorative.

It is not appropriate that recommendation 9 be adopted. It appears to be based on the views of a single witness before the Standing Committee who did not address the matters set out above.

Recommendation 17 states:

> "that the Guardianship Act require a review of any amendments relating to clinical trials to be undertaken one year after the proclamation of the Amendment Act relating to clinical trials."

Recommendation 12 complements Recommendation 17. It states:

> "That the independent review of amendments to the Guardianship Act (see Recommendation 17) specifically examine the experiences of "persons responsible" to whom the Board delegates consent for a clinical trial."

There will be comparatively few requests for participation of people unable to consent to their own treatment in clinical trials within a year after the relevant legislation comes into effect. Nevertheless, it would be very intrusive to examine the experiences of the "persons responsible" involved in this matter.

Under the Guardianship Amendment Act 1998, the Tribunal will be required to report on clinical trials it has approved in its Annual Report. The Tribunal would be able to use its Annual Report to advise on those clinical trials it did not approve and why it refused to approve them.

The suggested review, particularly as expanded by Recommendation 12, would cost many times more to undertake than the cost of the hearings themselves relating to the clinical trials. The funds for such a review would be better made available to the Tribunal to assist it in carrying out its increasing workload in other parts of its jurisdiction.

There was no publicly voiced concern about the Guardianship Board's role in dealing with clinical trials until it sought to clarify its jurisdiction in relation to them. There is no case for implementing these linked recommendations of the Standing Committee.

So far, 11 of the 20 recommendations have been dealt with. Four of the remainder, recommendations 4, 5, 6 and 20, relate to the NSW Minister for Health dealing with the Commonwealth Minister for Health on the question of ethics committees.

Recommendation 4 states:

> "that the Minister for Health request the Federal Minister for Health to ensure that the annual compilation of institutional ethics committee compliance reports by the Australian Health Ethics Committee are publicly available."

The Minister for Health will write to the Federal Minister for Health on this matter.

Recommendation 5 states:

> "that the Minister for Health request the Federal Minister for Health to amend the statement on human experimentation to require the inclusion of a subject representative on institutional ethics committees."

A review of the role and functioning of institutional ethics committees (IECs) was conducted in 1995 resulting in a comprehensive report to the Minister for Health and Family Services which was published in March 1996 by the Chalmers Committee (the Report of the Review of the Role and Functioning of Institutional Ethics Committees). The report was written following a two stage, national consultation process. As a result of the review and its many recommendations, the NHMRC Statement on Human Experimentation and Supplementary Notes 1992 is currently undergoing revision.

The issue of IEC membership is addressed by the Chalmers Committee in section 6.1 of its report and a number of recommendations regarding changes to the core IEC membership categories are contained therein.

The Chalmers Committee expressed the following view with regard to subject representation:

> "With regard to research subject representation it is the view of the Committee that no one person could be representative of all research subject groups. All IEC members are appointed to represent subjects in research. Consequently, it is the objective of all committee members to use their particular knowledge/skills to anticipate the rights, needs and experiences of research subjects. As a result there should be no need for a separate patient advocate or research subject representative on the committee."

The IEC system protects the participants of human research. The changes to membership proposed in the report will reflect the changing role of IECs away from a medically dominated view of research. The membership category 'Medical graduate with research experience' will be replaced by two new categories'.

1. 'Person with knowledge of and experience in research involving humans (medical, social, epidemiological as appropriate)

2. 'Person with knowledge of and experience in the professional care, counselling or treatment of humans (medical practitioner, clinical psychologist, social worker)'.

The inclusion of a specific research subject representative is not practical given the great variety of research studies reviewed by most IECs. A generic research subject representative would not be unlike the two layperson categories which already exist.

In addition, each member of an IEC brings their expertise and own personal experience to the committee rather than being a representative or advocate. The current Statement on Human Experimentation states:

> "Members shall be appointed as individuals for their expertise and not in a representative category."

The appointment of a research subject representative would be in contradiction to the objective role played by each of the other member categories.

Recommendation 6 states:

> "that the Minister for Health seek the support of the Federal Minister for Health for the amalgamation of small institutional ethics committees as recommended by the Chalmer's Review.

The amalgamation of some small institutional ethics committees in New South Wales has already occurred. The Minister supports that course of action. It is not appropriate for him to write to the Federal Minister for Health about this issue insofar as it relates to other States and Territories.

Recommendation 20 states:

> "that the Minister for Health recommend to the Federal Minister for Health that Institutional Ethics Committee include an item in their clinical trial application forms to establish whether an investigator has sought consent from the relevant guardianship authority in their State."

Again, it is appropriate for the Minister to confine his activities to New South Wales. The recommendation puts the cart before the horse. It is inappropriate for the Guardianship Tribunal in New South Wales to deal with an application to give access to new treatment available only through a clinical trial to people unable to give a valid consent to their own treatment unless and until the appropriate ethics committee has considered the clinical trial proposal and has given its approval to that proposal.

From time to time, institutional ethics committees may wish to give their approval to the clinical trial proposal conditional upon the Guardianship Tribunal also giving its approval. However, when an institutional ethics committee refuses its approval, that should be a barrier to the Tribunal giving its approval.

The provisions in the Bill, as it first went to Parliament, included the obtaining of approval from an institutional ethics committee as one of the safeguards in the legislation. The new Bill to be introduced will include the same safeguard.

Five recommendations remain, 13, 14, 15, 18 and 19, none of which proposed legislative action.

Recommendation 13 states:

> "that the Minister for Community Services instruct the Guardianship Board to produce a plain English guide to amendments to the Guardianship Act relating to clinical trials. This guide is to outline clearly the issues to be considered by the Guardianship Board and the matters which should be taken into account by a 'person responsible' in deciding whether to give consent to the participation of an individual in a clinical trial. The guide should be produced in several community languages and distributed widely."

Recommendation 14 states:

> "that the Minister for Community Services request the Guardianship Board to conduct briefings for 'persons responsible' who are requested to consent to the participation of an individual in a clinical trial."

These recommendations should be placed in context. The Guardianship Tribunal anticipates receiving approximately six requests for consent relating to clinical trials in any one year. In the 1996/97 financial year, the Guardianship Board received a total of 4,507 applications in relation to other matters.

The proposals in these recommendations become relevant only if the Tribunal gives its consent to people who cannot consent to their own treatment participating in a proposed clinical trial, then delegates its substitute decision-making powers in relation to the individuals being included in those trials to their 'persons responsible'. The Tribunal will not know who the 'persons responsible' are unless advised by those conducting the clinical trial. Because of the need for consent to be sought and obtained in a very short time-frame in relation to clinical trials for the treatment of stroke and other brain damage, these proposals are totally impractical.

The Tribunal already puts out clear and concise information about all aspects of its work in the form of information sheets. It intends to do so in relation to clinical trials.

The best way to give effect to the spirit of recommendations 13 and 14 is for the Guardianship Tribunal to provide an information sheet on what 'persons responsible' should take into account when deciding whether or not to consent to the person they are 'person responsible'

for being included in a clinical trial for a new treatment for a condition the person they are 'person responsible' for has. The Tribunal could then adopt a practice of requiring those seeking approval to involve people who cannot consent to their own treatment in clinical trials to include in their protocols a requirement that the Guardianship Tribunal's information be made available to 'persons responsible' before they make decisions.

In order to cover the situation where a particular 'person responsible' needed the information in a community language, the protocols could require that those conducting the clinical trial ensure, through telephone interpreters or other interpreters, that the 'person responsible' understands what it is that they are being asked to consent to and the matters they should take into account when determining whether or not to give their consent.

To implement the proposals as they are set out in the recommendations would involve the Guardianship Tribunal in a considerable amount of expense and would tie up its personnel in processes which represent a very inefficient use of its scarce resources.

Whilst recommendations 15, 18 and 19 clearly are beyond the terms of reference of the Standing Committee, they are addressed in this response.

Recommendation 15 states:

> "that upon clarification of the legal position of Advanced Directives, the Minister for Community Services, in conjunction with the Minister for Health and the Attorney General, develop a public information campaign to encourage people to make advanced directives or to appoint an enduring guardian."

Arrangements are in place within government for the issues relating to advance directives to be considered. Enduring guardianship is provided for in the Guardianship Amendment Act which came into force, 2 February 1998.

Steps are being taken to encourage non-government organisations to take up the promotion of enduring guardianship.

Recommendation 18 states:

> "that the Minister for Community Services support the creation of an appeals division in the Administrative Decisions Tribunal to hear appeals against decisions of the Guardianship Board and ensure that members of the Division have a similar range of skills and expertise as members of the Guardianship Board."

This is a matter for consideration after the Administrative Decisions Tribunal has commenced operations.

Recommendation 19 states:

> "that the Minister for Community Services instruct the Guardianship Board to conduct a series of briefings with Institutional Ethics Committees throughout New South

Wales after the Amendment Act is passed to inform Institutional Ethics Committees of their responsibilities under the Act."

As has been noted above, contact has already been made between the President of the Guardianship Tribunal and officers of the NSW Department of Health who have linkages with the Institutional Ethics Committees in this State. Appropriate briefing will take place when the Amendment Act is enacted.

Concluding Remarks

The Government will meet the central recommendations of the Standing Committee's report by introducing the Guardianship Amendment Bill 1998 to Parliament.

The Government will give direct effect to, meet by other more appropriate means or give effect to the spirit of most of the other recommendations in the report.