

**SYSTEM OF ETHICAL REVIEW OF HEALTH AND  
DISABILITY RESEARCH IN NEW ZEALAND  
(DISCUSSION DOCUMENT SEPTEMBER 2003)**

**SUBMISSION BY RESEARCHED MEDICINES INDUSTRY  
ASSOCIATION OF NEW ZEALAND INCORPORATED**

11 November 2003

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**PREAMBLE**

The Researched Medicines Industry Association of New Zealand Incorporated (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its 22 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of evidence-based medical and scientific knowledge about their products.

Data from internal surveys of members indicate that pharmaceutical companies invest in excess of \$25 million per annum on clinical research in New Zealand. Approximate data for 2001 shows that RMI companies were involved with 151 clinical studies in 269 sites in 108 different locations in New Zealand. These studies involved 1,228 staff (full & part-time) and 4,280 trial participants<sup>1</sup>.

The RMI promulgates the *Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-sponsored Clinical Trial* (December 1997).

**EXECUTIVE SUMMARY**

The RMI supports the recommendation from the Gisborne Inquiry that a national ethics committee should be established for the assessment of multi-centre or national studies. The RMI's preferred option under Section Two of the Discussion Document is Option 2(b).

The RMI also supports the recommendation from the Gisborne Inquiry that consideration should be given to processes to allow ethics committee decisions to be appealed to an independent body. The RMI's preferred option under Section Three of the Discussion Document is Option 2(b).

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<sup>1</sup> This information may not provide a complete picture of the contribution of the pharmaceutical industry to New Zealand research. Not all companies are members of the RMI, companies may withhold certain commercially sensitive data, and some trials may be commissioned directly by overseas companies or by contract research companies. These data do not differentiate between single-centre and multi-centre trials.

## **SECTION TWO: PROCESSES FOR THE REVIEW OF NATIONAL AND MULTI-CENTRE RESEARCH**

From an international perspective, New Zealand is generally considered to be an attractive place to conduct clinical research – English is the primary language, the regulatory systems are aligned with international good clinical research practices, the country has a well-developed health services infrastructure, the reputation of investigators is high, researchers deliver on time and on budget, and costs are relatively low compared with other OECD countries. It is clear, however, that the current processes for ethical review may act as a deterrent to pharmaceutical companies conducting multi-centre clinical trials in New Zealand.

There are a number of factors that are important for industry-sponsored multi-centre clinical trials, most notably:

- Timeliness of the ethical review of trial protocols.
- Administrative and compliance costs associated with the ethical review process.
- Consistency of decision making by ethics committees.

The NEAC review provides an opportunity to assess the current system of ethical review and hopefully improve the outcomes in each of these particular areas.

The current system for the review of multi-centre clinical trials has some positive elements. For instance, administrative processes are streamlined through having a national ethics committee application form, and the main researcher is presented with a single decision on the application from the lead ethics committee.

However, the current system also has drawbacks. A heavy administrative burden is imposed by the need to submit the protocol to all relevant regional ethics committees, and because of the extensive communication required between the lead committee and each of the regional committees. For these reasons, the process can be slow and cumbersome – the normal time for ethics committees to provide a decision on a clinical trial protocol is over 12 weeks in New Zealand, compared with 8 weeks or less in most comparable countries. In addition, the potential for ethics committees to arrive at different decisions does not sit well with the recent EU Directive on clinical trials, which indicates that a single opinion on a multi-centre trial should be given [for each Member State].

The RMI supports the recommendation from the Gisborne Inquiry that a national ethics committee should be established for the assessment of multi-centre or national studies. This would speed up the ethical review process, provide consistency of decision-making, avoid duplication of effort and relieve

a significant burden of workload from the regional ethics committees, particularly those that are not situated in the main population centres.

The national committee could be primarily responsible for assessing the acceptability of the overall research protocol and trial design. Ideally, the national committee should operate within defined timelines for the assessment of applications, consideration of comments from regional ethics committees and notification of its decisions to applicants.

The RMI considers that it is important to also have an assessment of the *local* ethical issues relating to any clinical trial. Hence, it may be appropriate for the regional ethics committee(s) to separately review locality-specific issues, such as the suitability of trial investigators & research facilities, local cultural issues, etc. Any concerns noted by the regional committees should be fed through to the national committee for consideration. Rather than repeating the overall assessment conducted by the national committee, however, regional committees should clearly focus their activities on the assessment of local issues; otherwise the potential benefits of the new system would not be realised. Strict timelines should apply to this process (e.g. maximum 4 weeks), so as not to hold up the review by the national committee.

Hence, the RMI's preferred option under Section Two of the Discussion Document is Option 2(b), i.e. national primary committee approval with only a locality assessment by each secondary committee.

The RMI has no firm view on whether the national ethics committee for the assessment of multi-centre/national studies should be established as a separate entity, or whether its role could be undertaken by the current NEAC or the Health Research Council Ethics Committee (HRCEC). Rather than create a profusion of different committees, however, it would seem appropriate to operate not more than two national committees – possibly one with a predominantly “operational” function, and one with a more “policy” role.

### **SECTION THREE: SECOND OPINION AND APPEALS PROCESSES**

The RMI supports the recommendation from the Gisborne Inquiry that consideration should be given to processes to allow ethics committee decisions to be appealed to an independent body.

Natural justice dictates that researchers should have the opportunity to challenge a decision made by an ethics committee, particularly where there may have been deficiencies in the process by which the committee reached its decision, or where an issue may have particular national significance. Such a

system would add robustness to the ethical review process and ensure consistency of decision-making across different ethics committees.

The RMI's preferred option under Section Three of the Discussion Document is Option 2(b). The NEAC would be an appropriate body to consider applications for appeal of a decision made by a regional ethics committee or the national ethics committee for multi-centre/national studies.

While there is merit in establishing a binding appeals process on a national basis, where possible it would be best to resolve any disputes at the local level. Ideally, challenges to a decision should follow a formalised process, whereby approaches are initially made to the local committee to review its decision, before second opinions are sought from another committee, or the matter then elevated to the national appeals committee.