

5th February 2008

Sally Cook
 National Co-ordinator, Ethics Committees
 Ministry of Health
 PO Box 5013
 WELLINGTON

Dear Sally

Consultation on the Draft National Application Form for Ethical Approval of a Research Project (NAF-2008-v1) and Guidelines (NAFG-2008-v1)

The Researched Medicines Industry Association of New Zealand (RMI) is the national body representing New Zealand’s research based pharmaceutical industry. Its 18 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and vaccines and the ongoing improvement of medical and scientific knowledge about their products.

The RMI’s comments on the draft documents are as follows:

	Page	Part	Q	Comment
Application Form	Cover	Checklist		Rewording is required to clarify that SCOTT and Ethics Committee approval can continue to be performed in parallel.
	14	B	19.2	
Application Form	27	4		Registered Drug Form – the form requires amending to clarify that only drugs outside standard treatment regimes should be described.
Guidelines	5	General Info	8	This point notes applicants should allow at least two months for the ethical review process to be completed. Timely review of applications is important if New Zealand is to compete internationally to conduct clinical trials. It is important, therefore, that there are specified timeframes which are acceptable to both applicants and the Committees. More frequent scheduling of Ethics Committee meetings (particularly) the Multi-region committee would also improve timeliness of approvals.
Guidelines	35	Appendix 4		In addition to the information provided, it would be useful to also include the NRL’s website address and/or the information sheet they provide.

Yours sincerely



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