RMI SUBMISSION ON THE
"NEW APPEALS PROCESS FOR ETHICAL REVIEW"
CONSULTATION DOCUMENT MARCH 2009

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

Q1: Do you have any comments regarding the suggested membership of the HRC ECA?

The RMI agrees with the suggested membership of the HRC ECA. The appointment of Augmented Members for the hearing of an appeal will allow selection of additional members with relevant expertise while retaining the expertise of the HRC CEC.

Q2: Given the selection criteria, do you believe that the pool of possible Augmented Members will achieve appropriate membership?

Yes. It makes sense to leverage members who already have Ministerial approval and prior experience.

It is critical, however, that they were not involved in the prior HDEC review(s) of the application and that they have served on an HDEC within the last 3 years. These conditions will ensure there is no conflict of interest and that their knowledge is current.

Q3: Do you think the provisions for the Chair are appropriate?

Yes.

Q4: Do you think the above process adequately deals with conflicts of interest?

Yes, but it is also important that a member was not involved in the prior HDEC review(s) of the applications.

Q5: What are your views of the HRC ECA potentially reviewing HRC funded research on appeal?

In principle, the member guidelines for appropriate conduct and behaviour should ensure a commitment to the protection of research participants and research excellence. Additionally, the requirement that an HRC ECA member involved in an application under appeal cannot participate in the assessment of that appeal ensures conflict of interest is adequately addressed in that area.

The only potential conflict would be where the HRCEC was involved in the evaluation for funding of the research. However, as the HRC ECA also includes the Augmented Members this should overcome any concerns re conflict or bias.

Q6: Are the provisions concerning expert advice adequate?

Yes.

Q7: Do you have any comments regarding who can lodge an appeal?

It is appropriate that any appeals are lodged by the principal researcher as they take overall responsibility for the conduct of the study, should it be approved. The proposed appeals process still allows for third parties (e.g. sponsors) to seek and appeal via the principal researcher provided they are in agreement.

Q8: Do you have any suggestions on what should be the grounds for seeking a second opinion/appeal?

A second opinion/appeal should be available to the principal researcher at all times.

The proposal currently suggests that the chair of the HRCEC may grant leave to the applicant to bypass the secondary review and proceed directly to appeal by HRC ECA if the circumstances require an expedited review. Such circumstances should be clearly defined and documented in advance.

Q9: Should new information be able to be presented during the secondary review? Please state your reasons.

Additional information should only be allowed during the secondary review if it supports or clarifies concerns raised during the initial review. This may aid good faith attempts to resolve differences before involvement of the HRC ECA.

Q10: Should new information be able to be presented during the appeal process? Please state your reasons.

The HRC ECA should be able to access further information, as the ultimate outcome desired is a "correct' decision and everything possible should be done to ensure that. It is possible for an HDEC to take a view not anticipated by the submitters and in those circumstances the ability to provide further material is important. However, it remains imperative that the information provided to the initial ethical review is as complete as possible.

Q1: Do you agree that the decision made by the HRC ECA should be binding?

Yes.

Q12: Are there any features of the proposed appeals process that you believe ought to be reconsidered?

It is a well designed process.

It may be useful to collect key metrics around the studies that are submitted for appeal (e.g. therapeutic area, type of research, reason for appeal, HRC ECA decision) as this may prove useful for future training and development. For example, it would allow trends to be identified (e.g. are there significantly more appeals being submitted against a particular HDEC?).

A time period for attaining both the secondary review and the appeal should be established. Very few research projects can afford long administrative delays; given the number of steps involved, the appeals process appears a lengthy one. The SCOTT outlines a time limit for review (which they operate well within), the HRC ECA (and the HDECs) should also be able to provide a time limit.

Debbie Wyber
Manager Technical & Scientific Affairs
Researched Medicines Industry Association

30 April 2009