

# Robert Cann

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**Mr Simon McKeon AO**  
**McKeon Review Secretariat**  
**Canberra**

Dear Mr McKeon,

I am a member of a Human Research Ethics Committee that itself has an ethics problem. We received a comprehensive application for a clinical trial that, for us, was unprecedented in that another HREC had already granted approval for the trial to proceed.

The committee applied due diligence in spending much time reviewing all the documentation and preparing responses, but it soon became evident that something was amiss. Many parts of the application would have precluded us from granting approval and I thought it incumbent on us to do something to protect future participants from wrongly approved trials. Being a retiree, I volunteered to relieve the busy committee members from this task.

According to your thirteen Matters for Review, the details of this lengthy saga are not required. Therefore, my submission relates only to your Term of Reference 7, and specifically to “governance of the health and medical research sector”, as follows:

1. I discussed the situation in some detail with a senior person of NHMRC at a Clinical Trial workshop and was told a) they were unable to assist us, and b) we should contact the Australian Health Ethics Committee (AHEC).
2. An email was sent to AHEC seeking advice, pointing out that the National Statement on Ethical Conduct in Human Research (2007) was not clear about what specific steps or responsibilities an HREC has when one ethics committee has approved a study that another would not have approved. An extract of that email is:

*There does not seem to be a process or mechanism that would address the problem of conflict of decision between ethics committees for a common application. Is it ethically our responsibility to address this situation? Do we have any responsibilities under the law regarding this?*

3. The anonymous reply was unsatisfactory. It was from NHMRC Health and Research Ethics and began, “Institutions are responsible for establishing procedures for the ethical review of human research including how to handle complaints.” It followed with several comments that did not address our queries and finished with, “NHMRC is unable to provide you with legal advice, and you may wish to seek independent legal advice.”
4. Shortly after that episode I was motivated to provide information about it to Professor Warwick Anderson AM, CEO of NHMRC, after having read his 2006 quote on an NHMRC website<sup>1</sup>:

*As the newly appointed CEO, I recognise that some of the past criticisms of the NHMRC were warranted and need to be addressed.*

5. I did not contact Professor Anderson after having read an article of his<sup>2</sup> that states:

*Currently, there is no formal complaint system at either the State/Territory or national levels.*

and,

*NHMRC receives complaints about researcher and research conduct or HRECs from time to time. The NHMRC's legislation does not provide a statutory capacity to investigate complaints.*

6. Following the above point, Professor Anderson states on the same page and under the heading WHERE TO FROM HERE?:

*However, improvements are needed. These might include:*

1. *Mandatory registration and accreditation or credentialing of HRECs.*
2. *A reliable method of monitoring compliance by researchers and HRECs with the National Statement and related guidelines.*
3. *A formal complaints process.*

7. NHMRC's impressive submission to your Review includes this statement<sup>3</sup>:

*Health and medical research must operate in a framework that promotes the highest ethical standards.*

After consideration of the above, I trust that your Review will recommend appropriate action be taken to provide NHMRC with a) a formal complaints process plus legislation giving it the statutory capacity to investigate complaints, and b) other improvements that it needs, such as items 1 and 2 of point 6.

Out of courtesy, a copy of this submission will be forwarded to Professor Anderson.

Yours sincerely,

*Robert Cann*

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1. **Med J Aust 2006; 185 (11): 613-615.** The quote is from paragraph 7 and the link is:

<https://www.mja.com.au/journal/2006/185/11/working-build-healthy-australia-new-era-nhmrc>

2. The link to this article is: [Editorial: Human Research Ethics Committees \(PDF, 46KB\)](#). **The quoted extracts are from item 4 on page 2.** (The article is the second-last on the NHMRC website, accessed from *About/ NHMRC senior staff/ NHMRC CEO Warwick Anderson AM/ Articles and speeches*. Underneath the link is, "This editorial was originally published in the NHMRC report [Challenging Ethical Issues in Contemporary Research on Human Beings](#)." Please note that the editorial does not appear in the 2006 publication that is accessed from that link.)

3. **Submission 222, on page 24 of 62**, under the heading: Challenge 10: keeping high ethical standards and retaining trust in research.