

## Ethics committees and guardianship legislation

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**TO THE EDITOR:** In addition to a complicated ethical approval process, new privacy laws have presented challenges for multicentre research studies.<sup>1</sup> In Victoria, an amendment to the *Guardianship and Administration Act 1986* came into effect on 1 January 2003. We wish to highlight its unanticipated ramifications.

We proposed to conduct a pilot study on the feasibility of ascertaining cases of Murray Valley encephalitis (MVE) in Victorian hospitals. Currently, there is no routine human surveillance for MVE, and we intended to perform diagnostic tests for several encephalitis aetiological agents on routinely collected samples. A study protocol was developed and submitted in November 2002 to five Human Research Ethics Committees (HRECs), one at the Department of Human Services and four at hospitals where the study was to be conducted. The case definition for encephalitis included the criterion that the patient had an “altered conscious state”, and could not therefore give informed consent.

Informed consent was to be provided by the patient’s next-of-kin, but, in late December, an HREC representative alerted us to an imminent amendment to the Act which stipulated that only a guardian appointed by the Victorian Civil and Administrative Tribunal (VCAT) could provide consent to participate in “any procedure carried out for the purposes of medical research” on behalf of a disabled patient (in this instance, a patient with an altered conscious state). The Act does not further define medical research. Surveillance involves no intervention, and it is unclear to us (and some ethics committees) whether surveillance was considered a “procedure”. We indicated our uncertainty in a letter to VCAT in January 2003.

If an application to VCAT were required for each patient we wished to enrol, then the study became unworkable. Under legislative requirements,

VCAT is only obliged to “commence to hear” an application within 30 days of its receipt, which would prevent surveillance being conducted in a timely manner.

Awareness of the legislative amendment differed between HRECs. In December 2002, two committees gave full approval for the study without reference to the amendment, while the remainder gave conditional approval, subject to complying with the amended Act. VCAT wrote to HRECs in February 2003 to clarify the amendment, and directly indicated to us that it did not apply to our proposed study. In May, despite the correspondence from VCAT, one HREC reaffirmed its position that applications must be made to VCAT for consent for studies such as this one.

Despite attempts at clarification, a legislative amendment in Victoria has created ongoing confusion about obtaining consent on behalf of disabled patients. Researchers planning studies involving invasive procedures (eg, blood chemistry or seroprevalence studies) need to be aware of the amendment’s potential impact. Differences in interpretation of the amendment by the tribunal and various ethics committees highlight the need for further clarification of the Act, as well as for centralised and consistent assessment of HREC applications.

1. Carapetis JR, Passmore JW, O’Grady K. Privacy legislation and research. *Med J Aust* 2002; 177: 523. □

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**COMMENT:** Fielding and Heath raise two issues. The first is the increasing barriers to the conduct of research as the law and Human Research Ethics Committees (HRECs) quite rightly ensure the safety of participants in human research. In the words of Cicero, *salus populi suprema est lex* (“the welfare of the people is the highest law”),<sup>1</sup> but the law is not immutable. The confusion uncovered by Fielding and Heath over the implications of the amendment to the *Guardianship and Administration Act 1986* may prompt legislators to re-examine the purpose of the Act in the

context of research involving patients with “altered conscious state”.

The second issue raised is more general. The plurality of HRECs’ interpretations of the amendment may be difficult to fathom by ordered scientific minds: data are data, so why the differences in HRECs’ opinions? These frustrating differences are the bane of researchers involved in multicentre research.<sup>2,3</sup> The 1999 *National statement on ethical conduct in research involving humans*<sup>4</sup> empowers HRECs to minimise duplication and allows for ethical and scientific assessments made by one HREC to be accepted by others.<sup>5</sup> Nevertheless, HRECs value their independence and are unlikely to relinquish it to others easily.<sup>6</sup> Various states are considering the feasibility of centralised ethical bodies,<sup>5</sup> but bureaucracy moves cautiously and change is always slow.

1. Cicero. De legibus.
2. Jamrozik K, Kolybaba M. Are ethics committees retarding the improvement of health services in Australia? *Med J Aust* 1999; 170: 26-28.
3. Loblay RH, Chalmers CRC. Ethics committees: is reform in order [editorial]? *Med J Aust* 1999; 170: 9-10.
4. National Health and Medical Research Council. National statement on ethical conduct in research involving humans. Canberra: NHMRC, 1999. Available at: www.nhmrc.gov.au/publications/pdf/e35.pdf (accessed Sep 2003).
5. Breen KJ, Hacker SM. Privacy legislation and research [letter]. *Med J Aust* 2002; 177: 523-524.
6. Pearn JH. The realities of ethical review of research in Australia. *Med J Aust* 1999; 171: 38-39. □

## Acute liver failure associated with the use of herbal preparations containing black cohosh

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**TO THE EDITOR:** We wish to report a case of acute liver failure associated with the use of a herbal preparation that contained several ingredients, including *Cimicifuga racemosa* (black cohosh).

In January 2003, a 52-year-old woman was referred to our unit with acute liver failure. She had taken a herbal preparation for three months (for severe tinnitus), but ceased four weeks before admission. The preparation was made and provided by a pharmacist. The preparation was supplied in a