

option to opt out would achieve the highest rates of screening while preserving the right of the individual to refuse an HIV test.

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Disclosure in research ethics

The issue of disclosure of decisions made by research ethics boards (REBs) is worthy of extended debate.¹ The US Food and Drug Administration (FDA) is soliciting public comments concerning the issue of institutional review board (IRB) "shopping" in anticipation of formulating a rule to address this issue.²

Disclosure of REB decisions should be made public through mandatory registration of trials in a publicly accessible register. In the US, for example, trial registration may involve Web-accessible registers such as www.clinicaltrials.gov. This kind of register should contain a hyperlink to a page where REB decisions would be recorded.

If the decision of an REB is one of disapproval, it should provide the reasons for the decision in one or more of the following categories: social and scientific value, scientific validity, fair subject selection, favourable risk-benefit ratio, informed consent and respect for potential and enrolled participants.³ Entries in a category may be limited to a specified number of words.

Accessible information will enable REBs to consider the decisions of other committees at the time of initial or con-

tinuing review of clinical trial protocols, and such disclosure will also serve the interests of potential trial participants and the general public. The case for trial registration has been summarized by Tonks.⁴

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[The author responds:]

Howard Mann's reply to my article¹ contributes to the discussion about IRB "shopping," and his ideas are very intriguing. His argument in favour of public access is important, but I wonder if the system should be fully publicly available.

Whatever mechanism Canada adopts in creating a centralized REB system, I believe it must be based on promotion of the public's interest, including the protection of our country's involvement in international pharmaceutical trials. Our national regulatory authority, Health Canada's Therapeutic Products Directorate, will need to determine if a trial registry with mandatory public disclosure rules, as opposed to more limited mandatory disclosures among REBs, will negatively influence decisions to proceed with trials. Issues of intellectual property will likely be raised and may reduce Canadian trial activity, thereby influencing the number and kinds of pharmaceutical drugs or devices available in the longer term.

If mandatory public disclosure

would reduce Canada's involvement in trials, then we may want to concentrate our efforts on other mechanisms to protect the public interest with respect to the conduct of clinical trials.

That being said, if the FDA were to legislate the system described by Mann, smaller countries with less market share potential would find it easier to adopt a similar system; such an action by the FDA would probably influence sponsors' acceptance of that regulatory practice. Given that international pharmaceutical trials often involve both the US and Canada, sponsors would likely accept harmonized regulatory practices with respect to public disclosure.

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Breast is best for more than 6 months

The trial reported by Cindy-Lee Dennis and coauthors¹ will undoubtedly help clinicians and public health professionals to choose effective interventions to prolong the duration of breast-feeding. Nevertheless, we would like to provide a clarification regarding the authors' advice, which is based on recommendations of the Canadian Paediatric Society (CPS)² and the American Academy of Pediatrics (AAP)³

In 1998, the CPS, Dietitians of Canada and Health Canada recommended that "breastfeeding may continue for up to 2 years of age and beyond."⁴ The AAP³ recommends that breast-feeding "continue for at least 12 months, and thereafter for as long as mutually desired." Nowhere in these recommendations is there a suggestion that breast-feeding should last only 6 months. *Exclusive* breast-feeding is rec-