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Ms. Sharon Freitag  
*President, CAREB*  
Manager, Research Ethics Board  
Research Ethics Office  
St. Michael's  
30 Bond Street  
Toronto, Ontario  
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Dear Ms. Freitag:

Thank you for your continued efforts and undertakings related to Canadian Research Ethics Boards (REBs) and the challenges being experienced in the management of Adverse Event (AE) reports.

This letter is in follow-up to the Health Canada-CAREB meeting of February 20, 2010, where CAREB indicated its intent to release their draft Guidance document on the reporting of adverse events (AEs) to REBs. At this meeting, Health Canada noted that a response would be provided regarding the compliance of the draft Guidance with applicable regulations, and any objections with the approach described in the draft Guidance; Health Canada also informed CAREB of the ongoing broader policy review related to the management of AE reports by REBs being undertaken by the Strategic Policy Branch (SPB).

Further to Health Canada's commitments as mentioned above, the following feedback is provided:

- While Health Canada's relevant regulations do include certain requirements for REBs involved in the submission process, we do not have jurisdiction over how REBs conduct their operations or establish standard operating procedures.

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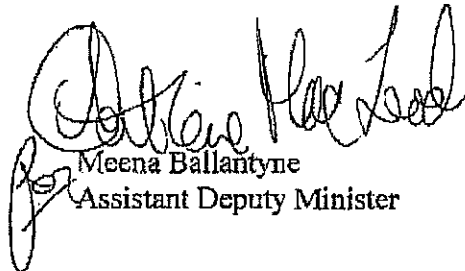
- While it is not Health Canada's role to endorse or take a position on external guidances, it is important to note that Sections C.05.001 and Section C.05.012 (3) (h) under Division 5 of the *Food and Drug Regulations* as well as ICH E6, stipulate that REBs have a responsibility to ensure the protection of the rights, safety and well-being of clinical trial subjects. Therefore, it is recommended that CAREB ensure that any Guidance Document it develops or endorses does not negatively impact, and rather enhances, this regulatory mandated responsibility of REBs in Canada.

We would also recommend that Canadian REBs consider the Canadian General Standards Board (CGSB) standards for REBs overseeing biomedical clinical trials when developing their operating procedures.

We recognize the challenges related to the management of AE reports by REBs, and will continue the broader policy analysis to consider and develop options for addressing the various issues.

Thank you for your continued efforts.

Yours sincerely,



Meena Ballantyne  
Assistant Deputy Minister

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