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HEALTH CANADA REB ATTESTATION

It is Sterling IRB's policy not to sign individual REB attestation forms for Health Canada regulated research. The Health Canada *Guidance for Clinical Trial Sponsors* states that REBs may develop similar documentation that meets the requirements of Part C, Division 5 of the Food and Drug Regulations. Consistent with this guidance, the attestation below, in conjunction with any specific approval issued by Sterling IRB, will serve as the research ethics board attestation in lieu of the form provided by Health Canada.

Attestation

In respect of the identified clinical trial, I certify, as a representative of the Sterling IRB North American panel that:

1. The membership of the Sterling IRB North American panel complies with the membership requirements for REBs defined in Part C Division 5 of the *Food and Drug Regulations*;
2. The Sterling IRB North American panel carries out its functions in a manner consistent with Good Clinical Practices; and
3. The Sterling IRB North American panel has reviewed and approved the clinical trial protocol and informed consent form for the trial. The approval and the views of the Sterling IRB North American panel have been documented in writing.

Kathye Richards

Kathye Richards, CIP, Institutional Official

Steven L. Saltzman, M.D.

Steven L. Saltzman, M.D., F.A.C.O.G., IRB Chairman