Health Canada Santé Canada

Protected B when complete

Research ethics board attestation
Natural and Non-prescription Health Products Directorate

An attestation must be completed by the Research Ethics Board that reviewed and approved the clinical trial protocol and informed consent form for this clinical trial at the site below. The completed attestation must be retained by the clinical trial sponsor for a period of 15 years.

Part 1: Clinical trial protocol information

Please check one of the following:

O Clinical trial application (CTA) O Clinical trial application amendment (CTA-A)

Protocol # (if known):

Protocol title:

Part 2: Natural Health Product (NHP) / Sponsor Information

A. NHP Information

Brand name/product code:

Medicinal ingredient(s):

Submission number (if known):

☐ See clinical trial application and attestation form

B. Sponsor of clinical trial

Name of sponsor (Full name – no abbreviations):

Street/Suite/PO box:

City/Town:	Province/State:	Country:	Postal/ZIP code:

C. Contact for this Clinical Trial

Contact name:

Company name (Full name – no abbreviations):

Street/Suite/PO box:

City/Town:	Province/State:	Country:	Postal/ZIP code:

Telephone No.:	Fax No.:

E-mail:

Canada

Part 3: Clinical Trial Site Information		
A. Clinical Trial Site		
Name of site (Full name – no abbreviations):		
Street/Suite/PO box:		
City/Town:	Province:	Postal code:
B. Qualified Investigator:		
Name:		
Title:		Language preferred: O English O French
Street/Suite/PO box:		
City/Town:	Province:	Postal code:
Telephone No.:	Fax No.:	
E-mail:		

Attach separate sheets (same format) for each Clinical Trial Site.

Number of pages attached: ☐

C. Research Ethics Board Approval	☐ Includes member knowledgeable in complementary or alternative health care (identify member and expertise in the cover letter)

Name of Research Ethics Board:	Date of approval:
Street/Suite/PO box:	

City/Town:	Province:	Postal code:
Name of Research Ethics Board chair:		
Title:		Language preferred: O English O French
Telephone No.:	Fax No.:	
E-mail:		

In respect of the identified clinical trial, I certify, as representative of this Research Ethics Board that:

1. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Part 4 of the *Natural Health Products Regulations*;
2. This Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices; and
3. This Research Ethics Board has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Board have been documented in writing.

Name, title and signature of Research Ethics Board representative	
Name:	
Title:	
Signature:	Date: Y Y Y Y M M D D