



Health
Canada

Santé
Canada

QUALIFIED INVESTIGATOR UNDERTAKING Natural Health Products Directorate

An undertaking must be completed by the qualified investigator responsible for the conduct of the clinical trial at the site specified below. The completed undertaking must be retained by the clinical trial sponsor for a period of 25 years.

Part 1: Clinical Trial Protocol Information

Please check one of the following:

- Clinical Trial Application (CTA)**
 Clinical Trial Application Amendment (CTA-A)
 Clinical Trial Notification

Protocol Title

Protocol # (if known)

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

A. NHP Information

Brand Name / Product Code:

Medicinal Ingredient(s):

- See Clinical Trial Application and Attestation Form

Submission Number (if known):

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

E-mail

Company Name (Full Name – No Abbreviations)

Street / Suite / PO Box

City / Town

Province / State

Country

Postal / ZIP Code

Telephone No.

Fax No.

Part 3: Qualified Investigator 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

English

French

Street / Suite / PO Box

City / Town

Province

Postal Code

E-mail

Telephone No.

Fax No.

In respect of the identified clinical trial, I certify, as the qualified investigator for this site that:

1. I am a physician or dentist and a member in good standing of a professional medical or dental association as defined in Part 4 of the *Natural Health Products Regulations*;
2. I will supervise the medical care and medical decisions respecting this clinical trial at this site;
3. I will conduct this clinical trial in accordance with Good Clinical Practices; and
4. I will immediately on discontinuance of the clinical trial by the sponsor, in its entirety or at a clinical trial site, inform both the clinical trial subjects and the Research Ethics Board for this site of the discontinuance, provide them with the reasons for the discontinuance, and advise them in writing of any potential risks to the health of clinical trial subjects or other persons.

Signature of Qualified Investigator

Date

YYYY

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