**Investigational Testing Notification Form**

This form is intended to be used by investigators or manufacturers to report information concerning some medical device clinical trials. This form does not apply when an investigational testing authorization (ITA) is currently required.

This notification form is required for:

* All new investigator-sponsored clinical trials
* All new in-house clinical trials

A single Investigational Testing Notification Form (ITNF) should be submitted for a clinical trial. The clinical trial may include more than one medical device.

All fields marked with an asterisk (\*) must be filled prior to submission of the form.

|  |
| --- |
|  |

How to submit

The completed form should be submitted by email to Health Canada’s Investigational Testing Division at: it-ee@hc-sc.gc.ca. **Unsolicited documents and information should not be submitted with this form, unless specifically requested by Health Canada.**

\* **The email subject line should state: “Investigational Testing Notification Submission”**

Health Canada will not confirm receipt.

Health Canada may, however, follow up if additional information is necessary. The submitter should have in place and maintain records of a monitoring process, which Health Canada may assess when verifying compliance.

|  |
| --- |
|  |

**Privacy Notice**

The personal information you provide to Health Canada will be used by the Health Products and Food Branch under the authority of section 23(1)(c) of the Food and Drugs Act and Medical Devices Regulations and handled in accordance with the Privacy Act.

**Why are we collecting your personal information?**

We collect your name and contact information as part of the compliance and enforcement activities related to Investigational Testing Notifications for medical devices.

**Will we use or share your personal information for any other reason?**

Your personal information is used to follow up with you concerning your Investigational Testing Notification. Your personal information may be shared with other Branches in Health Canada who have similar mandates.

**What happens if you don’t want to provide your personal information?** The collection of name and contact information for the organization is mandatory.

**What are your rights?** You have the right to access and request a correction and/or notation to your personal information. You also have a right to complain to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights, or about how we handle your personal information, please contact the Investigational Testing Unit at it-ee@hc-sc.gc.ca.

**For more information:** The collection of your personal information is described in Info Source at infosource.gc.ca. Refer to the personal information bank (PIB) HC PPU 405 – Compliance and Enforcement – Medical Devices. In addition to the requirements specified on the Treasury Board of Canada Secretariat Personal Information Request form, individuals requesting information described by this bank must provide the incident ID number, device name or company name.

|  |
| --- |
| Notification Information |
| 1. **Date of Submission**
 |
| 1. **Date of Submission\***

Click or tap to enter a date. |
| 1. **Submitter Information**
 |
| * + 1. **Submitter\***

The submitter is a principal investigator for an investigator-sponsored trial, or a manufacturer for an in-house trial.*Please provide name of Manufacturer:* Click or tap here to enter text. |
| * + 1. **Qualified Investigator Contact Information**
			1. Investigator Name**\***

Click or tap here to enter text. | * + - 1. Occupational Title**\***

Click or tap here to enter text. |
| * + - 1. Email Address**\***

Click or tap here to enter text. | * + - 1. Phone Number

Click or tap here to enter text. |
| * + - 1. **Qualified Investigator \***

[ ]  I attest that a qualified investigator will be overseeing this clinical trial. A qualified investigator is a member in good standing of a professional association of persons entitled under the laws of a province to provide health care in the province and who is designated, by the ethics committee of the health care facility at which investigational testing is to be conducted, as the person to conduct the testing. |
| 1. **Investigational Site Information**
 |
| 1. **Investigational Site Name(s) \***

Click or tap here to enter text. |
| 1. **Investigational Site Address(es) \***

Click or tap here to enter text. |
| 1. **Device Information**
 |
| 1. **Device Name(s) \***

Click or tap here to enter text. | 1. **Device MDL or Identifier**

Please specify MDL or Identifier if the device is licenced for use in Canada. Click or tap here to enter text. |
| 1. **Brief description of the device(s) \***

Please specify if the device contains any biological components and/or derivatives. Click or tap here to enter text. |
| 1. **Indications for use and/or intended use of the device\***

Click or tap here to enter text. |
|  |
| 1. **If this study was authorized through an ITA for other device(s) or components, please provide the application number(s).**

Click or tap here to enter text. |
| 1. **Protocol Summary**
 |
| 1. **Protocol Title and Protocol Number (if applicable) \***

Click or tap here to enter text. |
| 1. **Protocol Version\***

Click or tap here to enter text. | 1. **Protocol Date\***

Click or tap to enter a date. | 1. **Total Number of Participants in the Study (Canadian Sites ONLY) \***

Click or tap here to enter text. |
| 1. **Study Objectives (ensure that this information matches the protocol) \***

Click or tap here to enter text. |
| 1. **Study Design\***

Click or tap here to enter text. |
| 1. **Serious Adverse Events**
 |
| 1. **Is there a possibility the study may result in a serious adverse events?**
 |
| 1. **Adverse event description**

If yes was selected, please provide a brief description of the potential serious adverse events that may occur during the study. Click or tap here to enter text. | 1. **Rationale**

If no was selected, please provide a brief rationale as to why the trial will not result in serious adverse events. Click or tap here to enter text. |
| **F. Research Ethics Board Approval\*** |
| [ ] I, the Choose an item., confirm that I will obtain approval from a Research Ethics Board (REB) prior to study initiation.  |

|  |
| --- |
| **INSTRUCTIONS ON COMPLETING THE INVESTIGATIONAL TESTING NOTIFICATION FORM** |
| **Please read all form fields carefully and supply an answer. All form fields marked with an asterisk (\*) must be filled prior to submission****DEFINITIONS****Device Name:** The device name will specify any information necessary for the user to identify the device and to distinguish it from similar devices. The device name must match labelling material. * **In-house clinical trial:** Manufacturer-sponsored clinical trials where the development, manufacture and testing of the medical device are conducted by a manufacturer, including a clinical site (such as a hospital).
* **Investigator-sponsored clinical trial:** Clinical trials sponsored by a clinician or a health care facility, not by the device manufacturer.
* The data generated in the clinical trial are not intended to support medical device licence application, amendments or new marketing claims. These types of clinical trials would require an investigational testing authorization.

**Manufacturer:** A manufacturer is a person (or persons) who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf. An academic institution can meet the definition of manufacturer if the institution is the designer and/or owner of the device. **Principal investigator:** If a clinical investigation is conducted by a team of individuals at an investigation site, or over multiple investigation sites, the principal investigator is responsible for leading the team.**Qualified Investigator:** A qualified investigator is required to conduct a clinical trial. The qualified investigator is a person who is a member in good standing of a professional association of persons entitled under the laws of a province to provide health care in the province and who is designated, by the ethics committee of the health care facility at which investigational testing is to be conducted, as the person to conduct the testing.**Serious Adverse Event:** A hazard associated with the medical device that is relevant to the safety of the medical device (including issues related to effectiveness or quality) and that, without risk mitigation, would likely: * + be life-threatening
	+ result in persistent or significant disability or incapacity
	+ require inpatient hospitalization or prolonged hospitalization
	+ result in a serious health consequence such as loss of function or debilitating chronic pain
	+ result in death

An adverse event, as defined in ICH E2D[Reference8](https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/reporting-adverse-reactions-marketed-health-products-guidance-industry/guidance-document.html#fn8), means any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product.**A. DATE OF SUBMISSION****A1. Date of Submission:** Provide the date on which the notification was submitted. * 1. **SUBMITTER INFORMATION**

**B1. Submitter:** The submitter is a principal investigator for an investigator-sponsored trial, or a manufacturer sponsoring an in-house trial. If you are a Manufacturer submitting the notification, please also provide the Manufacturer name, as well as your Health Canada authorized company ID if applicable. **B2. Qualified Investigator Contact Information:** 1. **Name:** Provide the name of the qualified investigator conducting the trial.
2. **Occupational Title:** Provide the occupational title of the qualified investigator conducting the trial.
3. **Email Address:** Provide the email of the qualified investigator conducting the trial.
4. **Phone Number:** Provide the phone number of the qualified investigator conducting the trial. This field is optional.
	1. **INVESTIGATIONAL SITE INFORMATION**

Provide at least one study site where the investigational testing will be conducted. If additional sites are added in the future, you are not required to re-submit this form.**C1. Investigational Site Name(s):** Provide the name(s) of the study site(s) that will be included in the study.**C2. Investigational Site Address(es):** Provide the name(s) of the study site address(es) that will be included in the study. * 1. **DEVICE INFORMATION**

**D1. Device Name(s):** Provide the names of the device(s) that will be included in the study.**D2. Brief description of the device(s):** Provide a brief description of the device(s), such as hardware and software components, and materials used in its construction (i.e., physical and chemical characterization, key specifications and performance features and any key safety risks associated with the device, component parts, accessories, patient contact materials, and packaging materials). Please also provide a brief description of how the device works (e.g. philosophy behind its design and function). **D2. Indications for use and/or intended use of the device(s):** Provide description of the medical conditions, purposes and uses for which the device(s) is(are) manufactured, sold or represented.* 1. **PROTOCOL SUMMARY**

**E1. Protocol Title and Protocol Number (if applicable):** Provide the title of the clinical trial and number (if applicable).**E2. Protocol Version:** Given that clinical trial protocols may have a number of iterations, for document control purposes, provide the version number at the time of notification.**E3. Protocol Date:** Given that clinical trial protocols may have a number of iterations, for document control purposes, provide the clinical trial protocol date that has been determined at the time of notification. **E4. Total Number of Participants in the Study (Canadian Sites ONLY):** Provide the maximum number of participants expected to enroll at all Canadian sites.**E5. Study Objectives (Ensure that this information matches the protocol):** The objective of a clinical trial is to establish the effect of an intervention using the medical device. Provide the primary objective for the clinical trial. Secondary objectives may be optionally included.**E6. Study Design:** Briefly describe the study design (e.g. first in human, early feasibility, pivotal study). Include information describing the disease or condition to be treated, the study population (e.g. inclusion and exclusion criteria), information on how the device will be used in the study, how patient safety monitoring would be conducted, and the estimated time frame for the conduct of the study.As relevant, it is encouraged to select participants who are representative of the population intended to be treated with the device (i.e. sex and gender-based plus analysis to consider how diverse groups of people may be impacted).It is encouraged to select participants who are representative of the population intended to be treated with the device (i.e. sex and gender-based analysis plus to assess how diverse groups of people may be impacted in the clinical trial).**E7. Serious Adverse Events** 1. **Select Yes or No.**
2. **Adverse Event Description:** Provide a brief description of potential serious adverse events that may occur during the study.
3. **Rationale:** Provide a brief rationale as to why it is believed the study will not result in any serious adverse event.
	1. **RESEARCH ETHICS BOARD APPROVAL**

Research Ethics Board (REB) must be obtained prior to study initiation, in accordance with institutional policies. Study initiation means the date when the investigation site will be ready to enroll patients in the study. At this time, for the purpose of this notification, a copy of REB approval does not need to be provided to Health Canada, unless specifically requested. |