



## **TEMPLATE CONFIDENTIALITY AGREEMENT FOR PHARMACEUTICAL STUDIES**

The enclosed Confidentiality Agreement is the product of a collaborative effort of several interested parties with the goal of assisting clinical researchers in Canada. The Federation of National Specialty Societies of Canada (FNSSC) developed this template Confidentiality Agreement with the Canadian Medical Association (CMA) in consultation with the Canadian Medical Protective Association (CMPA). We gratefully acknowledge Barry Cappel, Corporate Secretary and Legal Counsel of McGill University Health Centre, for generously giving his time and effort to prepare the confidentiality agreement.

Frequently investigators are required to complete this type of agreement in advance of receiving information about proposed new pharmaceutical studies. This template Confidentiality Agreement has been developed in an effort to both standardize and approve the wording of the Agreement.

It is very important that clinical investigators do carefully read the Agreement and understand the responsibilities they assume by signing the Agreement.

Pharmaceutical companies have the right to control confidential information relating to the development of new and existing pharmaceutical agents. By entering into the Agreement, investigators undertake to keep the provided information confidential. Investigators who breach this agreement could face medico-legal consequences. While the assistance of the CMPA does not generally extend to allegations of breach of contractual agreements, any clinical investigator who has uncertainties about the extent of the duty of confidentiality imposed by the Agreement is strongly urged to contact the CMPA for advice.

## CONFIDENTIALITY AGREEMENT

This agreement (the "Agreement") is made

(INSERT DATE)

by and between (INSERT DETAILS AND MAY THEREAFTER REFERRED TO AS)

("PHARMA")

and (INSERT DETAILS AND MAY THEREAFTER REFERRED TO AS)

("INVESTIGATOR")

### W-I-T-N-E-S-S-E-T-H

**WHEREAS, PHARMA** possesses certain valuable and confidential information, data and expertise (collectively the "**INFORMATION**") relating to:

(INSERT NAME AND NUMBER OF PROTOCOL)

**WHEREAS,** such **INFORMATION** is considered by **PHARMA** to be secret and confidential and constitutes a valuable commercial asset to **PHARMA**, and

**WHEREAS, PHARMA** is willing, subject to the terms and conditions hereof, to disclose such **INFORMATION**, to **INVESTIGATOR** for the purpose of enabling **INVESTIGATOR** to evaluate such **INFORMATION** for the limited purpose of determining if it is expedient to proceed with the protocol, and for no other purpose whatsoever.

**NOW THEREFORE**, in consideration of the foregoing premises that are hereby incorporated as a part of this Agreement and the mutual covenants hereinafter set forth, the Parties hereto agree as follows:

1. Promptly after execution of this Agreement, **PHARMA** shall disclose to **INVESTIGATOR** all relevant **INFORMATION** within its possession or control as deemed necessary by **PHARMA**, to facilitate the feasibility of proceeding with the Protocol. **INVESTIGATOR** shall accept and hold such **INFORMATION** in confidence in accordance with the provisions of Section 2 below.

2. Without the prior written consent of **PHARMA**, the **INVESTIGATOR** shall neither willfully and knowingly (i) disclose to any third party or permit any third party to have access to any of the **INFORMATION** disclosed by **PHARMA**, nor (ii) use such **INFORMATION** for any purpose other than that stated in Paragraph 1 hereof. Notwithstanding the preceding sentence, **INVESTIGATOR** shall be permitted to disclose the **INFORMATION** to those of its consultants, agents, associates, employees or institution/facility who shall reasonably need to know the **INFORMATION** in order to undertake and perform the Protocol.

**INVESTIGATOR** agrees to take reasonable measures to require anyone to whom **INVESTIGATOR** gives Confidential **INFORMATION** to be bound by the confidentiality obligations under this Agreement. However, the aforesaid secrecy obligations assumed by the **INVESTIGATOR** shall not apply to any **INFORMATION** that the **INVESTIGATOR** can clearly demonstrate falls within any of the following categories:

(a) **INFORMATION** that is now generally known to the public or subsequently becomes generally known to the public through no fault of **INVESTIGATOR**;

(b) **INFORMATION** that, as of the time of disclosure to **INVESTIGATOR**, was already known to and in the possession of **INVESTIGATOR** as evidenced by written records;

(c) **INFORMATION** obtained after the date hereof by **INVESTIGATOR** from a third party lawfully in possession of, and having the right to disclose same; or

**(d) INFORMATION** that the **INVESTIGATOR** is required or permitted by law to disclose.

3. Except as provided in Section 1 hereof, no license or other right to use the **INFORMATION** is granted hereby.

4. The disclosure of **INFORMATION** by **PHARMA** to **INVESTIGATOR** shall not result in any obligation on the part of either party to enter into any future agreement relating to the **INFORMATION** or to undertake any other obligation not set forth in written agreement signed by the Parties hereto.

5. **INFORMATION** furnished by **PHARMA** to **INVESTIGATOR** under the Agreement shall remain **PHARMA's** property unless otherwise agreed, and any documents furnished containing such **INFORMATION** shall be promptly returned to **PHARMA** upon request.

6. **INVESTIGATOR** represents and warrants to **PHARMA** that he/she is not knowingly a party to any other agreement or under any obligation to or restriction by any third party which would prevent the **INVESTIGATOR** from entering into this Agreement or which would adversely affect this Agreement or any of the undertakings set forth herein in any manner. If the **INVESTIGATOR** becomes aware of an obligation or restriction by any third party which would prevent him/her from entering into this Agreement, he/she shall forthwith advise **PHARMA** and deliver to **PHARMA** all **INFORMATION** disclosed to the **INVESTIGATOR** subject to this Agreement.

7. The rights and obligations arising from, through or as a result of the terms of this Agreement shall continue in full force and effect for a period of five (5) years from the date hereof.

8. Neither party shall be entitled to assign its rights hereunder without the express written consent of the other party.

9. A waiver by either party of any term or condition of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or

condition for the future, or of any subsequent breach thereof. All rights, remedies, undertakings, or obligations contained in this Agreement shall be cumulative and none of them shall be in limitation of any other right, remedy, undertaking, or obligation of either party.

**10.** If and to the extent that any court of competent jurisdiction holds any provision or part of this Agreement to be invalid or unenforceable, such holding shall in no way affect the validity of the remainder of this Agreement.

**11.** The Parties hereby agree that this Agreement shall be governed by and construed in accordance with the laws of the Province of (PLEASE INSERT PROVINCE WHERE THE INVESTIGATOR IS SITUATED)

and the laws of  
Canada applicable therein, irrespective of any conflicts of law principles.

**12.** The Parties hereby acknowledge that the Courts of the Province of (PLEASE INSERT PROVINCE WHERE THE INVESTIGATOR IS SITUATED)

shall  
have exclusive and preferential jurisdiction, according to the laws of (PLEASE INSERT PROVINCE WHERE THE INVESTIGATOR IS SITUATED)

, to  
entertain any complaint, demand, claim or cause of action whatsoever arising out of this Agreement. The Parties hereby agree that if either of them commence any such legal proceedings, they will only be commenced in the Province of (PLEASE INSERT PROVINCE WHERE THE INVESTIGATOR IS SITUATED)

**13.** This Agreement contains the entire understanding between the Parties with respect to the matters contemplated herein and supersedes all previous written and oral negotiations, commitments, and understandings. This Agreement cannot be altered or otherwise amended except pursuant to an instrument in writing signed by each of the Parties hereto and making specific reference to this Agreement.

**14. (IF A QUEBEC AGREEMENT)** The Parties to this Agreement have expressly requested that the Agreement and all other notices and other related documents be drafted in the English language.

*Les parties à cette convention ont expressément requis que cette convention et tout avis et autres documents y afférents soient rédigés en langue anglaise.*

**IN WITNESS HEREOF**, the Parties hereto have caused this Agreement to be executed as of the date first above written.

**PHARMA**

**INVESTIGATOR**

By: \_\_\_\_\_

By: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_