Non-Disclosure Agreement

I, _____, hereinafter the "**Recipient**", agree, to the following:
(Please print your name and/or company name)

1. The Recipient has been invited to and wishes to participate in the Scientific Advice Program of the Canadian Agency for Drugs and Technologies in Health (CADTH).

2. The Recipient and CADTH expect that, in the course of participating in the Scientific Advice Program, CADTH may disclose to the Recipient, or allow the Recipient access to, certain Confidential Information (defined below).

3. In consideration of receiving the Confidential Information from CADTH and the mutual covenants herein, the Recipient is entering into this Agreement that sets forth the manner in which the Confidential Information will be treated.

4. **Confidential Information:**

   "Confidential Information" means information including the name of the applicant; the name and nature of the drug that is the subject of the application; scientific and technical information including reports, studies, specifications, data, commercial information, applicants' documents, documents produced by CADTH; and other Confidential Information obtained from or on behalf of CADTH, whether directly or indirectly, and whether in writing, orally, or in graphic, electronic, drawing or any other form or medium now or hereafter known. Further, Confidential Information will also include any information derived from or incorporating the foregoing information. However, Confidential Information shall not include information that the Recipient can prove:

   (a) is in the public domain prior to its disclosure or becomes public through no fault of the Recipient

   (b) is already known by the Recipient prior to its disclosure

   (c) is developed independently by the Recipient

   (d) is lawfully disclosed to the Recipient by a third party

   (e) is disclosed as required by law or by judicial decree.

5. A combination of separate parts of the Confidential Information shall not be deemed to fall within the abovementioned exceptions merely because one of the parts is in the public domain, in the Recipient's possession, or otherwise lawfully disclosed.

6. Any Confidential Information is provided "as is" and CADTH makes no implied or express representations or warranties as to the accuracy or completeness of the Confidential Information.

7. The Recipient shall treat as confidential the Confidential Information and shall not use, copy, reproduce in any form, store, manipulate, exploit, or disclose it (except in accordance with the terms of this Agreement) without the express, advance written permission of CADTH. The Recipient shall protect the Confidential Information from unauthorized access, use, or disclosure with at least the same diligence and care with which the Recipient protects the confidentiality of the Recipient's own information.

8. The Recipient will comply with all applicable requirements of Canadian federal or provincial legislation now in force or that may in the future come into force governing the collection, use, disclosure, and protection of the Confidential Information.

9. All Confidential Information will remain the property of CADTH or the applicant, as applicable, and the Recipient shall, upon CADTH's written request, promptly return to CADTH or destroy (and certify as to such destruction) all Confidential Information and any copies, records, or embodiments thereof, in whatever form or media.

10. The Recipient shall comply with and be bound by the terms and conditions of CADTH's *Confidentiality Guidelines for Scientific Advice* (the "**Guidelines**"), attached hereto as **Schedule A**.

11. In the event of any conflict or inconsistency between the provisions of this Agreement and the provisions of the Guidelines, the provisions of the Guidelines shall prevail.

12. The covenants and commitments set out herein shall survive any termination of the Recipient's participation in the Scientific Advice Program and/or any termination of this Agreement.

13. This Agreement supersedes any and all prior arrangements between the Recipient and CADTH, whether oral or written, express or implied, with respect to the Confidential Information.

14. This Agreement is personal, indivisible, and non-transferable, and may not be assigned or transferred in whole or in part by the Recipient.

15. If any term of this Agreement shall be held to be illegal, invalid, or unenforceable by a court of competent jurisdiction, such term shall be deemed severed from this Agreement and the remaining terms shall remain in full force and effect.

16. This Agreement is governed by and construed in accordance with the laws of Ontario and the federal laws of Canada applicable therein, and CADTH and the Recipient irrevocably and unconditionally attorn to the exclusive jurisdiction of the courts of such province and all courts competent to hear appeals therefrom.

17. The Recipient shall do all such further things or execute all such further documents in connection with this Agreement that CADTH may reasonably require, in order to give effect to this Agreement.

SIGNED, this _____ day of _____ , 20 _____
(month) (year)

_____
(Signature)

_____
(Print Name)

_____
(Print Title)

_____
(Affiliation, if any)

Schedule A

Confidentiality Guidelines for Scientific Advice

These guidelines are intended to ensure that Confidential Information obtained and produced pursuant to the Scientific Advice Program is protected and handled in a consistent manner by CADTH. By applying to the CADTH Scientific Advice Program, the applicant consents to these guidelines, and agrees to be bound by the terms and conditions herein.

Confidential Information

All information and documentation submitted by or on behalf of an applicant as part of the Scientific Advice Program, including drug name and company name, and all information and documentation produced by CADTH as part of the Scientific Advice Program, are considered to be "Confidential Information." All written and verbal communication related to the Scientific Advice application are also considered to be Confidential Information. Applicants and CADTH must clearly and conspicuously mark documents as Confidential.

Access to Information and Freedom of Information Legislation

CADTH is a private, not-for-profit organization and is therefore not subject to either federal access to information or provincial/territorial freedom of information statutes.

Handling Confidential Information

1 Responsibilities of Recipients of Confidential Information

a) Recipients of Confidential Information (i.e., CADTH, applicants, authorized recipients, and/or patient representatives, as applicable) will use reasonable care to prevent the unauthorized use, disclosure, publication, or dissemination of all Confidential Information.

b) Recipients of Confidential Information (i.e., CADTH, applicants, authorized recipients, and/or patient representatives, as applicable) will not disclose any Confidential Information submitted by or on behalf of the applicant or produced by CADTH as part of the Scientific Advice Program to any third party except as permitted by these guidelines; as agreed by expressed, advance, written permission from both CADTH and the applicant; or as required by law or by order of a legally qualified court or tribunal.

2 Responsibilities of CADTH

a) CADTH will use the applicant's Confidential Information solely for the purpose of carrying out its responsibilities pursuant to the Scientific Advice Program.

b) CADTH shall utilize secure filing and storage, websites, and tracking processes for handling applicants' Confidential Information and Scientific Advice information. Scientific Advice files will be kept separate from other CADTH files.

3 Disclosure of Information

a) All applicant documents and Confidential Information submitted as part of the Scientific Advice Program and all documents produced by CADTH as part of the Scientific Advice Program may be released to the following "authorized recipients":

- CADTH staff, as required (requirement to be determined at CADTH's sole discretion)
- External experts involved in the Scientific Advice Program.

b) Applicant documents and Confidential Information submitted as part of the Scientific Advice Program and documents produced by CADTH as part of the Scientific Advice Program may be released to patient representatives involved in the Scientific Advice Program only with express written permission from the applicant, as indicated in the declaration section of the Scientific Advice application form.

c) CADTH staff involved in the Scientific Advice Program and any other CADTH staff with whom Scientific Advice information is shared are required to comply with these guidelines. All CADTH staff must also comply with the confidentiality clauses in their employment contracts and with the CADTH *Conflict of Interest Policy for Employees*.

d) External experts involved in the Scientific Advice Program are required to comply with these guidelines in the same manner and to the same extent as CADTH, and will be subject to a *Non-Disclosure Agreement*. All external experts contracted by CADTH must also comply with the CADTH *Conflict of Interest Guidelines for Contractors*.

e) Patient representatives involved in the Scientific Advice Program are required to comply with these guidelines in the same manner and to the same extent as CADTH, and will be subject to a *Non-Disclosure Agreement*. All patient representatives must also comply with the CADTH *Conflict of Interest Guidelines for Contractors*.

4 Recording of Meeting Minutes

a) Applicants, CADTH staff, external experts, and patient representatives may record minutes, in writing, from teleconferences and face-to-face meetings, as required. Written meeting minutes are considered to be Confidential Information.

b) Audio recordings of teleconferences and face-to-face meetings are not permitted by any party.

5 Documents That May Be Shared With Authorized Recipients

a) All or sections of the following documents may be shared with authorized recipients, and when permitted under section 3 b) hereof, with patient representatives, and may be posted on a confidential website accessible only by persons authorized according to these guidelines:

- Completed application form
- *Briefing Book for CADTH Scientific Advice*
- *Clarification on the Briefing Book for Scientific Advice*
- *Addendum to Briefing Book for CADTH Scientific Advice*
- *Record of Scientific Advice* (drafts and final)
- *Clarification on the Record of Scientific Advice*
- Meeting minutes.

b) No documents will be posted on the CADTH public website.

6 Archiving and Disposal of Documents Containing Confidential Information

a) One complete set of all electronic documents associated with a Scientific Advice application is kept on file in secure storage for as long as there may be a need to refer to the documents.

b) CADTH will determine, at its sole and absolute discretion, if there is a need to refer to this information.

c) CADTH staff undertakes regular reviews of archived material. Any material that CADTH determines to be no longer required is disposed of as subsequently described in sections 6 d) and 6 e).

d) At the completion of a Scientific Advice application, CADTH disposes of all hard copies of documents supplied by the applicant and produced by CADTH as part of the Scientific Advice Program by confidential shredding.

e) At the completion of a Scientific Advice application, external experts and patient representatives must delete or dispose of all documentation (electronic and hard copy) that was provided and produced as part of the Scientific Advice Program, including information which may have been stored on a hard drive of a computer or in emails.