TEMPLATE
COLLABORATION AGREEMENT WITH WHO

This [*title*] **Agreement** (the "**Agreement**") is entered into as of [*date*] (the "**Effective Date**") by and between:

- Partner 1: title, address, (hereinafter referred to as "**XXX**");
- Partner 2: title, address, (hereinafter referred to as "**XXX**")
- Partner 3: title, address, (hereinafter referred to as "**XXX**")
- the World Health Organization, having its headquarters at 20, avenue Appia, 1211 Geneva 27, Switzerland (hereinafter referred to as "**WHO**").

1. WHO is coordinating, on a non-exclusive and world-wide basis, efforts to develop [*short explanation of what WHO will be doing and the scope of the work to be undertaken …*] (hereinafter referred to as "**the Field**").

2. [*list of partners…*] and WHO (hereinafter referred to as "**the Parties**" or "**Collaboration members**") wish to collaborate on the [*provide a short statement of the purpose of the collaboration*] (the "**Purpose**").

3. Now, therefore, the Parties hereby establish a Collaboration (the "**Collaboration**") for achieving the Purpose and the sharing of resulting information under the terms and conditions set forth herein.

4. Each Collaboration member shall appoint one (1) official representative, and each Collaboration member may include one (1) additional individual as an observer in meetings and discussions. WHO's official representative will serve as the chairperson of the Collaboration. The chairperson shall prepare and circulate agendas (with input from other Collaboration members), convene and preside at Collaboration meetings, and prepare and circulate meeting minutes.

5. **Communication**

   The Collaboration shall meet at least once per month or at any time as deemed necessary by one of the members of the Collaboration for accelerated attainment of

the Purpose. The Collaboration may meet in person or by video or audio conference, and each Collaboration member shall bear the expense of its representative's participation in Collaboration meetings.

6. Each Party shall develop independently the protocol for the Trial to be conducted by it. The Parties agree to share the final protocols as well as associated documents, including but not limited to Informed Consent Forms for the Trials, with WHO and to promptly inform WHO of any submission to, and any approval from, any regulatory or ethical body with regard to the conduct of the Trial.

7. **Intellectual Property**

   (a) For the purpose of this section of the Agreement, "**Inventions**" are defined as any inventions, know-how, discoveries and ideas that are made or developed under this Agreement or otherwise in connection with the Collaboration's activities, whether or not patentable or copyrightable.

   (b) Subject to the terms of this Agreement, the Parties shall promptly disclose to WHO any and all Inventions that directly relate to the Purpose and are made or developed by them under this Agreement or otherwise in connection with the Collaboration's activities, whether solely or jointly with other Collaboration members, whether or not patentable or copyrightable. All rights, title and interest in and to any and all Inventions made or developed under this Agreement or otherwise in connection with the Collaboration's activities, including all intellectual property rights therein, shall be owned by the Party or Parties that made or developed them, provided that the relevant Party or Parties hereby grant WHO a worldwide, royalty-free, sub-licensable and irrevocable, non-exclusive license to such Inventions for the purpose of further developing, registering and commercializing those Inventions for use in the Field.

   (c) Without prejudice to this section, the industrial or commercial exploitation (including licensing) of any intellectual property rights arising from the Collaboration shall be done in a manner fully consistent with the Technical Services Agreements (TSAs) to be concluded between WHO and each of the other Parties hereto.

8. **Data Management**

(a) Any and all data and information that are made or developed by the Parties under this Agreement or otherwise in connection with the Collaboration's activities, shall be owned by the Party or Parties generating such data or information, provided that WHO is hereby vested with a worldwide, royalty-free, sub-licensable, irrevocable and perpetual, non-exclusive license in all such data and information made or developed covering all applications and uses for which the rights may be exercised, including but not limited to publication of the data and/or information.

(b) **…**

9. **Sharing of information**

(a) Each Party shall, on request, disclose to the other Parties, in the form of written documentation, on a confidential basis in accordance with the terms of paragraph 10 below, all data and information already available to it, or developed by it during the course of this Collaboration Agreement, relating in any way to the Purpose.

(b) Each party should take the responsibility to ensure that results – even when preliminary – are adequately robust and have undergone quality control, prior to public disclosure.

(c) Each party has an obligation to publicly disclose quality controlled interim results according to a specific expedited timeline commitment for results sharing that should be made in protocols and analysis plans before trial commencement.

(d) Prior to the start of any clinical trial (ie prior to the first subject receiving the first experimental intervention) a clinical trial registry entry is to be made on a WHO ICTRP primary registry. Where the registry has a results summary section, public disclosure of interim and final results should occur using the results summary component of the registry.

(e) Final results are to be publicly disclosed, no later than 28 days after the primary study completion date, using the results summary section of the registry entry.

10. **Confidential Information**

(a) When information provided in the context of this Collaboration Agreement is described by the Party providing it as confidential (the "**Confidential Information**" of such Party), the receiving Parties shall take all reasonable measures to keep such Confidential Information confidential and shall only use such Confidential Information for the purpose for which it was provided but in any event only in connection with this Agreement. Disclosure shall be made only to those persons who have a need to know such Confidential Information for the aforesaid purpose, and who are bound by similar obligations of confidentiality and restrictions on use as contained herein. In this connection, each Party shall obtain appropriate written non-disclosure undertakings from any persons having access to confidential information of the disclosing Party, it being understood, however, that (i) WHO staff are bound by obligations of confidentiality as contained in WHO's Staff Rules and Regulations, and shall not therefore be required to execute separate written non-disclosure undertakings as aforesaid.

Notwithstanding any of the foregoing, there shall be no obligations of confidentiality or restrictions on use where the receiving Party can demonstrate through competent evidence:

(i) the information is publicly available, or becomes publicly available otherwise than by action of the receiving Party; or

(ii) the information was already known to the receiving Party (as evidenced by its written records) prior to its receipt hereunder; or

(iii) the information was received, without an obligation of confidentiality, from a third party not in breach of an obligation of confidentiality owed to the disclosing Party.

Unless another period is stipulated by the Party providing the information, the obligations of this paragraph 10 shall continue for a period of ten years after the termination of this Collaboration Agreement.

(c) Upon termination of this Agreement, each receiving Party shall promptly

return to the disclosing Party the latter's Confidential Information, including any copies thereof; provided that such receiving Party may retain a single copy of such Confidential Information for legal archival purposes only.

11. **Publication**

(a) Subject to the remainder of this paragraph 11, results generated by a Party pursuant to the activities under this Collaboration Agreement may be published by that Party. After a Trial is completed, and/or after a Trial has generated preliminary data through interim analyses, the applicable Collaboration member shall have the right to publish or otherwise make public results from such Trial; provided, however, that in order to avoid prejudicing proprietary rights the submitting Party shall transmit to the other Parties the material intended to be published at least seven (7) working days before a proposed publication is submitted to any editor, publisher, referee or meeting organizer.

(b) Any publication relating to results generated pursuant to the activities under this Collaboration Agreement shall be published in accordance with the WHO policy on open access. The policy is available at the following link: http://www.who.int/about/policy/en/.

In accordance with the policy, manuscripts must be published in one of the following ways:

- In an open-access journal.
- In a subscription journal that offers the hybrid open-access fee option.
- In a subscription journal that allows authors to deposit the accepted author manuscript in Europe PubMed Central/PubMed Central within 12 months of the date of publication.

c) Any publication relating to results generated pursuant to the activity shall comply with timeframes for publication as outlined in www.who.int/ictrp/results/reporting

12. **Regulatory**

Each Party shall be solely responsible for preparing (with input and assistance of the other Collaboration members) and submitting any regulatory filings required for the Trials and shall solely own all such regulatory filings. The Parties shall keep WHO promptly informed of regulatory developments relating to the Trials.

13. **Funding**

(a) Unless expressly specified otherwise in the Agreement, each Party will be responsible for covering all the costs it incurs in the set up and implementation of the activities under this Agreement. Any given expense or cost can only be committed in writing by the Party responsible for paying the cost in question. In no case can one Party commit and expense on behalf of another Party, without the prior written consent of that other Party.

(b) In the event that there is financial support available from WHO to specific Collaboration members for the attainment of the Purpose, any financial support will be provided under separate Technical Services Agreements (TSAs) to be concluded between WHO and each of the other Parties as appropriate.

14. **Consistency**

The Parties will ensure that any agreements they may conclude with regard to the activities associated with this Collaboration Agreement shall be fully consistent with and not in any way prejudice the terms and conditions of this Agreement and/or the TSA as the case may be.

15. No Party shall use the name or any trademark or logo of any other Party in any press or product advertising, or for any other commercial purpose, without the prior written consent of the other Party.

16. Nothing in this Collaboration Agreement shall be deemed to constitute a partnership between the Parties or to constitute any Party as the agent of another.

17. In the event that liability insurance for activities associated with this Agrement has not been obtained by a Party at the time of the signature of this Agreement, that Party shall obtain reasonable liability insurance for the activities they conduct, such insurance to be (a) reasonably acceptable to WHO (b) name WHO among the parties insured and (b) obtained before the commencement of the activities.

18. The liability of any Party to the others for any breach of this Agreement, for any

negligence, or arising in any other way out of the subject-matter of this Agreement, will not extend to any special or punitive damages, or any economic loss or loss of profits suffered by the other Parties.

19. This Collaboration Agreement shall be binding upon the Parties, as well as their successors and assignees, and the name of a Party appearing in this Collaboration Agreement shall be deemed to include the names of its successors and assignees, provided that nothing herein shall permit any assignment of this Collaboration Agreement by a Party without the prior written agreement of the others (such agreement not to be unreasonably withheld).

20. This Collaboration Agreement shall continue in force for an initial period of two years from the Effective Date and for additional periods of one year each in the absence of notice by a Party of its intention to terminate the Agreement, given at least three months before the end of the then current term. Notwithstanding the foregoing, the rights and obligations of the Parties set forth in paragraphs [*provide correct paragraph numbering*] as well as this sentence of article 18 shall survive the termination of this Collaboration Agreement.

21. Any matter relating to the interpretation or application of this Collaboration Agreement, which is not covered by its terms, shall be resolved by reference to the laws of Switzerland. Any dispute relating to the interpretation or execution of this Collaboration Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be held at a mutually acceptable independent location, in the English language, and shall otherwise be conducted in accordance with the modalities to be agreed upon by the Parties, or in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The Parties shall accept the arbitral award as final.

22. Nothing contained herein shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Accepted on behalf of XXX:

Signature:

Name

Title:

Date:

Accepted on behalf of XXX:

Signature:

Name:

Title:

Date:

Accepted on behalf of the World Health Organization:

Signature:

Name:

Title:

Date: