UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE

CVD

GEMS

GEMS CONSORTIUM

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement is made as of _____ (the **"Effective Date"**) between [_____] ("**Provider**,") and **[**_____] ("**Recipient**").

BACKGROUND

WHEREAS, Provider is a member of the Global Enteric Multi-Center Study Consortium (the **"GEMS Consortium"**), which is a network of research institutes, centers and academic units created to collaborate in the implementation of the scientific research plan of the GEMS, namely the creation of knowledge on the etiology and burden of pediatric diarrheal disease among infants and young children in developing countries, in order to provide a basis for the sound implementation of existing interventions and investment in the highest priority needed new interventions (the **"GEMS Project"**).

WHEREAS, the GEMS Project is funded by a grant from the Bill & Melinda Gates Foundation (the **"Foundation"**) to the University of Maryland pursuant to a grant entitled "Diarrheal Disease in Infants and Young Children in Developing Countries."

WHEREAS, Provider possesses certain enteric pathogens, fecal specimens and other materials accumulated in the course of the GEMS Project, and which, along with any derivatives created therefrom by Recipient, constitute the "**Materials**."

WHEREAS, Recipient has submitted a request to use the Materials for conducting the research described in the "**Material Transfer Registration Form"** via the secure GEMS Project website, and such request has been approved by the GEMS Pan-Site Specimen Repository Committee.

Now, therefore, the parties agree to the following terms:

DEFINITIONS:

"Commercial Purposes" means the use of Materials by or on behalf of or for research sponsored by (or transfer of Materials to) a for-profit company.

"Global Access Objectives" means (i) the broad and prompt dissemination of research information generated through use of the Materials to the scientific community and (ii) the development of a vaccine through use of the Materials that will be made accessible to the people most in need in the developing world in its use of the Materials and any improvements, modifications, or inventions that may arise through such use.

"Modifications" means any modification which contains or incorporates any of the Materials.

"**Research**" means the research described in the Material Transfer Registration Form submitted via the secure GEMS Project website, which was approved by the GEMS Pan-Site Specimen Repository Committee

TERMS AND CONDITIONS OF THIS AGREEMENT:

1. Recipient agrees that the Materials are to be used solely for the Research and for the duration described in the Material Transfer Registration Form.

2. Recipient shall use the Materials in accordance with safe laboratory practices and the highest standards of skill and care. Recipient shall ensure compliance with any applicable laws and regulations governing the transportation, keeping or use of the Materials.

3. Materials are to be used only in the Recipient's laboratories, and only under the direction of authorized personnel.

4. Materials will not be given or made available to any third party unless approval to do so has been given by Provider or the GEMS Pan-Site Specimen Repository Committee. If such approval is given, any permitted transfer will also be under the conditions of this Agreement. Recipient will refer to the GEMS Pan-Site Specimen Repository Committee any request for Materials from any third party.

5. Provider retains ownership of the Materials and any Modifications. Except as specifically set forth in this Agreement, no express or implied license or other rights are provided to Recipient under any proprietary rights of Provider.

6. Recipient agrees and acknowledges that:

(a) Materials will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects unless such use is expressly approved by Provider in writing and Recipient's use shall be in accordance with the relevant clinical protocol, informed consent and subject to any required Institutional Review Board and/or ethics review committee approvals and/or other necessary approvals as applicable;

(b) Materials will not be used for Commercial Purposes;

(c) Materials will only be used by individuals who are legally obligated, in the manner and to the extent required in the applicable Material Transfer Registration Form, to allocate their respective right in any and all inventions (and any patent rights or other rights arising therefrom);

(d) Recipient acknowledges that the Materials were generated through the use of funding by the Bill & Melinda Gates Foundation;

(e) Recipient will adhere to the Global Access Objectives;

(f) Materials are provided without personal identification codes;

(g) Recipient accepts responsibility to respect the identity, confidentiality, and privacy of the individual research subjects enrolled in the GEMS Project who provided the relevant samples, and to similarly respect the families of these subjects and the communities where they reside;

(h) GEMS investigators at each site, and the members of the GEMS Executive Committee, worked for many years to generate the Materials and to store them; and

(i) If required by applicable law or regulation of the country from which the Materials originated, Recipient must destroy any Materials after a period of thirty six (36) months. However, this

period may be extended for an additional thirty six (36) months upon written request by the Recipient and consideration by the GEMS Pan-Site Specimen Repository Committee.

7. It is acknowledged that the results of the research using the Materials may be important to Provider in its attempts to attract good researchers and secure research funding for its research. Such recognition may be primarily established by reference to the use of Materials by third parties, such as Recipient, in publications. It is further acknowledged that the failure to obtain such recognition may adversely affect Provider's ongoing research activities and funding. Accordingly, Recipient agrees that it will notify Provider and, at least 30 days prior to submission, provide a copy of any Publication concerning the Research to Provider. Recipient shall reasonably consider any comments Provider offers and will make appropriate attributions (co-authorship or acknowledgement) in all such publications where Provider's Materials were used in Recipient's Research. Recognition for the contribution of Provider should be established by acknowledging use of the Materials by Recipient in any such publication.

8. Recipient will inform Provider, in confidence, of results of the Research, with a written report of the results within sixty (60) days after conclusion of the Research.

9. Any Materials transferred pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. Provider MAKES NO REPRESENTATIONS NOR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER THIRD PARTY PROPRIETARY RIGHTS, OR THAT THE MATERIALS WILL NOT POSE A HEALTH OR SAFETY RISK.

10. Recipient shall pay Provider for any reasonable shipping and related costs that may be incurred when preparing and sending the Materials to Recipient. Payment shall be in made in the manner indicated on the Material Transfer Registration Form.

11. All Materials will be shipped EXW [1] Provider's place of business for activities carried out pursuant to this Agreement (unless Provider and Recipient mutually agree to a different Incoterm shipping classification).

12. Except to the extent prohibited or, where applicable, to the extent authorized by law, Recipient assumes all liability for claims for damages that may arise from its use, storage, and/or disposal of the Materials for activities carried out pursuant to this Agreement. Provider will not be liable to Recipient for any loss, claim, or demand made by Recipient, or made against Recipient by any other party, due to or arising from the use, storage, and/or disposal of the Materials by Recipient, except to the extent permitted by applicable law when such loss, claim, or demand is caused by the gross negligence and/or willful misconduct of Provider.

13. Recipient agrees to handle, store, and use the Materials in a safe manner and in compliance with all applicable statutes and regulations, including applicable governmental regulations and

[1] EXW is an Incoterm abbreviation for "EX Works." EX Works means that the Provider delivers when he places the goods at the disposal of the Recipient at the Provider's premises or another named place (i.e. works, factory, warehouse, etc.) not cleared for export and not loaded on any collecting vehicle. This term thus represents the minimum obligation for the Provider, and the Recipient has to bear all costs and risks involved in taking the goods from the Provider's premises.

guidelines as well as the requirements of national drug regulatory authorities and other relevant regulatory agencies.

14. Recipient certifies that it has obtained any Institutional Review Board and/or ethics review committee and/or other approvals that may be required for the use of Materials received under this Agreement as outlined in the respective Material Transfer Registration Form.

15. This Agreement will terminate upon completion of the Research by Recipient. At that time, Recipient will discontinue use of the Materials and will promptly give written notice to Provider. The Provider may, at its option, direct Recipient to either:

(a) Destroy any remaining Materials and Modifications, and to certify that destruction in writing; or

(b) Return any remaining Materials and Modifications which consist of fecal specimens and nucleic acids (but not bacterial strains). The cost of shipment will be at Provider's expense.

16. Expiration or termination of this Agreement does not relieve either party of any obligation which arises before expiration or termination, including without limitation obligations for payment and reporting. Any provision of this Agreement which contemplates performance or observance subsequent to any termination or expiration of this Agreement shall survive any termination or expiration of this Agreement and continue in full force and effect.

17. Any dispute or controversy arising in connection with this Agreement shall first be referred to the parties' respective officers that signed this document, on behalf of Recipient and Provider, or their successors, for attempted resolution in good faith negotiations within thirty (30) days of notice of such dispute. If such officers are not able to resolve the dispute within the thirty (30) day period, or any agreed upon extensions, Recipient and Provider shall be free to resolve the dispute through any dispute resolution mechanism they may individually or collectively choose.

Provider		**Recipient**	
Signature:	_____	Signature:	_____
Name:	_____	Name:	_____
Title:	_____	Title:	_____
Date:	_____	Date:	_____