

AMENDMENT TO MATERIALS REPOSITORY AND DISTRIBUTION AGREEMENT

The purpose of this Amendment (“Amendment”), entered into as of _____ (“Effective Date”), by and between President and Fellows of Harvard College (“Repository”) through Harvard T.H. Chan School of Public Health and Harvard Pilgrim Health Care, Inc. (“HPHC”) (each a “Party” and collectively the “Parties”) is to modify Section 8.6 of the Materials Repository And Distribution Agreement (“Agreement”) entered in by the Parties with an effective date of June 2, 2015 concerning the Primary Project.

DEFINITIONS – The defined terms have the same meaning as the definitions in the Agreement.

“**Primary Project**” means the project based at HPHC primarily by National Institute of Allergy and Infectious Disease entitled *Conjugate vaccine impact of pneumococcal carriage, disease, and population (SPARC2) Prime Award No. 1R01A1066304*.

Study is the clinical study under which the Materials described in this MTA were collected.

Unidentified Materials are Materials that were collected without identifiers of any kind. Materials may retain demographic or diagnostic information and still be considered unidentified if such information cannot be used to reveal the identity of the source.

Unlinked Materials are Materials that were either initially collected without identifiers or were collected with identifiers that were irreversibly stripped from the Materials before transfer so that no one could link any individual Material to its source. However, certain clinical, pathological, and/or demographic information may have been attached to Unlinked Materials before subject identifiers were removed.

In accordance with section 8.6 (Amendment; Amendment to Comply with Law, Severability), Section 3 of the Agreement is deleted and a new section 3 is inserted to read as follows:

3. HPHC Obligations

3.1 HPHC agrees to transfer to Recipient the Materials and related Limited Data Set which was collected as part of the Primary Projects under IRBNet protocol numbers s190254 and 190392_____.

3.2 The Materials are being provided under this Amendment for the purpose of the Repository distributing the Materials to the research community. HPHC hereby grants the Repository explicit permission to distribute the Materials to the research community as a research resource.

3.3 HPHC certifies that the Materials were collected according to 45 CFR Part 46, “Protection of Human Subjects” at all the Study sites and that the MATERIALS ARE NOT TO

BE USED IN HUMAN SUBJECTS OR FOR THE TREATMENT OR DIAGNOSIS OF HUMAN SUBJECTS.

3.4 HPHC certifies that its Institutional Review Board has reviewed and verified that submission of Materials to the Repository for subsequent sharing for research purposes is consistent with the informed consent of study participants from whom the Materials were obtained.

3.5 HPHC and the Recipient acknowledge that the Materials may be limited in quantity and that their distribution for research purposes will be based on the scientific merit of a proposed research project. Scientific merit of all requests for Materials will be reviewed according to the Recipient's distribution guidelines. The Materials will be made available by the Repository to qualified scientists, under a separate distribution agreement. HPHC acknowledges that the Recipient may periodically assess the ongoing scientific utility of Materials. Materials determined to be of low scientific utility may be discarded.

3.6 HPHC agrees to provide to Recipient a clear statement identifying all restrictions or limitations on the use or distribution of Materials (e.g., for heart research only) specified in the Study participants' informed consent documents. If no restrictions or limitations exist, HPHC should write "NONE" in Appendix 1, attached hereto. The Recipient agrees to provide notice to any third-party recipient regarding restrictions or limitations described by HPHC in Appendix 1 in any separate distribution agreements entered into by Repository.

3.7 HPHC Scientist may request the Materials from the Repository using the same procedures as other investigators. HPHC and HPHC Scientists, who may retain the code for the Materials and thus can identify their sources, will be responsible for compliance with any applicable federal, state, and local laws and regulations (e.g., 45 CFR, Part 46) and any institutional policies relevant to their future research use of the Materials.

3.8 In order to respect the privacy of the human subjects, the Recipient agrees not to contact or make any effort to identify individuals, families, communities, tribes, or populations that are or may be the sources of the Materials.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed and delivered in their name and on their behalf as of the date first set forth above.

HARVARD PILGRIM HEALTH CARE, INC.

REPOSITORY:

By: _____

By: _____

Name: Charlotte A. Johnson

Name: Richard Alcock

Title: Director, Office of Sponsored Programs

Title: Senior Associate Director of Technology Transactions

Date: 6/27/16

Date: 06/23/2016

APPENDIX 1

Restrictions specified in the Study participants' informed consent documents:

Bacteria collected from your child may be used in additional analysis performed by laboratories at Harvard School of Public Health, Boston Medical Center or other collaborating investigators or institutions. No information that can identify you from the questionnaire and medical record for additional analyses on infections in children. The authorization to use your child's Protected Health Information will expire at the end of the research study. The study team will need to keep the information we collect for several years after the research is concluded. We will not keep any information that can identify your child.