Agreement ID: VUMC 80900

FDP Data Transfer and Use Agreement ("Agreement")

Provider: Vanderbilt University Medical Center	Recipient: Asia Cohort Consortium
Provider Scientist Name: Xiao-Ou Shu, M.D., Ph.D. Email: Xiao-ou.Shu@vumc.org	Recipient Scientist Name: Manami Inoue Email: mnminoue@ncc.go.jp
Agreement Term Start Date: Date of last signature below End Date: Five(5) Years after the Start Date	Project Title: Asian Cohort Consortium Pooling Projects Attachment 2 Type: De-identified Data about Human Subjects

Terms and Conditions

1) Provider shall provide the data set described in Attachment 1 (the "Data") to Recipient for the research purpose set forth in Attachment 1 (the "Project"). Provider shall retain ownership of any rights it may have in the Data, and Recipient does not obtain any rights in the Data other than as set forth herein.

2) If applicable, reimbursement of any costs associated with the preparation, compilation, and transfer of the Data to the Recipient will be addressed in Attachment 1.

3) Recipient shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Recipient Scientist and Recipient's faculty, employees, fellows, students, and agents ("Recipient Personnel") and Collaborator Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement(collectively, "Authorized Persons").

4) Except as authorized under this Agreement or otherwise required by law, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Provider. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in Attachment 2.

5) Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research.

6) Recipient is encouraged to make publicly available the results of the Project. Before Recipient submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the Provider will have thirty (30) days from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected. Provider may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to protect proprietary information.

Agreement ID: VUMC 80900

7) Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient's research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1.

8) Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 13, this Agreement shall expire as of the End Date set forth above. Either party may terminate this Agreement with thirty (30) days written notice to the other party's Authorized Official as set forth below. Upon expiration or early termination of this Agreement, Recipient shall follow the disposition instructions provided in Attachment 1, provided, however, that Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.

9) Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO 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 DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Provider, to the best of its knowledge and belief, has the right and authority to provide the Data to Recipient for use in the Project.

10) Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement.

11) Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other party provided that any such statement shall accurately and appropriately describe the relationship of the parties and shall not in any manner imply endorsement by the other party whose name is being used.

12) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project:

I. Attachment 1: Project Specific Information
II. Attachment 2: Data-specific Terms and Conditions
III. Attachment 3: Identification of Permitted Collaborators (if any)
IV. Appendix 1 - Publications

13) o modification or waiver of this Agreement shall be valid unless in writing and executed by duly-authorized representatives of both parties.

Agreement ID: VUMC 80900

14) The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.

By an Authorized Official of Provider:	By an Authorized Official of Recipient:
Libby Salberg Digitally signed by Libby Salberg Date: 2020.05.21 14:39:48 -05'00'	May 19, 2020
Date	Date
Name: Libby D. Salberg, B.A., J.D.	Name: Teruhiko Yoshida
Title: Director, Office of Contracts Managment	Title: Director, Center for Research, NCC
Contact Information for Formal Notices:	Contact Information for Formal Notices:
Name: Vanderbilt University Medical Center	Name: National Cancer Center
Address: Office of Contracts Management 3319 West End Avenue; Suite 100 Nashville, TN 37203	Address: Center for Research Administration and Support (CRAS) 5-1-1 Tsukiji, Chuo-ku, Tokyo 104-0045, Japan
Email: research.contracts@vumc.org	Email: tyoshida@ncc.go.jp
Phone: (615) 322-2281	Phone: +81-3-3547-5249

BO

Read & Acknowledged by:

Xiao-Ou Shu, M.D., Ph.D.

Date: 5/21/2020

Agreement ID: VUMC 80900

Attachment 1
Data Transfer and Use Agreement
Project Specific Information

1. Description of Data:

   De-identified data from the Shanghai Women's Study (SWHS), the Shanghai Men's Health Study (SMHS) and the Southern Community Cohort Study (SCCS) will be provided to Asian Cohort Consortium for approved pooling projects.

2. Description of Project:

   The data to be provided will be used in consortium approved and PIs of the Shanghai Women's Health and/or Shanghai Men's Health Study opted in research projects which aim to identify risk and projected factors for cancer and other chronic diseases.

3. Provider Support and Data Transmission:

   Provider shall transmit the Data to Recipient: (select one) ☑ electronically or ☐ by mail to:

Name:	ACC coordinating center
Address:	5-1-1 Tsukji, Chuo-Ku, Tokyo 104-0045, Japan
Email:	cc@asiacohort.org
Phone:	+81-3-3547-5201

Agreement ID: VUMC 80900

Upon execution of this Agreement, Provider shall send any specific instructions necessary to complete the transfer of the Data to the contact person listed above, if not already included below in this section of Attachment 1.

4. Reimbursement of Costs:

☑ None

☐ As governed by a separate written agreement between the parties
Reimbursement Agreement Reference # (if required):
_____

☐ As set forth herein:

5. Disposition Requirements upon the termination or expiration of the Agreement:

Data shall be destroyed according to relevant regulations / guidelines.

Agreement ID:

Attachment 2
Data Transfer and Use Agreement
Data-specific Terms and Conditions:
De-identified Data about Human Subjects

Additional Terms and Conditions:

1. The Data will not include personally identifiable information as defined in NIST Special Publication 800-122. If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

2. If Provider is a Covered Entity, the Data will be de-identified data, as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

3. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board (IRB) approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.

4. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.

5. Recipient shall promptly report to the Provider any use or disclosure of the Data not provided for by this Agreement of which it becomes aware.

6. Arbitration: Any dispute, controversy or Claim Arising under, out of or relating to this Agreement and any subsequent amendments of this Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be referred to and finally and exclusively determined by arbitration in accordance with U.S. Federal and New York state law and governed by the rules for the International Centre for Dispute Resolution. The place of arbitration shall be New York, New York, United States. The language to be used in the arbitral proceedings shall be English.

7. Export Controls: It is understood that VUMC is subject to United States laws and regulations controlling the export of technical data, software, and information ("Technology"), and commodities, laboratory materials, and other physical items ("Items"). VUMC's obligations hereunder are contingent on compliance with applicable U.S. export laws and regulations. The transfer or sharing of any such Technology or Items subject to the various U.S. export laws and regulations may require a license or authorization from the United States Government, and/or may require written assurances by the receiving party that it shall not re-export or share such Technology or Items to certain foreign destinations and/or to certain recipients without prior approval of the U.S. Government, and/or may require that the involved individuals and entities will comply with conditions of such government license(s) or authorization(s). While VUMC agrees to cooperate in securing any license(s) deemed necessary in connection with this Agreement, VUMC cannot guarantee that such license will be granted. No party shall share, disclose, or release any Technology or Items with any person, party, location, or territory subject to U.S. trade sanctions, as listed at https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx.

8. Governing Language: In the event that a translation of this Agreement is prepared and signed by the parties, this English language version shall be the official version and shall govern if there is a conflict between this English language version and the translation. All disputes (litigation and arbitration) under this Agreement shall be resolved and conducted, regardless of the means of authority, in the English language.

9. Foreign Corrupt Practices Act: Recipient agrees that, in connection with this Agreement, it (including, if and as applicable, its members, trustees, directors, officers and employees) will adhere to and comply with all applicable U.S. and non-U.S. anti-bribery and anti-corruption laws, regulations and other measures, such as the Foreign Corrupt Practices Act. Recipient agrees that, in connection with the activities undertaken pursuant to this Agreement, it shall not offer or provide money or anything of value to any governmental official or employee or candidate for political office in order to influence their actions or decisions, to obtain or retain business arrangements, or to secure favorable treatment in violation of such measures, either directly or indirectly.

NIH Confidentiality Requirements. The Data is protected under a Certificate of Confidentiality issued by the National Institutes of Health. In accordance with NIH requirements, Recipient agrees to:

(a). Abide by all applicable human subjects and other regulations and guidance, which may include:

1. The Privacy Act of 1974, as amended, at 5 U.S.C. section 552a ("Privacy Act"), the Health Information Portability and accountability Act of 1996 (HIPAA) or other equivalent privacy regulations; and
2. 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and FDA Good Clinical Practice Guidelines (ICH E6 Good Clinical Practice: Consolidated Guidance, 62 FR 25692 (1997); and
3. A certificate of Confidentiality issued by NIH in accordance with 42 U.S.C. 241(d) of the Public Health Service Act.

(b) Maintain any transferred information in a secure manner that restricts access by any individual not involved in the Research Project (e.g. , for paper records – locked file cabinets or continual physical presence in a room that locks, or for electronic records – encryption and password protection); and

(c). Remove or destroy any information that may be used to identify the Human Subject at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the Research Project; and

(d) Make no further use or disclosure of the information unless approved by the Provider or required by Federal, State, or local laws (e.g. as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments). Notwithstanding the foregoing, is immune from the legal process, and will not, without the consent of the Human Subject, be admissible as evidence or used for any purpose in any action, suite, or other judicial, legislative, or administrative proceeding.

Agreement ID: VUMC 80900

Attachment 3
Data Transfer and Use Agreement
Identification of Permitted Collaborators (if any)

For all purposes of this Agreement, the definition of "Collaborator Personnel" checked below will pertain:

☐ "Collaborator Personnel" means: None. No collaborators are permitted on the Project.

-OR-

☑ "Collaborator Personnel" means as set forth below and agreed upon between the Parties:

Asia Cohort Consortium (ACC) which includes members of the participating cohorts (a total of 118) who can submit an application to use the ACC data which include the SWHS/SMHS data. If an application is approved by the ACC Steering Committee, each cohort PI can opt in or out of the project. If we opt in, data will be remotely accessed by the project investigator(s). Data will never leave the ACC coordinate center.

In compliance with U.S. Export Control regulations, approval for the Iranian cohort participants is limited to the Golestan cohort only. Any other Iranian cohort participants shall only be applicable upon submissions of the names and institutions and approval by Provider prior to any data being shared .

Appendix 1

Appendix- PUBLICATIONS

a. Recipient will collaborate with Vanderbilt on any publication involving Data. At leasttwo investigators from the SWHS and SMHS must be included as a co-investigator/co-author.

b. If a publication is based primarily on the SWHS/SMHS data, all statistical programs used to analyze the data must be submitted to the statistical group of the SWHS/SMHS for review along with the final version of the manuscript reporting the results, and the program(s) must call the original dataset from the SWHS/SMHS, not datasets that have been generated and altered by the applicants.

c. Recipient will acknowledge Vanderbilt's contribution in any publication involving Data.

d. The investigators must acknowledge the funding sources for the SWHS/SMHS in publication(s): The SWHS (UM1 CA182910) and SMHS (UM1 CA173640) are supported by the US National Institutes of Health.