EXPAND PROGRAM - DATA SHARING AGREEMENT
for EXPAND Repository

This Data Sharing Agreement ("DSA") is an agreement regulating the transfer of DATA and MODIFICATIONS (as defined hereinafter) by Baylor College of Medicine ("BCM"), located at One Baylor Plaza, Houston, TX 77030, USA and _____ ("DATA RECIPIENT"), for the sole purpose of the repository data analysis PROJECT entitled "_____" as specified in the RECIPIENT's Project Request submission. DATA RECIPIENT and BCM may each be referred to as Party or collectively as Parties. The EXPAND (Enhancing eXploration Platforms and Analog Definition) Program was launched by the Translational Research Institute for Space Health (TRISH) at BCM to collect preflight, postflight, and in-flight health data from private space flight participants in the EXPAND Repository.

I. Definitions

1. DATA: Data provided by BCM to DATA RECIPIENT pursuant to this Agreement. It includes specified coded data on individuals, in electronic format contributed by all partners of EXPAND .

2. MODIFICATIONS: New data generated as a result of combinations, transformations, or other processing of data items in the DATA, such as in analyses performed by the PROJECT.

3. DATA PROVIDER: Organization providing DATA and/or MODIFICATIONS to BCM as part of the PROJECT.

4. PROJECT: The analysis of DATA from the EXPAND Repository in connection with research conducted with respect to commercial space flights, which is further defined in the request submitted through the EXPAND Portal.

5. RECIPIENT SCIENTIST: A person identified herein who will be the contact person for the DATA RECIPIENT.

6. DATA RECIPIENT (or RECIPIENT): The organization identified in the preamble herein which will receive DATA from BCM, and may provide MODIFICATIONS to BCM, under the conditions specified herein.

7. RE-IDENTIFICATION. Seeking to identify a subject from the DATA.

II.   Data Ownership and Licenses:

1. DATA RECIPIENT acknowledges that all DATA and MODIFICATIONS shall be owned exclusively by BCM and licensed to DATA RECIPIENT under the terms of this Agreement. DATA RECIPIENT hereby assigns all right, title, and interest in MODIFICATIONS to BCM. DATA RECIPIENT hereby assigns all right, title, and interest in MODIFICATIONS to BCM.

III.   Use and Handling of Data

1. THE DATA WILL NOT BE USED BY RECIPIENT TO TREAT OR DIAGNOSE HUMAN SUBJECTS.

2. The DATA are provided at a cost calculated to cover the time and resources needed to process the PROJECT request and provide DATA to RECIPIENT.

3. RECIPIENT shall send the MODIFICATIONS generated by the PROJECT's analysis as directed by BCM, in electronic format, by direct upload to the EXPAND platform, or other format or other destination as requested by BCM. RECIPIENT agrees to provide BCM any IRB approval from the RECIPIENT's institution or company. Any MODIFICATIONS delivered to BCM pursuant to this Agreement is understood to be a complete and accurate copy of the MODIFICATIONS retained by the RECIPIENT.

4. DATA will be handled and stored in accordance with all applicable laws, regulations, and relevant institutional policies, procedures, and security.

5. BCM agrees that the MODIFICATIONS shall be stored in a manner that complies with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research. BCM agrees to retain control over the MODIFICATIONS and shall disclose or otherwise grant access to the MODIFICATIONS solely as permitted under this agreement and applicable law. BCM agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the MODIFICATIONS and comply with any other special requirements relating to safeguarding of the MODIFICATIONS as may be set forth herein.

6. Subject to applicable law, obligations that BCM may owe to third parties, and approval by BCM's Data Privacy and Release Board ("Board") BCM will provide DATA coded format to RECIPIENT in electronic format, via direct download from BCM's database as instructed by BCM. RECIPIENT will not sell any of the DATA or share any data elements the DATA received from BCM with any third party without the prior written permission from BCM.

7. BCM and RECIPIENT each agrees to use all DATA in compliance with all applicable requirements, statutes and regulations, including, as applicable, any imposed by a Data Privacy and Release Board (DPRB), an applicable IRB or

those relating to research involving the use of humans. BCM and RECIPIENT each agrees that it will make no attempt whatsoever to Re-Identify any record in any Data. If either Party receives Data, or information ascertained through its use of the Data, that can be used to determine a subject's identity, either alone or when combined with other personal or identifying information, such Party agrees to abide by all applicable human subjects and other regulations and guidance, which may include the Privacy Act of 1974, as amended, at 5 U.S.C. §552a, the Health Information Portability and Accountability Act of 1996 (HIPAA) or other equivalent privacy regulations.

8. Any breach, or suspected breach, of DATA shall be reported to the other party within five (5) business days from confirmation of such breach or suspected breach. BCM and RECIPIENT shall cooperate with each other to investigate, correct, and/or mitigate such breach, suspected breach, or other unauthorized use or disclosure. BCM acknowledges that RECIPIENT may have an obligation to make further notifications as set forth in Subpart D of 45 CFR §164 or under applicable state law and shall cooperate with the RECIPIENT to the extent necessary to enable RECIPIENT to meet all such obligations.

9. Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." NEITHER PARTY MAKES ANY REPRESENTATION OR 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 DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

10. RECIPIENT to the best of its knowledge and belief, has the right and authority to provide the MODIFICATIONS to BCM for use in the EXPAND Repository.

11. Upon Project Close-out, the RECIPIENT agrees to destroy all copies, versions, and MODIFICATIONS of the dataset(s) retrieved from EXPAND, on both local servers and hardware, and if cloud computing was used, delete the data and cloud images from cloud computing provider storage, virtual and physical machines, databases, and random access archives, in accord with standard practices. However, the RECIPIENT may retain these data as necessary to comply with any institutional policies (e.g., scientific data retention policy), law, and scientific transparency expectations for disseminated research results, and/or journal policies. Notwithstanding the foregoing, RECIPENT agrees to refer to EXPAND, any request for the DATA or MODIFICATIONS from anyone other than those persons working under the RECIPIENT scientist's direct supervision. A RECIPIENT who retains data for any of these purposes continues to be a steward of the data and is responsible for the management of the retained data in accordance with EXPAND data sharing policies. Any retained Data may only be used by the PI and RECIPIENT to support the findings (e.g., validation) resulting from the research described in the PROJECT that was

submitted by the RECIPIENT and approved by the DPRB. The Data may not be used to answer any additional research questions, even if they are within the scope of the approved PROJECT, unless the RECIPIENT submits a new PROJECT and is approved by the DPRB to conduct the additional research. These terms remain in effect until the Data is destroyed.

IV.   Publications

1. BCM agrees to recognize, and require others to recognize, the contribution of the RECIPIENT as the source of the MODIFICATIONS submitted by RECIPIENT in all written, visual, or oral public disclosures concerning research using the repository DATA, as appropriate in accordance with scholarly standards.

2. This Agreement shall not be interpreted to prevent or delay publication by any party of research findings resulting from the use of any Data.

3. If any publication or research within such publication was supported by the Translational Research Institute for Space Health (TRISH) funding or makes use of Data, RECIPIENT shall include the following acknowledgement: "This work is supported by the Translational Research Institute for Space Health (TRISH) through NASA NNX16AO69A."

4. Research abstracts, publications or presentations utilizing the Data and/or biosamples requested from the EXPAND Repository must be submitted to EXPAND personnel for review prior to any submission to a journal or conference to ensure that the privacy of subjects is protected in accordance with their consent agreements. The RECIPIENT 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. BCM 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.

5. Pooled data points are the standard for publication from Data and/or biosamples received from the EXPAND Repository. Individual data points may be included in an abstract, publication or presentation only with prior written approval from the DPRB.

6. Investigators shall inform EXPAND of all publications arising from the use of EXPAND Data and/or biosamples. After the approved project using Data and/or biosamples is completed, the researchers are responsible to submit the final analytical dataset which corresponds to the publication back to EXPAND for future reference and related collaborative projects.

V.   Term and Termination

The term of this Agreement shall begin on the date of the last signature and will end on the date provided in the request submitted through the EXPAND Portal. The term of this

Agreement shall not exceed the PROJECT request end date, (unless extended by written amendment), and may be terminated by either Party on thirty (30) calendar days written notice to the other Party.

VI.   Miscellaneous

1. This Agreement constitutes the entire agreement between the Parties and supersedes all communications, arrangements and agreements, either written or oral, between the Parties with respect to the matter hereof, except where otherwise required in law. This Agreement may be varied by exchange of letters between the Parties. No variation or extension to this Agreement shall be binding upon either Party unless in writing and acknowledged and approved by both Parties in writing.

2. Notices required by this agreement may be made via email to all representatives identified below of the other Party.

3. Except to the extent prohibited by law, each Party assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. Neither Party shall be liable to the other Party for any loss, claim, or demand made by such other Party, or made against such other Party by any other party, due to or arising from the use of the Data. No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement.

4. 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.

5. This Agreement shall not be assignable absent prior written consent from the other Party, which shall not be unreasonably withheld, conditioned, or delayed; provided that this Agreement shall be assignable by BCM to an affiliate of BCM without such prior written consent.

6. Each Party bears its own costs generated in performance of this agreement.

7. The Parties intend to remain silent regarding issues of governing law and venue. All disputes and controversies arising out of this Agreement including the existence, constructions, validity, interpretation, performance, nonperformance, enforcement or breach of any provision, shall be settled by mediation and, if necessary, arbitration in accordance with the

Commercial Arbitrations Rules of the American Arbitration Association ("AAA"). The parties agree to submit any dispute or controversy to binding arbitration before one (1) impartial arbitrator selected by AAA with costs to be borne equally by the parties. The federal rules of civil procedures shall apply, including with respect to depositions, with respect to arbitration. The findings of the arbitrators shall be final and binding upon the parties. Any award of arbitration may include attorney's fees and costs, including but not limited to expert witness fees, payable to the prevailing party in the arbitration, as determined by the arbitrators.

SIGNATURES BEGIN ON THE FOLLOWING PAGE

Acknowledged and agreed to:

<u>**For**</u>

BAYLOR COLLEGE OF MEDICINE

_____

Institutional Official Signature   Date

Name: Kimberly Weiderhold, PhD, MBA
Title: Director, Research Administration
                   Baylor College of Medicine
Address: One Baylor Plaza, BCM 310
                   Houston TX 77030-3411
Email: mta@bcm.edu:

_____

BCM Signature   Date

Name: Jimmy Wu
Title: Deputy Director and Chief Engineer, Translational Research Institute for Space
Health
Address: TMCx
                   2450 Holcombe Blvd Houston TX 77021
Phone: 713-357-1030
Email: jimmy.wu@bcm.edu
BCM REF – 64120-I

Signatures continue on the following page

For DATA RECIPIENT
The individual named below is the authorized signatory for the institution receiving the DATA, and agrees to abide by the details of the DSA outlined herein.

_____   _____
Institutional Signing Official Signature   Date

Name:
Title:
Address:

Phone:
Email:

<u>RECIPIENT SCIENTIST</u>

The individual named below is the person responsible for the PROJECT for which the DATA is being received and agrees to abide by the details of the DSA outlined herein.

_____
RECIPIENT SCIENTIST Signature   Date

Name:
Title:
Address:

Phone:
Email: