**Data Transfer and Use Agreement (“Agreement”)**

**Provider:**

**Recipient:**

The Trustees of the University of Pennsylvania

**Provider Scientist**

Name:

Email:

**Recipient Scientist**

Name: Benjamin S. Abella MD MPhil

Email:

Benjamin.Abella@pennmedicine.upenn.edu

**Agreement Term**

Start Date:

End Date: Three (3) years

after the Start Date

**Project Title:**

Evaluation of the Clinical Impact and Safety of Focused Transesophageal Echocardiography During Resuscitation of Critically Ill Patients in the Emergency Department and Intensive Care Settings

**Attachment 2 Type:** Limited Data Set

**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 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.
7. 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.
8. 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.
9. 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.
10. 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.
11. 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:
    1. Attachment 1: Project Specific Information
    2. Attachment 2: Data-specific Terms and Conditions
    3. Attachment 3: Identification of Permitted Collaborators (if any)
12. No modification or waiver of this Agreement shall be valid unless in writing and executed by duly-authorized representatives of both parties.
13. 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:



Signature Date

Name:

Title:

Contact information for formal notices:

Name:

Address:

Email:

Phone:

By an Authorized Official of Recipient:



Signature Date

Name:

Title:

Contact information for formal notices:

Name:

Address:

Email:

Phone:

**Attachment 1**

Data Transfer and Use Agreement

Project Specific Information

1. Description of Data:

Population included in data: Adult patients who as part of their routine clinical care receive focused TEE in the emergency department or intensive care setting. Children (age under 18 years) will not be eligible for inclusion in this study.

Number of subjects included: As many eligible cases, defined above, as possible will be included in this study.

Study under which data is obtained: Evaluation of the Clinical Impact and Safety of Focused Transesophageal Echocardiography During Resuscitation of Critically Ill Patients in the Emergency Department and Intensive Care Settings. IRB Protocol #:

1. Description of Project:

The Agreement authorizes the transfer of data to the Recipient for the Resuscitative TEE Collaborative Registry, a research registry housed at the Recipient institution. As such, the Recipient will collect and protect provided data within REDCap, a secure web platform for building and managing online databases and surveys. The Provider can access all data submitted by the Provider to the Resuscitative TEE Collaborative Registry via direct access to REDCap. The Provider and other institutions may submit new project proposals using the data request form established by the Resuscitative TEE Collaborative Registry. Upon approval by the Resuscitative TEE Collaborative Registry Scientific Oversight Committee, the Provider may retrieve compiled data from the requested dataset collected by the Resuscitative TEE Collaborative Registry to complete the proposed study. Therefore, the Recipient may provide data from the Provider to outside parties. These other institutions are not a party to this Agreement but will have signed a substantially similar agreement. In the event that a project proposal from an outside party is approved by the Resuscitative TEE Collaborative Registry Scientific Oversight Committee, the Recipient will notify the Provider of the intended use of the data.

1. Provider Support and Data Transmission

The Provider shall transmit data to Recipient by direct entry into the REDCap database. The Recipient shall provide access to the REDCap project upon completion of this Agreement. Because the Provider will be submitting data directly into the REDCap database housed at the Recipient institution, the Recipient has already designed the Data dictionary, and the Provider will format the data accordingly prior to provision. If errors are found by the Recipient, the Recipient will contact the Provider for collaboration in correcting said errors.

1. Reimbursement of Costs

None

As governed by a separate written agreement between the parties

Reimbursement Agreement Reference # (if required):



As set forth herein:

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

As stated previously, the Recipient is collecting data for the Resuscitative TEE Collaborative Registry. Therefore, to retain the integrity of the Resuscitative TEE Collaborative Registry, the Recipient reserves the right to link the datasets from the Provider to other equivalent datasets provided by outside parties (see Attachment 1, Item 2: Description of Project). Furthermore, upon expiration or early termination of this Agreement, the Recipient may retain data from the Provider, but must continue to notify the Provider of any changes to or plans for using the data, and the Provider may retain a REDCap account from the Recipient institution.

**Attachment 2**

Data Transfer and Use Agreement

Data Specific Terms and Conditions:

Limited Data Set

**Additional Terms and Conditions**

1. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements of Provider under 45 CFR 164.514.
2. Recipient shall not use or further disclose the Data other than as permitted by this Agreement or as otherwise required by law.
3. Recipient shall report to the Provider any use or disclosure of the Data not provided for by this Agreement within 5 business days of when it becomes aware of such use or disclosure.
4. Provider is a HIPAA Covered Entity, and the Data will be a Limited Data Set as defined by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). In accordance with Section 164.514(e)(2) of the HIPAA Privacy Rule, the Data shall exclude the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(i) Names;  
(ii) Postal address information, other than town or city, State, and zip code; (iii) Telephone numbers;  
(iv) Fax numbers;  
(v) Electronic mail addresses;  
(vi) Social security numbers;  
(vii) Medical record numbers;  
(viii) Health plan beneficiary numbers;  
(ix) Account numbers;  
(x) Certificate/license numbers;  
(xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers;  
(xiii) Web Universal Resource Locators (URLs);  
(xiv) Internet Protocol (IP) address numbers;  
(xv) Biometric identifiers, including finger and voice prints; and  
(xvi) Full face photographic images and any comparable images.

If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

1. 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 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.
2. 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.
3. The parties agree to take such action as is necessary to amend this Agreement, from time to time, in order for the Provider to remain in compliance with the requirements of HIPAA.

**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:

Faculty, employees, fellows, or students of an academic institution, which institution has agreed to participate in the Resuscitative TEE Collaborative Registry and executed an agreement that is substantially similar to this Agreement.