**Pulmonary Hypertension Association Registry (PHAR)**

**Data and Materials Distribution Agreement**

**For Receipt of De-Identified Dataset**

The undersigned parties hereby enter into this Data and Materials Distribution Agreement (DMDA) as of the date specified on the final page hereof.

**INTRODUCTION**

The Pulmonary Hypertension Association Registry (PHAR) is a project funded by the Pulmonary Hypertension Association (PHA) to collect registry data from clinic sites.

Failure to comply with this DMDA could result in its termination, denial of further access to PHAR and other Pulmonary Hypertension Association resources, and may leave violators liable to legal action on the part of PHAR participants, their families, or the PHA.

The undersigned parties entering into this DMDA include: the Recipient and Recipient’s Principal Investigator (defined in the next section), and the PHAR Data Coordinating Center (DCC), on behalf of PHAR and under the direction of the PHAR Steering Committee.

**DEFINITIONS**

For purposes of this agreement,

**"Data"** refers to any and all study data, including laboratory, examination, and questionnaire results, and associated records either obtained directly from PHAR participants or obtained from PHAR Study Investigators.

“**Resultant Data**” refers to data derived in whole or in part by Recipient from Data provided under this DMDA.

**“PHAR Study Investigator”** is a research investigator who works with PHAR either as an employee of the participating Pulmonary Hypertension Care Centers or through a current and active contract or consulting agreement with the Pulmonary Hypertension Association or one of its contractors.

**“Research Project”** refers to any project which uses methods approved by PHAR P&P and data provided by PHAR.

**“Recipient”** refers to the institution or other entity receiving access to PHAR Data requested for a Research Project.

**“Principal Investigator (PI)”** refers to the Research Project director for the Recipient.

**“Provider”** refers to an institution that, as a PHA-Accredited Pulmonary Hypertension Care Center (PHCC), enrolls participants into PHAR and contributes study data to PHA and the PHAR DCC as per the terms of a Data Use Agreement (DUA). The DUA authorizes PHAR DCC to distribute data from the Provider to the Recipient as outlined in the terms of this agreement.

**“PHAR P&P”** refers to the Publications and Presentations committee, which reviews Research Projects and tracks all intended analyses, presentations, and publications that result from PHAR Data and Research Projects.

**TERMS AND CONDITIONS**

It is mutually agreed as follows:

1. **Data.** PHAR agrees to provide Recipient with Data described as follows:

\_(This will be completed following approval of the Research Project)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PHAR will provide Recipient with the name and contact information of Study Investigators and all other investigator(s) who generated such Data.

**2. Research Project.**

**2.1** These Data will be used by Recipient's PI solely in connection with research projects reviewed and approved by PHAR P&P.

**3. Non-transferability.** This DMDA is not transferable.

Recipient and Recipient’s PI agree that substantive changes made to a Research Project require approval by PHAR P&P. Appointment by Recipient of another Principal Investigator and/or transfer of Recipient’s PI to another institution or other entity to complete a Research Project requires execution of a separate DMDA. Recipient may not distribute Data to any other individual or entity, regardless of the intended use of such Data. However, nothing in this section precludes Recipient from publishing results of Research Projects through the usual channels of scientific publication.

**4. Conduct of Research Project.** Recipient’s PI is responsible for the conduct of Research Projects and shall be responsible for assuring that any co-investigator(s) comply with the terms of this DMDA.

**5. Publication.** Prompt publication of the results of Research Projects is encouraged. PHAR and the Pulmonary Hypertension Association request that the Recipient’s PI provide to the authorized representative for the PHAR Coordinating Center (named below) and to the PHAR P&P a copy of any abstract two (2) weeks in advance of submission for publication and any manuscript or other disclosure document six (6) weeks in advance of submission for publication, in order to permit review and comment and ensure compliance with the confidentiality requirements of this DMDA. All abstracts and manuscripts must be reviewed and approved by PHAR P&P before submission for meetings and/or publication.

**6. Acknowledgments.** Recipient and Recipient’s PI agree to acknowledge the contribution of PHAR Study Investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data. All publications using PHAR Data should include the acknowledgment found in the Protocol (on the PHAR website at <http://phccregistry.org>):

“The Pulmonary Hypertension Association Registry (PHAR) is supported by Pulmonary Hypertension Care Centers, Inc., a supporting organization of the Pulmonary Hypertension Association. The authors thank the other investigators, the staff, and particularly participants of the PHAR for their valuable contributions. A full list of participating PHAR sites and institutions can be found at www.PHAssociation.org/PHAR”.

**7. Non-Identification.** Recipient and Recipient’s PI agree that Data will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the participants from whom Data were obtained or derived.

**8. Use Limited to Research Projects.** Recipient and Recipient’s PI agree that Data will not be used in any experiments or procedures unless said experiments or procedures are disclosed and approved as part of a Research Project.

**9. No Distribution.** Recipient and Recipient’s PI agree to retain control over Data. Recipient and Recipient’s PI further agree not to transfer Data with or without charge to any other entity or individual.

**10. Confidential Data Security Plan.** Recipient and Recipient’s PI agree to comply with the following core data security requirements and any additional requirements deemed appropriate for safeguarding the Data by the DCC at the time of the DMDA request. Any additional requirements required would be incorporated via an addendum to this DMDA:

**10.1** Core data security requirements:

**10.1.a** Recipient agrees to PHAR DCC specifications on passwords and encryption.

**10.1.b** Recipient satisfactorily responds to all security questions about security features to provide necessary restrictions on access to the dataset and any derivatives.

**10.1.c** Recipient satisfactorily responds to all security questions about security features to provide necessary restrictions on electronic and physical storage of the dataset, any derivatives, temporary files, and backup files.

**10.1.d** Recipient satisfactorily responds to all security questions about changes in Research Staff or Institution.

**10.1.e** Recipient agrees to notify PHAR DCC immediately if a request is made by any outside entity to access the dataset, including requests made by funders of the research for which the dataset are requested, as well as any legal entity or law enforcement agency.

**10.1.f** Recipient satisfactorily responds to all security questions about how and when electronic and printed copies of the data and any derivatives must be destroyed.

The Confidential Data Security Plan will be revised as needed to safeguard against unforeseen risks and technological advances that may impact security of the data.

**11. Resultant Data to be Provided to PHAR and the Pulmonary Hypertension Association.** Recipient and Recipient’s PI agree to provide PHAR with a report every twelve (12) months during the term of this DMDA, if requested. The report shall include a description of the activities performed and Resultant Data obtained during the twelve (12) months before the reporting date.

**12. Costs/No Warranties.** Cost for Data distribution will be determined on a case by case basis. Costs are subject to change following written notification from PHAR with the approval of the Pulmonary Hypertension Association. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE DATA PROVIDED TO RECIPIENT UNDER THIS AGREEMENT.

**13. Non-Endorsement.** Recipient and Recipient’s PI agree not to claim, infer, or imply PHA endorsement of Research Projects, the entity, or personnel conducting a Research Project, or any resulting commercial product(s) except as described in section 6.

**14. Accuracy of Data.** Recipient agrees that the PHA and PHAR are not responsible for the accuracy of Data provided.

**15. Recipient's Compliance with Recipient IRB’s Requirements.** Recipient certifies that the conditions for use of the Data in conjunction with the Research Project have been reviewed by the Recipient's Institutional Review Board (IRB) or similar human subjects oversight body in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions and with the participants' informed consent documents, and any additional conditions that may be imposed by the PHAR IRB(s). Recipient agrees to report promptly to PHAR and the Pulmonary Hypertension Association any unanticipated problems or proposed changes in the Research Project. Recipient also agrees to report to Recipient’s IRB any unanticipated problems or changes in the Research Project that involve additional risks to participants or others. Recipient remains subject to applicable state and local laws and regulations and institutional policies that provide additional protections for human subjects.

**15.1. (Optional) Waiver of IRB Review.** The Recipient retains the option to seek acknowledgment from the Recipient’s IRB that the de-identified PHAR Data constitutes minimal risk, non-human data and is therefore exempt from human subjects regulations and does not require IRB review or approval.

**16. Amendments.** Amendments to this DMDA must be made in writing and signed by authorized representatives of all parties.

**17. Termination.** This DMDA shall terminate at the earliest of: the completion of all approved Research Projects; five (5) years after the effective date of this DMDA; abandonment of all Research Projects; or violation by Recipient of any provisions of this DMDA not remedied within 30 days after the date of written notice by the Pulmonary Hypertension Association and PHAR of such violation. In addition, this Agreement will be terminable without cause by either party upon 90 days’ written notice to the other party. Upon termination of this DMDA:

1. Recipient agrees to consult with PHAR and the Pulmonary Hypertension Association regarding the disposition of all remaining Data.

**18. Data Use Cessation.** In the event a Provider cancels its data use agreement with the PHAR DCC, the PHAR DCC will notify the Recipient in writing and require that use of Data from that Provider be terminated and the Data from that Provider be returned. The Recipient will have three months to comply with termination and return of the Data.

**19. Disqualification, Enforcement.** Failure to comply with any of the terms of this DMDA may result in disqualification of Recipient from receiving additional Data. The PHA and/or PHAR may have the right to institute and prosecute appropriate proceedings at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this DMDA, the limitations on the use of the Data provided, or both. Proceedings may be initiated against the violating party, or legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding at law or in equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient and Recipient’s PI acknowledge that a breach or threatened breach of the confidentiality requirements or use limitations of this DMDA may subject Recipient and Recipient’s PI to legal action on the part of PHAR participants, their families, or both.

**20. Representations.** Recipient and Recipient’s PI expressly certify that the contents of any statements made or reflected in this document are truthful and accurate.

**21. Prior Distribution Agreements.** By execution of this DMDA, Recipient certifies its good faith belief that it is in compliance with the terms and conditions of all existing DMDAs with PHAR and/or the Pulmonary Hypertension Association.

**RECIPIENT’S PRINCIPAL INVESTIGATOR AND RECIPIENT’S AUTHORIZED REPRESENTATIVE:**

*Name and Title of Recipient’s Principal Investigator*

*Surface Mail Address of Recipient’s Principal Investigator*

*Email Address of Recipient’s Principal Investigator*

*Telephone and Fax Number of Recipient’s Principal Investigator*

*Signature of Recipient’s Principal Investigator and Date*

 **,** **[ ]** *[non-profit] OR* **[ ]**  *[for-profit] corporation/institution*

*Name of Recipient (Corporation/Institution),*

*organized under the laws of (State/Country):*

*with a principal address at:*

*Name and Title of Recipient's Authorized Representative*

*Signature and Date of Recipient's Authorized Representative*

**COORDINATING CENTER FOR Pulmonary Hypertension Association Registry (PHAR)**

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*Name and Title of PHAR Coordinating Center Authorized Representative*

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*Signature and Date of PHAR Coordinating Center Authorized Representative*

**This Distribution Agreement is entered into as of:  \_\_\_\_\_\_\_\_\_\_\_     (effective date)**