

**The Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED)
Data Distribution Agreement**

The National Heart, Lung, and Blood Institute (NHLBI) and ro hereby enter into this Distribution Agreement as of the date specified on the final page hereof.

PRELIMINARY STATEMENT

The National Heart, Lung, and Blood Institute (NHLBI) has supported collection of data from participants in The Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED), hereafter referred to as “Study”. This well-characterized population provides a unique scientific resource. Promoting optimal use of it on a national scale will require a large and concerted effort that may exceed the research capacity of currently available Study investigators. The NHLBI and the researchers it supports have a responsibility to the public in general, and to the scientific community in particular, to encourage as rapid scientific progress as possible using this resource, subject to appropriate terms and conditions. In order to take full advantage of the resource and maximize its research value, it is important that the data that were collected with public funds be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Although data collected by the Study have been stripped of all personal identifiers, the wealth of data available on individual participants might make possible their identification. To protect the confidentiality and privacy of Study participants, Recipients who are granted access to Study data must adhere to the requirements of this Distribution Agreement and obtain IRB approval for their project. IRB approval may be from an expedited or convened review, but a simple IRB letter granting an exemption is not sufficient. Failure to comply with this Distribution Agreement could result in denial of further access to Study Data. Violation of the confidentiality requirements of this agreement is considered a breach of confidentiality and may leave requesting investigators liable to legal action on the part of Study participants, their families, or the U.S. Government.

The Study Investigators have made a substantial long-term contribution in establishing and maintaining the clinical database. The NHLBI encourages appropriate collaborative relationships by outside investigators with the Study Investigators and proper acknowledgement of the contributions of the Study Investigators.

discouraged from publishing individual pedigree structures and are prohibited from investigating issues such as non-paternity.

1.3. The Research Project (check one) [does][does not] involve PIOPED Study Investigator(s) as co-investigator(s). If the Project does involve PIOPED Study Investigator(s), their names are: si n

and the work they will perform is described below or in an attached Exhibit B:
work des

1.4. Recipient will promptly notify the NHLBI of any substantive changes to the proposed Research Project or of any new projects to be initiated from the requested Data. Such notification will consist of a new project description as described in paragraph 1.2. Data will be used solely for Research Projects disclosed to the NHLBI.

1.5. This Agreement will terminate three (3) years from the effective date of this agreement. Continued use of the Data will require execution of a new Distribution Agreement as specified in paragraph 6.

2. Non-transferability. This Distribution Agreement is not transferable. Recipient agrees that appointment by Recipient of another Principal Investigator to complete the Research Project will require execution of a new Distribution Agreement in which the new Principal Investigator is designated. Recipient also agrees that it will recover from the PI all Data received under this agreement should the PI's employee relationship with the Recipient terminate for any reason.

3. Publication. Prompt publication or other public disclosure of the results of the Research Project is encouraged. Recipient agrees to provide to the NHLBI a copy of any manuscript or other disclosure document thirty (30) days in advance of submission for publication, in order to ensure compliance with the confidentiality requirements set forth in paragraphs 4,5,6,7, and 8 of this Agreement.

4. Acknowledgments. Recipient agrees to acknowledge the contribution of the Study Investigators in any and all oral and written presentations, disclosures, or publications resulting from any and all analyses of Data.

4.1. Collaborations/Acknowledgments. If the Research Project involves collaboration with Study Investigators (see paragraph 1 above), then the PI will comply with all policies established by the Study's publications committee. In addition, the Recipient will acknowledge the source of the data by including language similar to the following either in the acknowledgment or in the text of the manuscript: 'This manuscript was prepared using a limited access dataset obtained from the NHLBI'.

and the agents and employees of each of them, harmless and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use of Data for any purpose.

10. Recipient's Compliance with IRB Requirements. Recipient acknowledges that the conditions for use of Data are not exempt from review and have been approved by the Recipient's Institutional Review Board (IRB) operating under an Office of Human Research Protections (OHRP) - approved Assurance and in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions. Recipient agrees to report promptly to the NHLBI any proposed change in the research project and any unanticipated problems involving risks to subjects or others. This Agreement is made in addition to, and does not supercede, any of Recipient's institutional policies or any local, State, and/or Federal laws and regulations that provide additional protections for human subjects.

11. Amendments. Amendments to this Agreement must be made in writing and signed by authorized representatives of all parties.

12. Termination. The NHLBI may terminate this Agreement if Recipient is in default of any of its conditions and such default has not been remedied within 30 days after the date of written notice of such default by an authorized representative of the NHLBI.

13. Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional Data. The United States Government shall have the right to institute and prosecute any proceeding at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this agreement, the limitations on the use of the data provided, or both. Proceedings may be initiated against the violating party, legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding in law or 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 acknowledges and agrees that a breach or threatened breach of the confidentiality requirements or use limitations of this agreement may subject Recipient to legal action on the part of Study subjects, their families, or both.

14. Accurate Representations. Recipient certifies that the contents of any statements made or reflected in this document are truthful and accurate.

15. Duplication of Research. Recipient acknowledges that other researchers are entitled to access to Data on the same terms as Recipient so that duplication of PI's research may occur.

Signatures begin on the next page.

This Agreement is entered into as of : _____ (effective date)

RECIPIENT:

Name of Recipient :ri

Name and Title of Recipient's Authorized Institutional Business Official: _____

Signature and Date of Recipient's Authorized Institutional Business Official: _____

PRINCIPAL INVESTIGATOR:

Principal Investigator's Name and Title:

Principal Investigator's Surface Mail Address:

Principal Investigator's E-Mail Address:

Principal Investigator's Telephone Number:

Principal Investigator's Fax Number:

Principal Investigator Signature and Date: _____

NHLBI:

NHLBI Authorized Representative -- Name and Title: _____

NHLBI Authorized Representative -- Signature and Date: _____

ATTACHMENT 1: Guidelines for Manuscripts and Abstracts from Investigators Who Use Limited Access Datasets

Manuscript Review Policy

The NHLBI reviews manuscripts from PIs who use limited access datasets only for compliance with the terms of this Data Distribution agreement. Specifically, manuscripts should not present case studies that describe the characteristics of individual participants, or of just a small number of participants. The PI must be a coauthor on all manuscripts and abstracts, and the acknowledgment as set forth in section 4 must accompany all manuscripts. Manuscripts and abstracts should be submitted to the NHLBI authorized representative prior to the end of the three (3) year limit on use of the data.

Abstracts, in general, can not use the acknowledgment as described in section 4; therefore, abstracts should clearly indicate within the text that the source of the data was a limited access dataset obtained from the NHLBI.

In addition to a review for compliance with the terms of this Data Distribution Agreement by NHLBI's authorized representative, manuscripts and abstracts may be forwarded to NHLBI staff familiar with the Study or to Study investigators for comment. If NHLBI staff or Study investigators choose to offer additional comments, these are provided to the Principal Investigator only as a courtesy. Limited access investigators are not obligated to incorporate additional comments from other NHLBI staff or Study investigators; however, these comments may provide the investigator with additional insights towards improving the manuscript.

Additional Guidelines for Manuscripts/Abstracts using Limited Access Data

Since many limited access databases are from ongoing studies, manuscripts and abstracts should not use the name of the study in the title of the manuscript/abstract unless the title clearly denotes the source of the data as being from a limited access database (e.g., "...An application from the PIOPED limited access dataset"). The purpose is to delineate manuscripts from Study investigators who must obtain prior Study approval and review from those prepared by investigators who do not have to do so.

Manuscripts submitted to the NHLBI by investigators using limited access datasets are reviewed within 10-14 days and abstracts are reviewed within 3-7 days. Expedited reviews can be requested. Additional comments from NHLBI staff or Study investigators, if any, are forwarded to the limited access investigator once they are received by the NHLBI authorized representative. Additional comments from NHLBI staff or Study investigators may be forwarded to the Principal Investigator prior to or after the review by the NHLBI authorized representative.