The Thrombolysis in Myocardial Infarction Trial 3 (TIMI 3)
Data Distribution Agreement

The National Heart, Lung, and Blood Institute (NHLBI) and [redacted] 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 Thrombolysis in Myocardial Infarction Trial 3 (TIMI 3), 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.

DEFINITIONS

Data: For purposes of this agreement, "Data" refers to the following information that has been collected and recorded from Study participants through the periodic examinations and follow-up contacts conducted pursuant to the Study Investigators' contracts or awards with the NHLBI and through associated ancillary studies (where available):

Data from The Thrombolysis in Myocardial Infarction Trial 3 (TIMI 3).

TIMI 3 Investigator: A "TIMI 3 Study Investigator" is a research investigator with a current and active contract or consulting agreement with the NHLBI or one of its contractors to work on the TIMI 3 study.

RECIPIENT: Recipient is (check one):

☐ a non-profit organization organized under the laws of the State of _____ OR
☐ a for-profit corporation organized under the laws of the State _____ OR
☐ a government agency organized under the laws of the _____ .

Principal Investigator:
_____, with a principal address at _____
requests access to Study data at his/her sole risk and at no expense to the Study or the NHLBI.

AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Research Project.

1.1 The PI, for the Requestor requests (check one)

☐ Non-Commercial Purpose Data Set
☐ Commercial Purpose Data Set

1.2. These Data will be used by the PI in connection with the following research project ("Research Project"), specifically described in an attached Exhibit A. The Project description should include: project title, a 1-2 paragraph description of the objectives and design, and a brief description of the analysis plan.
Note: If the PI is requesting a Genetic/Pedigree Data Set, the Research Project description must describe a specific need for it. Investigators using these data are strongly

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 TIMI 3 Study Investigator(s) as co-investigator(s). If the Project does involve TIMI 3 Study Investigator(s), their names are:

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

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'.

4.2. Other Studies/Acknowledgments. If the Research Project does not involve collaboration with Study Investigators (see paragraph 1 above), all manuscripts or other disclosure documents should be submitted to the NHLBI thirty (30) days in advance of submission for publication. In addition, the PI will use the acknowledgment printed below. [The process for review of manuscripts by NHLBI is described in Attachment 1.]

> "The Thrombolysis in Myocardial Infarction Trial 3 (TIMI 3) is conducted and supported by the NHLBI in collaboration with the TIMI 3 Study Investigators. This Manuscript was prepared using a limited access dataset obtained from the NHLBI and does not necessarily reflect the opinions or views of the TIMI 3 or the NHLBI."

5. Non-Identification. Recipient agrees that Data will not be used, either alone or in conjunction with any other information**,** in any effort whatsoever to establish the individual identities of any of the subjects from whom Data were obtained.

6. Use Limited to Three (3) Years**.** Recipient agrees that Data will be removed or destroyed when three (3) years have elapsed from the effective date of this Agreement. Further use of the Data beyond that time requires completion of a new Distribution Agreement along with a current IRB approval resulting from either IRB review of a new research protocol or continuing review of the existing research protocol.

7**.** No Distribution. Recipient agrees to retain control over Data, and further agrees not to transfer Data, with or without charge, to any other entity or any individual.

8. Non-Data. Notwithstanding the definition of "Data" or the agreed Terms and Conditions of this Distribution Agreement, Recipient's obligations under this Distribution Agreement shall not extend to any information:

(a) that can be demonstrated to have been publicly known at the time of disclosure; or
(b) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to Recipient from another source prior to the disclosure; or
(c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Recipient; or
(d) that can be demonstrated as independently developed or acquired by Recipient without reference to or reliance upon Data provided under this Agreement; or
(e) that is required to be disclosed by law, provided the Recipient takes responsible and lawful actions to avoid and/or minimize such disclosure.

9. Non-Endorsement, Indemnification. Recipient agrees not to claim, infer, or imply endorsement by the United States government or any of its agencies of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s) except as described in paragraph 4. To the extent permitted by law, Recipient agrees to hold the United States Government, Study Investigators, and all other investigator(s) who generated Data

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 :

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 TIMI 3 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.