Data Distribution Agreement for
PLACEBO CONTROLLED CLINICAL TRIAL OF A STANDARDIZED EXTRACT OF *HYPERICUM PERFORATUM* IN MAJOR DEPRESSIVE DISORDER (Hypericum Study)

INTRODUCTION

The National Institute of Mental Health (NIMH) has supported collection of data from participants in "Placebo-Controlled Clinical Trial of a Standardized Extract of *Hypericum perforatum* in Major Depressive Disorder"—(Hypericum Study) hereafter referred to as "Study". This well-characterized population provides a rare and valuable scientific resource. Promoting optimal use on a national scale of such a resource will require a large and concerted effort, which may exceed the research capacity of currently available Study Investigators. The NIMH 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 these resources, subject to appropriate terms and conditions. In order to take full advantage of such resources and maximize their research value, it is important that data collected with public funds be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Data collected by the Study have been stripped of all personal identifiers but the wealth of data available on them might make possible the individual identification of some subjects. To protect and ensure the confidentiality and privacy of these participants, the Recipient who is granted access to these data must adhere to the requirements of this Distribution Agreement. 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 NIMH seeks to encourage appropriate collaborative relationships by outside investigators with the Study Investigators and to ensure that the contribution of the Study Investigators is appropriately acknowledged.

DEFINITIONS

For purposes of this agreement, "Data" refers to the information that has been collected and recorded from participants in the Hypericum Study. Data from Study participants were collected through the periodic examinations and follow-up contacts conducted pursuant to the Study Investigators' Cooperative Agreement grants and contracts.

A "Hypericum Study Investigator" is defined as a research investigator with a past or current/active grant, contract, or consulting agreement with NIMH or one of its contractors to work on the study.

The "Recipient Principal Investigator" and his/her organization may be a non-profit or for-profit organization or corporation. The Recipient Principal Investigator requests access to Study data at its sole risk and at no expense to the Study and NIMH.

AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Research Project. These Data will be used by Recipient Principal Investigator solely in connection with the "Research Project", specifically indicated and described in Exhibit A (Description of Research Project for Which Study Data are Requested). If the Project does involve a Hypericum Study Investigator(s), their names and the work they will perform is also included in Item 3.

   This Distribution Agreement covers only the Research Project as specified in the title of this agreement. Recipient will submit a completed Distribution Agreement (this document) for each research project for which Data are requested.

2. Non-transferability of Agreement. This Distribution Agreement is not transferable. Recipient agrees that substantive changes made to the Research Project described and/or appointment by Recipient of another Principal Investigator to complete the Research Project, require execution of a new Distribution Agreement, or an amendment to the Distribution Agreement, in which the new Principal Investigator and/or new Research Project are designated.

3. Non-Identification of Subjects. 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.

4. Use Limited to Research Project. Recipient agrees that Data will not be used in any research that is not disclosed and approved as part of the Research Project.

5. No Distribution of Data. 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.

6. Notification of NIMH of Publication. Prompt publication or any public disclosure of the results of the Research Project is encouraged. Recipient agrees to notify NIMH in advance as to when and where a publication (or other public disclosure) of a report from the Research Project will appear. In addition, Recipient agrees to provide to NIMH, in advance of its appearance, a copy of any manuscript or other public disclosure document.

7. Acknowledgments. Recipient agrees to acknowledge the contribution of the Study Investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data, whether or not Recipient is collaborating with Study Investigators.

   The manuscript should include the following acknowledgement:

   > The Placebo-Controlled Clinical Trial of a Standardized Extract of *Hypericum perforatum* in Major Depressive Disorder was conducted and supported by the National Institute of Mental Health (NIMH) and the National Center for Complementary and Alternative Medicine (NCCAM) in collaboration with the study Investigators. This manuscript reflects the views of the authors and may not reflect the opinions or views of all the study investigators, the NIMH, or the NCCAM.

   If the Research Project involves a collaboration with Study Investigators or NIMH staff (as

indicated in Recipient Information Section of this Agreement), then Recipients will acknowledge Study Investigators or NIMH staff as co-authors, as appropriate, on any publication.

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:

    1. that can be demonstrated to have been publicly known at the time of disclosure; or

    2. 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 (with no duty to any party to keep the information confidential) prior to the disclosure; or

    3. that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Recipient; or

    4. that can be demonstrated as independently developed or acquired by Recipient without reference to or reliance upon Data provided under this Agreement; or

    5. 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 Responsibility. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s) except as described in paragraph 7. The United States Government, Study Investigators, and all other investigator(s) who generated Data and the agents and employees of each of them, shall be liable for any loss, claim, damage or liability that said party incurs only as a result of said party's activities under this Agreement, except that the United States Government assumes liability only to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680). Recipient shall be liable for any loss, claim, damage or liability that it incurs arising from Recipient's actions and use for any purpose of the Data.

10. Recipient's Compliance with IRB Requirements. Recipient acknowledges that the conditions for use of these 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 (or equivalent if Recipient is outside the U.S.). Recipient agrees to comply fully with all such conditions. Recipient agrees to report promptly to the NIMH 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 supersede, any of Recipient's institutional policies or any local, State, and/or Federal laws and regulations which provide additional protections for human subjects.

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

12. Termination. NIMH may terminate this Distribution Agreement if Recipient is in default of any condition of this Distribution Agreement and such default has not been remedied within 30 days

after the date of written notice by NIMH's Authorized Representative of such default.

13. Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional Data (from this study and from other studies).

    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 expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

15. Duplication of Research. The recipient of the limited access data acknowledges that other researchers have access to this dataset, and that duplication of research is a distinct possibility.

Agreement Information

1. Name of NIMH-sponsored Study from which Data are being requested:

[PLACEBO CONTROLLED CLINICAL TRIAL OF A STANDARDIZED EXTRACT OF *HYPERICUM PERFORATUM* IN MAJOR DEPRESSIVE DISORDER]

2. Recipient Information:

Principal Investigator (PI) Information

Principal Investigator Name:

PI Title:

PI Complete Mailing Address (Delivery cannot be made to P.O. Boxes):

Street 1

Street 2

City , State Zip

PI Telephone: ( ) - Extension

PI Fax: ( ) -

PI E-mail: @

Co-Principal Investigator Information (if applicable)

Co-Principal Investigator Name:

Co-PI Telephone: ( ) - Extension

Co-PI Fax: ( ) -

Co-PI E-mail: @

PI Institution/Organization Name:

3. Recipient plans to collaborate with Study Investigators:

○ Yes ○ No

If yes, please indicate Name(s) of those Study Investigators with whom the Recipient will collaborate:

Name 1:

Name 2:

Name 3:

Name 4:

4. Recipient plans to collaborate with NIMH Staff:

○ Yes ○ No

If yes, please indicate Name(s) of those NIMH Staff with whom the Recipient will collaborate:

Name 1:

Name 2:

Name 3:

Name 4:

5. Scientific Purpose of Request (Scientific Aims):

6. Publication Intentions/Goals (paper in peer-reviewed journal, presentation, etc):

7. Signatures:

Recipient Principal Investigator

Signature **Date**

_____ Month ____ Day ____ Year ____

Recipient Co-Principal Investigator

Signature **Date**

_____ Month ____ Day ____ Year ____

Recipient's Authorized Institutional Business Official

Title of Recipient's Authorized Institutional Business Official:

Signature **Date**

_____ Month ____ Day ____ Year ____

A complete Data Distribution Agreement includes all pages of this "Data Distribution Agreement" AND a letter of approval from your IRB.

Inquiries and Requests for Data regarding the Placebo-Controlled Clinical Trial of a Standardized Extract of *Hypericum perforatum* in Major Depressive Disorder should be sent to:

Public Data Set Request
Clinical Trials Operations and Biostatistics Unit
Division of Services and Intervention Research
National Institute of Mental Health
National Institutes of Health
6001 Executive Boulevard, Room 7167, MSC 9649
Rockville, Maryland 20892-9649
(if overnight delivery): Rockville, Maryland 20852

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH • NATIONAL INSTITUTE OF MENTAL HEALTH
NIMH National Institute of Mental Health