Data Access Request and Use Certification
for the
NIMH Clinical Research Datasets: Clinical Trial of Intervention Effectiveness in Patients with X
(ACRONYM)

I request access to data collected by the *"Clinical Trial of Intervention Effectiveness in Patients with X"* (ACRONYM) group for the purpose of scientific investigation described in the Data Access Request and Use Certification (DUC). I agree to the following terms:

1. Research Use

I, my research staff and institutional organization, and my prime contractor and/or subcontractors (listed on the DUC if any), will use the ACRONYM Study Dataset(s) only for research purposes, as described briefly on the DUC and in accordance with federal, state, and local laws, and any relevant institutional policies. This applies to all versions of the ACRONYM Study Dataset(s).

2. Federal Wide Assurance and Human Subjects Review

My institution or organization is covered by a Federal Wide Assurance (FWA) issued by the HHS Office of Human Research Protections, and I will comply with all applicable federal and state laws for the use of this data, which may include 45 C.F.R. Part 46. I understand that my institution may view this research activity as human subjects research requiring certain review or approval. This review and approval may include Institutional Review Board (IRB) approval, exemption from IRB review, and/or a determination regarding whether or not human subjects are involved. I will review this issue with appropriate institutional officials and follow all applicable human subject protections, if any.

3. Non-transferability

I will retain control over the data and, subject to applicable law, agree not to distribute the raw data in any form to any entity or individual other than my research staff who also agree to the terms within this DUC. I and my institution acknowledge responsibility for ensuring appropriate use of these data by research staff.

Any investigator from another institution with whom I may collaborate and who requires access to the data must complete an independent DUC before he/she may gain access to the data.

4. Change of Institution

If I change institutions and wish to take the ACRONYM Study Dataset(s) with me, I will submit a new DUC in which the new institution acknowledges and agrees to the

provisions of the DUC. If I change institutions and do not take the ACRONYM Study Dataset(s) with me, this DUC will be terminated and I will securely destroy all copies of the ACRONYM Study Dataset(s) obtained under this DUC, including backup or working copies at the original site. Thus, I will not transfer the authorization to use the ACRONYM Study Dataset(s) requested under this DUC to anyone else without obtaining permission from NIH.

5. Non-identification

I will not use ACRONYM Study Dataset(s), or any other information, to identify or contact any individual ACRONYM Study participant, except as permitted by law (e.g., in connection with a separately negotiated collaboration with the original research team).

6. Non-Governmental Endorsement

I will not claim, infer, or imply U.S. Governmental endorsement of any research project, the entity or personnel conducting the research project, or any resulting commercial product(s).

7. Indemnification

I understand that although reasonable efforts have been taken to ensure the accuracy and reliability of the data in the ACRONYM Study Dataset(s), NIH does not and cannot warrant the results that may be obtained by using any data included therein. NIH disclaims all warranties as to the accuracy of the data in the ACRONYM Study Dataset(s) or the performance or fitness of the data for any particular purpose.

8. Possible Duplication of Research

I understand that other researchers have access to the ACRONYM Study Dataset(s) and that duplication of research is a distinct possibility. I also understand that it is possible that the participants whose data are in the ACRONYM Study Dataset(s) may also be participants in other studies so that there is no guarantee that all NIH Study Datasets that may be distributed are or will be mutually exclusive in terms of participants.

9. Limitations of Dataset Use

I will use the ACRONYM Study Dataset(s) solely in connection with this DUC, which includes a 1-2 paragraph description of the research objectives and a brief analysis plan. New research using this data outside of the description included in DUC or significant modifications to this research description will require submission of a new request by completion of a new DUC, even if a new copy of the ACRONYM Study Dataset(s) is not required.

10. Publication of Abstracts or Oral Presentations and Acknowledgement of the NIH

If I publish abstracts or make oral presentations using data from the ACRONYM Study Dataset(s), I agree to the following:

a. I will cite the ACRONYM Study and the federal funding sources in the abstract as space allows.

b. I will include a reference to the specific version of the ACRONYM Study Dataset(s) analyzed.

11. Publication of Manuscripts and Acknowledgement of the NIH

If I publish manuscripts using data from the ACRONYM Study Dataset(s), I agree to the following:

a. I will include the specific version number of the dataset used.

b. I will acknowledge the source of the data and the funding agencies by including a statement, such as the following:

"Data used in the preparation of this article were obtained from the limited access datasets distributed from the NIH-supported "*Clinical Trial of Intervention Effectiveness in X"* (ACRONYM). This is a multisite, clinical trial of persons with X comparing the effectiveness of randomly assigned medication treatment. The study was supported by NIMH Contract #N01MH##### to the University of Y. The ClinicalTrials.gov identifier is NCT########."

c. I will include the following statement: "This manuscript reflects the views of the authors and may not reflect the opinions or views of the ACRONYM Study Investigators or the NIH."

12. Notifying NIH of Publications

Upon acceptance for publication, I will notify the NIH at nimhdatasets@mail.nih.gov as to when and where a publication of a report from any research using the ACRONYM Study Dataset(s) will appear.

13. ***Privacy Act Notification:***

I agree to provide the information requested below and on the attached SF 424. I agree that information collected from me as part of this DUC and SF 424 may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below and on the attached SF 424 from the recipient comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and

Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0156 (**http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm**) covering " Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD." The primary uses of this information are to document, track, and monitor and evaluate use of the limited access datasets, as well as to notify recipients of updates, corrections or other changes to the database.

I understand that the Federal Privacy Act protects the confidentiality of my NIH records. The NIH and any sites they designate to distribute the limited access datasets will use the data collected from me for the purposes described above. In addition, the Act allows the release of some information in my records without my permission; for example, if it is required by members of Congress or other authorized individuals. I understand the information requested is voluntary, but necessary for me to obtain access to data.

By signing and dating the DUC, my Institutional Official and I certify our agreement to the NIH principles, policies and procedures for the use of ACRONYM Study Dataset(s) as described in this document. We further acknowledge that we have shared this document with any research staff members who will use the ACRONYM Study Dataset(s) and other appropriate institutional staff and officials.

14. Information Technology (IT) Security

I acknowledge the expectation that I will follow information security practices designed to keep the ACRONYM Study Dataset(s) secure.

Suggested “best-practices” include the following:

a. Retaining the original version of the data encrypted, with the password secured separately.
b. Keeping track of any copies or extracts made of the data and how they are used.
c. Only downloading data from the original CD-ROM onto a secured computer or server with strong password protection and avoiding or limiting the storage of data on a laptop or other portable medium.
d. If and when storing data on a portable device, encrypting the data. Most operating systems have the ability to natively run an encrypted file system or encrypt portions of the file system. (e.g., Windows=EFS or Pointsec and Mac OSX=File Vault)
e. For computer hosting data, ensuring that they have the latest security patches and are running virus protection software.
f. Making sure the data are not exposed to the Internet or posted to a website that may be discovered by Internet search engines such as Google or MSN.
g. Maintaining a secure password policy for computers on which data reside. Secure password policy includes:

- Choosing passwords of at least seven characters including at least three of the following types of characters: capital letters, lower case letters, numeric characters, and other special characters.
- Changing my password every six months.
- Protecting my password from access by other individuals; for example, storing it electronically in a secure location.

h. When leaving my office, closing data files and locking my computer.
i. Using a timed screen saver with password protection.
j. When finished using the data, destroying the data or archiving it securely for a required period of time and arranging for its destruction at a defined date, as permitted by law and institutional policies.
k. Protecting the data, providing access solely to authorized researchers with permitted access to such data at my institution or to others as required by law.
l. Notifying the NIMH (at nimhdatasets@mail.nih.gov), as permitted by law, of security incidents and incidents of suspected fraud, waste or misuse of ACRONYM Study Dataset(s).
m. Ensuring that anyone directed to use the data is aware of these information security best- practices.

This DUC is being submitted for the following purpose:

Check one:

- ☐ initial request for this dataset
- ☐ not requesting new dataset; request is to use existing dataset for a purpose not stated in the initial request (see Item 9)
- ☐ not requesting new dataset; request is to use existing dataset at another Institution (see Item 4)
- ☐ not requesting new dataset; I am collaborating with a data recipient, will have access to that dataset, and am at an Institution different from the recipient (see Item 3)
- ☐ other (explain) _____

Check if applicable:

- ☐ my request includes collaborators at different institutions who will have direct access to the data (see Item 3)