Research Data Use Agreement (RDUA)

I. Introduction and Definitions

1. The Critical Illness Stress-Induced Immune Suppression (CRISIS) Prevention Trial ("STUDY") Public Use Data Set (the "Data Set") has been prepared by staff at the Data Coordinating Center, University of Utah School of Medicine ("UTAH"), on behalf of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Collaborative Pediatric Critical Care Research Network (CPCCRN). The Data Set is available to qualified researchers of RECIPIENT who agree to comply with this Research Data Use Agreement ("Agreement"). The purpose of this availability is to provide the Data Set to qualified investigators who wish to analyze the data in a secondary study designed to enhance the public health benefit of the original work.

2. For purposes of this Agreement, "Principal Investigator (PI)" is the individual judged by the RECIPIENT to have the appropriate expertise and authority to conduct the scientific analysis that is proposed in the Research Plan attached to this Agreement. By signing this Agreement, RECIPIENT certifies that PI is a qualified investigator as defined herein.

3. "Research Plan" is a description of the proposed research that will use this Data Set. The Research Plan must include the project title, names of the RECIPIENT and the PI, and a one- to two-paragraph paragraph description of the proposed research protocol including the research objectives and scientific design.

4. The RECIPIENT and PI acknowledge their responsibility for ensuring adherence to the terms of this Agreement, subject to applicable Federal and State laws and regulations, including the privacy and security provisions of HIPAA and HITECH.

5. The Data Set meets the definition of a Limited Data Set as defined in 45 CFR Section 164.514(e).

II. Data Set Description and Support

1. The Data Set will be provided on a CD or DVD as SAS datasets or CSV text files suitable for importation in statistical software. Electronic copies of the data worksheets, the final study protocol, and a data dictionary will also be provided on the disks. No further support whatsoever will be provided by UTAH, STUDY investigators, CPCCRN, or NICHD to the RECIPIENT or PI.

III. Approved Research Uses

1. The RECIPIENT and PI agree that they will use the Data Set solely in connection with the research project described in the Research Plan attached to this Agreement.

Substantive modifications to the research project require submission to UTAH and acceptance by UTAH of a revised RDUA.

IV. Institutional and Approved User Responsibilities

1. The RECIPIENT and PI acknowledge that use of the Data Set is not exempt from review and approval 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. Evidence of RECIPIENT's IRB approval from an expedited or convened review to conduct the Research Plan with the Data Set must be attached to this Agreement. It is not permissible for the RECIPIENT's IRB to consider the use of the Data Set exempt, and the RECIPIENT and PI must assure annual IRB review of the project.

V. Non-Identification of Subjects

1. The RECIPIENT and PI agree that they will not attempt to identify or contact the subjects or institutions that are included in the Data Set.

VI. Non-Transferability of Data/Security of Data

1. The RECIPIENT and PI agree to maintain control over the Data Set and further agree not to release or distribute the Data Set in any form to any entity or individual for any purpose except as may be required by law or as permitted by this Agreement. If multiple investigators are collaborating and it is necessary to share the Data Set, each investigator who will have a copy of the Data Set must sign a separate Agreement with UTAH.

2. The PI agrees that if his or her relationship with the RECIPIENT terminates and a relationship with a different RECIPIENT is established during the period of the RDUA, a new RDUA from the second RECIPIENT will be submitted and approved by UTAH before the PI resumes use of the Data Set. Any versions of the Data Set stored at the first RECIPIENT will be destroyed and their destruction documented and reported to UTAH.

3. RECIPIENT and PI agree to use appropriate safeguards to ensure that Data Set is not used or disclosed in a manner inconsistent with this Agreement. RECIPIENT and PI agree to immediately report to UTAH any use or disclosure of the Data Set not in compliance with this Agreement and to provide all reasonable information requested by UTAH related to such use or disclosure.

4. With respect to the Data Set, RECIPIENT and PI agree to comply with the security and privacy standards for Electronic Protected Health Information as defined in 45 CFR parts 160 and 164, Subpart C, as may be amended thereafter; RECIPIENT and PI also

agree to comply with the Health Information Technology for Economic and Clinical Health (HITECH) Act effective February 17, 2009, and its implementing regulations.

VII. Duration of Agreement

1. This RDUA will be in effect for a period of three (3) years from its effective date for the requested Data Set. The RDUA may be extended upon submission of a new PUDDA document accompanied by the most recent RECIPIENT IRB approval of the Research Plan. At the end of the three (3) year period or extension, if another new extension is not in place, the RECIPIENT and PI agree to destroy all copies of the Data Set, including derivative datasets that contain individual-level information.

VIII. Acknowledgment of Data Resource

1. The RECIPIENT and PI agree to acknowledge the contribution of the STUDY in all oral and written presentations, disclosures, or publications resulting from any analyses conducted on the Data Set:

2. The PI will acknowledge the source of the Data Set by including language similar to the following either in the acknowledgement or in the text of the manuscript: "This manuscript was prepared using the Critical Illness Stress-Induced Immune Suppression (CRISIS) Prevention Trial Data Set obtained from UTAH, and does not necessarily reflect the opinions or views of the CRISIS investigators or the NICHD. The CPCCRN was funded by the NICHD." Manuscripts and meeting abstracts may not use the name of the STUDY in the title, nor may the name of the STUDY or CPCCRN be included in the byline of the publication.

IX. Publication

1. The RECIPIENT and PI agree to provide to UTAH a copy of any manuscript thirty (30) days in advance of submission for publication, in order to ensure compliance with the terms of this Agreement. In addition, UTAH may in its discretion forward the manuscript to STUDY investigators for comment. If STUDY investigators choose to offer additional comments, these are provided to the PI only as courtesy. The PI is not obligated to incorporate additional comments from STUDY investigators; however, these comments may provide the PI with additional insights towards improving the manuscript.

X. Duplication of Research

1. The RECIPIENT and PI acknowledge that other researchers are entitled to access to the Data Set on the same terms as RECIPIENT, and duplication of the PI's research may occur.

XI. **Non-Endorsement/Indemnification**

1. The RECIPIENT and PI acknowledge that although reasonable efforts have been taken to ensure the accuracy and reliability of the Data Set, UTAH and the STUDY investigators do not and cannot warrant the research results or conclusions that may be obtained by using any data included therein. All contributors to the Data Set disclaim all warranties as to performance or fitness of the Data Set for any particular purpose.

2. RECIPIENT and PI agree that they will indemnify and hold harmless UTAH from and against any and all losses, expenses, damages, or injuries that UTAH sustains as a result of, or arising out of a breach of this Agreement by RECIPIENT or PI or their agents or subcontractors, including but not limited to any unauthorized use or disclosure of the Data Set.

XII. Termination and Violations

1. UTAH may terminate this Agreement if either RECIPIENT or PI is in default of any terms and conditions of this Agreement and such default has not been remedied within 10 days after the date of written notice of such default. UTAH may unilaterally terminate this Agreement for any reason within 90 days written notice to RECIPIENT.
2. Upon termination of this Agreement for any reason, RECIPIENT and PI shall destroy any copies of Data Set in their possession, including derivative datasets that contain individual-level information, and shall document and report such destruction to UTAH.

XIII. Amendments

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

XIII. Choice of Law

1. RECIPIENT and PI agree that laws of the State of Utah will apply to any disagreement, including litigation, regarding this Agreement, and that the forum for any legal proceedings arising therefrom will be in Salt Lake City, Utah.

Signatures Page

By submission of the RDUA, the RECIPIENT and PI attest to the PI qualifications for access to and use of the STUDY Data Set and certify their agreement to adhere to the principles, policies and procedures for use of the Data Set as articulated in this Agreement.

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

BY RECIPIENT:

Name of RECIPIENT Institution: _____

Name of RECIPIENT Authorized Institutional Business Official: _____

Title of RECIPIENT Official: _____

Signature of RECIPIENT Official: _____

BY PRINCIPAL INVESTIGATOR:

Name and Title: _____

Surface Mail Address: _____

_____

Email Address: _____

Telephone Number: _____

Signature and Date: _____

BY UNIVERSITY OF UTAH:

Name and Title: _____

Signature and Date: _____