Data Sharing Agreement

This DATA SHARING AGREEMENT (this "Agreement") is effective as of _____, 20[XX] (the "Effective Date") between _____ [RECIPIENT INSTITUTION NAME] ("[RECIPIENT INSTITUTION]") located at [RECIPIENT INSTITUTION ADDRESS]
and _____ [SUPPLYING INSTITUTION NAME] ("[SUPPLYING INSTITUTION]") located at [SUPPLYING INSTITUTION ADDRESS].

1) **Definitions**

a) "Data Set" means the study information and data which may include any of the following: participant-level data, appropriate extracts from clinical study reports, and/or the protocol from the study. The contents of the Data Set are described in the Analysis, as hereinafter defined.

b) "[SUPPLYING INSTITUTION] Confidential Information" means all information (including, without limitation, the Data Set, research specifications or Protocols, reports, computer programs, or models and related documentation, know how, trade secrets, or business or research plans) of [SUPPLYING INSTITUTION] or [SUPPLYING INSTITUTION]'s affiliates that are provided to [RECIPIENT INSTITUTION] in connection with this Agreement.

c) "New Intellectual Property" means all discoveries, developments, inventions (whether patentable or not), improvements, methods of use or delivery, know-how or trade secrets that are made by [RECIPIENT INSTITUTION] in connection with the use of [SUPPLYING INSTITUTION] Confidential Information under this Agreement.

d) "Analytical Tools" includes but is not limited to any methodology, statistical methods, formulae or other methods or tools used by [RECIPIENT INSTITUTION] in conducting the Analysis.

e) "Safety Concerns" means any new information that might influence the evaluation of the risks and benefits of the product to which the Data Set pertains.

2) **Data Sharing**

a) [RECIPIENT INSTITUTION] desires access to a Data Set assembled by [SUPPLYING INSTITUTION] for the sole purpose of analysis according to the [RECIPIENT INSTITUTION]'s approved research plan (the "Analysis"). This plan is set forth in EXHIBIT A, which provides a detailed description of the Analysis and the information required (e.g., diagnosis, gender, and age) to achieve its purpose. In addition to restricting its use of any Data Set shared under this Agreement to the Analysis, [RECIPIENT INSTITUTION] agrees to comply with any additional requirements that have been imposed by applicable law or regulation or that

were identified by the independent review panel that approved the Analysis. Requirements identified by the independent review panel, if any, are set forth in EXHIBIT B.

b) [RECIPIENT INSTITUTION] agrees that it will inform [SUPPLYING INSTITUTION] immediately of any Safety Concerns identified as part of the Analysis. [RECIPIENT INSTITUTION] agrees that [SUPPLYING INSTITUTION] may take action regarding such Safety Concerns, including informing regulatory authorities or healthcare providers, or otherwise making the Safety Concerns public, including in advance of publication of the Analysis by [RECIPIENT INSTITUTION].

3) **Confidentiality**

a) [RECIPIENT INSTITUTION] agrees that it will use [SUPPLYING INSTITUTION] Confidential Information only for the Analysis and associated obligations. [RECIPIENT INSTITUTION] may transfer Confidential Information to third parties who collaborate with, or perform services on behalf of, [RECIPIENT INSTITUTION] as part of the Analysis, but only to the extent necessary for the performance of their duties and only after providing [SUPPLYING INSTITUTION] with written notice of such transfer and ensuring that such third parties are bound by obligations of confidentiality at least as restrictive as those found in this Agreement.

b) The obligations of confidentiality and limited use under this Section 3 shall not extend to any information:
   i. which is or becomes publicly available, except through breach of this Agreement;
   ii. which [RECIPIENT INSTITUTION] can demonstrate that it possessed prior to, or developed independently from, disclosure under this Agreement;
   iii. which [RECIPIENT INSTITUTION] receives from a third party which is not legally prohibited from disclosing such information; or
   iv. which [RECIPIENT INSTITUTION] is required by law to disclose, provided that [SUPPLYING INSTITUTION] is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement.

c) [RECIPIENT INSTITUTION] agrees that it will not attempt to re-identify or contact persons who are the subjects of data contained in the Data Set.

d) The obligations of this Section 3 shall survive this Agreement for a period of eight (8) years after the Effective Date, provided that as applied to participant-level data, the obligations of this Section 3 shall continue indefinitely.

4) **Intellectual Property**

a) [RECIPIENT INSTITUTION] will notify [SUPPLYING INSTITUTION], promptly and in writing, of any New Intellectual Property. [RECIPIENT INSTITUTION] hereby grants to [SUPPLYING INSTITUTION] and to [SUPPLYING

INSTITUTION]'s Affiliates a perpetual, non-exclusive, royalty-free, worldwide license with right to sublicense (with an exclusive option, to be exercised within one hundred eighty (180) days from notice of the New Intellectual Property to negotiate in good faith an exclusive, fee-bearing, worldwide license with right to sublicense) to all rights, title and interest which [RECIPIENT INSTITUTION] may have or obtain in any New Intellectual Property, each without additional consideration from [SUPPLYING INSTITUTION]. [RECIPIENT INSTITUTION] will provide reasonable assistance to [SUPPLYING INSTITUTION], upon commercially reasonable terms that are at least as favorable to [SUPPLYING INSTITUTION] as the terms agreed with any other licensee for such assistance, to facilitate [SUPPLYING INSTITUTION] in fully utilizing any New Intellectual Property.

b) If [SUPPLYING INSTITUTION] exercises its option to negotiate an exclusive license, [SUPPLYING INSTITUTION] and [RECIPIENT INSTITUTION] will exclusively negotiate in good faith, for up to one hundred eighty (180) days or such mutually agreeable longer period, regarding commercially reasonable terms for an exclusive, worldwide, fee-bearing license, including the right to sublicense, for [SUPPLYING INSTITUTION] and [SUPPLYING INSTITUTION]'s Affiliates to make, have made, use, sell or otherwise dispose of the subject matter of the New Intellectual Property or products incorporating the subject matter of the New Intellectual Property. In the event that [SUPPLYING INSTITUTION] does not exercise its option to negotiate an exclusive license, or in the event [RECIPIENT INSTITUTION] and [SUPPLYING INSTITUTION] fail to agree to commercially reasonable exclusive license terms following good faith negotiation, then [RECIPIENT INSTITUTION] may negotiate license terms with third parties. Any such terms shall be consistent with the non-exclusive license granted to [SUPPLYING INSTITUTION] in Section 4(a) above. Should any terms be agreed with a third party in accordance with this Section 4(b), then for five (5) years after the Effective Date, [RECIPIENT INSTITUTION] will notify [SUPPLYING INSTITUTION], within thirty (30) days of the effective date of any such agreement, of the identity of the third party.

c) [RECIPIENT INSTITUTION] agrees to obtain written agreements with [RECIPIENT INSTITUTION] employees, agents, and subcontractors which assign, without additional consideration, all rights, title and interests in New Intellectual Property to [RECIPIENT INSTITUTION] for subsequent licensing to [SUPPLYING INSTITUTION]. The obligations of this Section 4(c) shall survive termination of this Agreement.

5) **Publication**

a) [RECIPIENT INSTITUTION] agrees to post a summary of the Analysis plan on a publicly-available Internet register or website prior to conducting the Analysis, and to post summary results of the Analysis on the same publicly-available Internet register or website within one year of completing the Analysis. Websites eligible for this posting include, but are not limited to, clinicaltrials.gov.

b) [RECIPIENT INSTITUTION] also agrees to make the results of the Analysis publicly available in printed form, on the internet, or in a presentation in a learned forum, in a timely and complete manner ("Publication"), and shall use best efforts to obtain publication in a peer-reviewed journal, all as described in the Publication plan attached as EXHIBIT C, with such Publication appropriately disclosing the strengths and weaknesses of the Analysis methodology. [RECIPIENT INSTITUTION] shall submit to [SUPPLYING INSTITUTION] a copy of the summary results of the Analysis at the time of posting the summary results as well as a copy of any proposed Publication within five (5) days of submission to a scientific congress or journal. Additionally, [RECIPIENT INSTITUTION] shall provide [SUPPLYING INSTITUTION] with a reference citation upon publication.

c) [RECIPIENT INSTITUTION] agrees to include the following acknowledgment in any publication or presentation of the results of research you conducted, or to which you contributed, using [SUPPLYING INSTITUTION] Confidential Information: "This [publication or presentation, as applicable] is based on research using data from [SUPPLYING INSTITUTION]. [SUPPLYING INSTITUTION] has not contributed to or approved, and is not in any way responsible for, the contents of this publication."

d) [OPTIONAL: In the event [SUPPLYING INSTITUTION] submits Analysis results to regulatory authorities with the potential to impact product labeling, [RECIPIENT INSTITUTION] agrees that [SUPPLYING INSTITUTION] may post a summary of the Analysis results on [SUPPLYING INSTITUTION]'s Clinical Trial Register.] [RECIPIENT INSTITUTION] agrees, following publication, to provide other researchers with additional details of the Analysis on request and to provide access and reasonable assistance to those other researchers to utilize and implement any Analytical Tools for the sole purpose of reproducing the Analysis.

e) The obligations of this Section 5 shall survive termination of this Agreement.

6) **Independent Contractor**

The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind that purports to bind the other without the other's prior written authorization.

7) **Representations and Warranties**

a) [RECIPIENT INSTITUTION] represents and warrants that it does not have, and will not enter into, any legal or contractual obligations that would prevent it from complying with its obligations under this Agreement, including without limitation, the obligations of Section 4.

b) [RECIPIENT INSTITUTION] represents and warrants that it has the authority to

bind to the terms of this Agreement any individual proposed by[RECIPIENT INSTITUTION] to have access to [SUPPLYING INSTITUTION] Confidential Information, and that the term [SUPPLYING INSTITUTION] shall apply to all such individuals.

c) [RECIPIENT INSTITUTION] agrees that it will obtain any regulatory or ethics approvals necessary to conduct the Analysis.

d) [RECIPIENT INSTITUTION] acknowledges the importance of data privacy of individuals to whom accessed data may relate, and commits to comply with all applicable data privacy laws and regulations. In the event of a conflict between applicable laws and regulations, the stricter law or regulation will apply.

e) [RECIPIENT INSTITUTION] agrees not to attempt to identify the participants in the study and others who could be identified from the study data that have been provided under this agreement (including but not limited to clinical research staff and relatives of participants). [RECIPIENT INSTITUTION] further agrees not to combine accessed data with other sources of data in a manner that could lead to the identification of any individual. The obligations of this Section 7(e) shall survive termination of this Agreement and extend indefinitely.

8) **Indemnification**

a) [RECIPIENT INSTITUTION] shall indemnify and hold harmless [SUPPLYING INSTITUTION], and its respective directors, officers, employees and agents from and against any and all claims, suits, losses, liabilities, damages, costs, fees and expenses (including reasonable attorney fees) (collectively, "Losses") arising out of or resulting from, directly or indirectly, (a) any material breach of, or inaccuracy in, any representation or warranty made by [RECIPIENT INSTITUTION] in this Agreement, (b) any breach or violation of any material covenant or agreement of such [RECIPIENT INSTITUTION] in or pursuant to this Agreement, and (c) the gross negligence or willful misconduct by [RECIPIENT INSTITUTION] and its respective directors, officers, employees and agents, except to the extent that such Losses arise out of or result from directly or indirectly, any material breach of, or inaccuracy in, any representation or warranty in this Agreement made by [SUPPLYING INSTITUTION], or any breach or violation of any covenant or agreement of [SUPPLYING INSTITUTION] in or pursuant to this Agreement, or the gross negligence or willful misconduct of [SUPPLYING INSTITUTION].

9) **Governing Law**

This Agreement shall be governed by and interpreted in accordance with the laws of [INSERT CHOICE OF LAW JURISDICTION].

10) **Entire Agreement**

This Agreement represents the entire and integrated agreement between the parties and

supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter.

[SUPPLYING INSTITUTIONNAME]	**[RECEIVING INSTITUTION NAME]**
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

Acknowledged and Agreed by:

Investigator Name: _____

Investigator Signature: _____

Attachments:
Exhibit A: Analysis Plan; Exhibit B: Independent Review Panel Requirements; Exhibit C: Publication Plan