

Data Use Agreement

This Data Use Agreement (this "Agreement") is entered into effective as of _____, by and among _____ ("Sponsor"), _____ ("Principal Investigator") of _____ ("Group"), and University Hospitals of Cleveland ("Institution") in order to comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191), 42 U.S.C. Section 1320d, et. seq., and regulations promulgated thereunder, as may be amended from time to time (statute and regulations hereafter collectively referred to as "HIPAA"). Institution, Group and Sponsor may be referred to herein individually as a "Party" or collectively as the "Parties". Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms set forth in the Clinical Study Agreement, dated _____, among Sponsor, Institution and Principal Investigator (as defined therein).

1. Encoding Study Data. Sponsor represents and warrants that the information that is requested on the case report form(s) from Institution and Principal Investigator meets the criteria of a "limited data set", as defined in 45 C.F.R. § 164.514(e)(2), and that its case report forms (a) do not request any identifiers that are set forth in 45 C.F.R. § 164.514(e)(2); and (b) do not request patient or subject initials. Such information reported to Sponsor shall be referred to as "LDS" or "LDS information" herein.

2. Purpose of Sponsor's Use of LDS. Subject to, and in accordance with, applicable law, Sponsor shall use and disclose LDS information for the following research purposes only (and for no other purpose):

- reviewing the safety or effectiveness of the Study Drug;
- conducting performance reviews of the Study Drug or retrospective reviews of the Study Drug or the Data; and
- future medical research conducted by Sponsor that is directly related to the Study Drug.

3. Disclosure of LDS Information by Sponsor.

Sponsor shall only disclose LDS information to and permit the following persons or classes of persons to use such information for the purpose(s) set forth in Section 2 of this Agreement: (a) Sponsor's employees directly responsible for researching the Study Drug; (b) the employees of an affiliate of Sponsor if such employees and affiliate are directly responsible for researching the Study Drug; and (c) contract research organizations if such organizations are directly responsible for researching the Study Drug. The Sponsor will ensure that all such parties assume the data protection responsibilities of Sponsor as set forth in this Agreement.

4. Protection of the LDS Information. Sponsor shall, with respect to the LDS information:

a. not use or disclose LDS information in any manner that would violate the requirements of HIPAA, if such use or disclosure was made by Institution and/or Group;

b. not use or further disclose the LDS information other than as permitted or required by this Agreement or as otherwise required by law;

c. develop, document, use, and keep current appropriate procedural, physical, and electronic safeguards, sufficient to comply with the requirements of HIPAA, to prevent any use or disclosure of LDS information other than as provided by this Agreement. Sponsor agrees to notify Institution and Group, as applicable, of the location of any LDS information disclosed by Institution and/or Group or created by Sponsor and held by, or under the control of, Sponsor or those to whom Sponsor has disclosed such LDS information;

d. report to Institution and Group any use or disclosure of the information not provided for by this Agreement of which it becomes aware within two (2) days of Sponsor's discovery of such use or disclosure. In the report, Sponsor shall provide the following information: (1) the nature of the use or disclosure; (2) the information used or disclosed; (3) who made the use or disclosure; and (4) what corrective action will be taken by Sponsor as a result of the use or disclosure. Sponsor shall take any other actions available to it to mitigate any detrimental effects of the use or disclosure;

e. ensure that any agent, including a subcontractor (and including any person or entity set forth in Section (3) of this Agreement including Sponsor's affiliates), to whom it provides the information agrees to the same restrictions and conditions set forth in this Agreement that apply to Sponsor with respect to the LDS information. Sponsor shall require that the agents or subcontractors notify Sponsor of any instances of which they are aware that the confidentiality of the LDS information has been breached and report the information set forth in Section 4(d)(1-3) to Sponsor (and Sponsor shall report such information within two (2) days of Sponsor's receipt of such information to Institution); and

f. shall not (nor shall any agents or subcontractors of Sponsor) identify or attempt to identify the individual(s) to whom the LDS information pertains or contact or attempt to contact the individual(s) who Sponsor believes to be the subject of any LDS information.

The obligations set forth in this Section 4 shall survive the termination or expiration of this Agreement for any reason.

5. Right of Termination This Agreement may be terminated by a Party upon thirty (30) days' advance written notice to the other Party, and this Agreement may be terminated upon mutual written agreement signed by both of the Parties.

Sponsor acknowledges and agrees that Institution and Group shall have the right, in their respective and sole discretion, to immediately terminate this Agreement in the event Sponsor breaches or fails to comply with a term or condition of this Agreement. Upon a breach or violation by Sponsor of a term or condition of this Agreement, Institution and Group also respectively reserve the right, in their sole discretion, to discontinue disclosure of LDS information to Sponsor immediately and to report the breach or violation to the U.S. Department of Health and Human Services.

Sponsor agrees that upon termination of this Agreement, Sponsor shall, at its expense, (a) return or destroy all LDS information received from, or created or received by Sponsor or any of Sponsor's subcontractors or agents and that Sponsor or its subcontractors or agents maintain or control in any form or manner and retain no copies of such information; or (b) if such return or destruction is not feasible, immediately notify Institution and Group of the reasons return or destruction is not feasible, and extend indefinitely the protection of this Agreement to such LDS information and limit further uses and disclosures to those purposes that make the return or destruction of the LDS information not feasible. If Sponsor elects to destroy all LDS information, Sponsor shall immediately provide a certificate of the destruction, executed by a Vice President or person of higher authority within Sponsor, to Institution and Group. The obligations set forth in this Section 5 shall survive the termination or expiration of this Agreement for any reason.

6. Indemnification.

a. Of Institution. Sponsor will indemnify and hold harmless Institution and any affiliate, officer, director, employee or agent of Institution in accordance with and to the fullest extent permitted by applicable law, including, without limitation, from and against any claim, cause of action, liability, damage, cost, or expense, including attorneys' fees and court or proceeding costs, arising out of or in connection with any violation of this Agreement or the requirements of HIPAA by Sponsor or any of its subcontractors or agents or persons under Sponsor's control.

b. Of Group. Sponsor will indemnify and hold harmless Group and any affiliate, officer, director, employee or agent of Group in accordance with and to the fullest extent permitted by applicable law, including, without limitation, from and against any claim, cause of action, liability, damage, cost, or expense, including attorneys' fees and court or proceeding costs, arising out of or in connection with any violation of this Agreement or the requirements of HIPAA by Sponsor or any of its subcontractors or agents or persons under Sponsor's control.

7. Assignment. Sponsor, Group and Institution shall not assign or transfer any rights or obligations hereunder, or any part hereof, without the prior written consent of the other Party.

