Appendix B: Policies Governing Transfer of Data Materials

Appendix B-1: Policies Governing Transfer of Data/Materials from UCB

The above DATA/MATERIALS being requested is the property of the Regents of the University of California and is made available as a service to the REQUESTING PARTY.

The principal investigator for the research study described shall be responsible for the scientific and technical conduct of the research as set forth in this DATA/MATERIALS Request.

The REQUESTING PARTY will use the requested DATA/MATERIALS only for the purposes of the study outlined in this DATA/MATERIALS Request.

The DATA/MATERIALS are not for use in human subjects, including for purposes of diagnostic testing.

The DATA/MATERIALS will be used for not for profit research purposes only.

The DATA/MATERIALS will not be further distributed to others without the Study PI(s)' written consent. The party requesting DATA/MATERIALS shall refer any request for the DATA/MATERIALS to the Study PI(s).

The party requesting DATA/MATERIALS shall notify the Study PI(s) whenever DATA/MATERIALS are sent to contract labs or collaborators. Notice shall include a detailed description of the DATA/MATERIALS sent, to whom they were sent, and the date sent. Nothing in this paragraph supersedes the language in the preceding paragraph requiring written consent before further distribution of any DATA/MATERIALS

The party requesting DATA/MATERIALS agrees to acknowledge the contribution of the Study PI(s) in all written or oral public disclosures concerning research using the DATA/MATERIALS, by co-authorship, as is appropriate. Before the requesting party submits a manuscript for publication or otherwise intends to disclose any experimental results, the requesting party will provide Study PI(s) with at least (30) days to review such publication or other public disclosure. Study PI(s) may request an additional thirty (30) days to protect any intellectual property.

Any authors of papers involving Study PI(s) DATA/MATERIALS should meet the authorship criteria of the International Committee of Medical Journal Editors (updated February 2006 - http://www.icmje.org/). These criteria state:

"Authorship credit should be based on: 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3." Authors should meet all three conditions.

The REQUESTING PARTY understands that the DATA/MATERIALS delivered hereby are experimental in nature, and the Regents of the University of California MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA/MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS.

In no event shall the Regents of the University of California be liable for any use of the DATA/MATERIALS or any derivatives resulting therefrom. The Recipient Institution agrees to defend, indemnify, and hold Regents harmless from any loss, claim, damage or liability of whatsoever kind or nature, which may arise from or in connection with this agreement or the use of such data hereunder.

The REQUESTING PARTY agrees to use the DATA/MATERIALS in compliance with all applicable statutes and regulations.

The DATA/MATERIALS are provided at no cost, or with an optional transmittal fee solely to reimburse the Study PI(s) for its preparation and distribution costs.

The DATA/MATERIALS may be protected by the Federal Privacy Act and/or a Certificate of Confidentiality. The REQUESTING PARTY agrees to comply with all applicable statutes, regulations and ethical requirements to protect the identity and privacy of human subjects from whom the DATA/MATERIALS was collected.

This request is effective from the date of Study PI(s) approval. The termination date for the transfer of DATA/MATERIALS made pursuant to this request shall be the date of acceptance of the final publication resulting from use of the DATA/MATERIALS or issuance of a final report to Study PI(s), whichever occurs last.

When the research is completed, any newly generated data derived from the DATA/MATERIALS will be provided to the Study PI(s).

Each Party shall keep the other Party informed of the data, results and other information ("Results") developed, derived or produced from work in connection with this DATA/MATERIALS Request in a timely manner through written reports and meetings.

The preceding notwithstanding, the Study PI(s) has/have the right to terminate the transfer of DATA/MATERIALS made pursuant to this request at any time. Upon termination of agreement by Study PI(s) to provide DATA/MATERIALS, the REQUESTING PARTY will discontinue its use of the DATA/MATERIALS, and upon direction of the Study PI(s) will promptly return any remaining MATERIALS to the study specimen repository of UCB at REQUESTING PARTY'S expense.

Please note: Other appendices may be applicable depending on the nature of your request. ICARE staff will review your application and if applicable, will advise you of any other needed document(s).