



a. The term "proprietary information" as used herein, in the case of documentary information, shall include only that documentary information which is clearly marked as proprietary at the time when it is given to the receiving party. "Proprietary information" which is originally orally disclosed shall include only that information which is identified as being proprietary by written communication sent within a reasonably prompt period of time after it is disclosed.

b. The term "proprietary information" as used herein shall not include any information which the recipient clearly shows by appropriate documentation:

- (1) Was at the time of receipt both legally and independently known to the receiving party, its agents, or employees;
- (2) Without breach of this Agreement by the receiving party has been published or is otherwise within the public knowledge or is generally known to the public at the time of disclosure;
- (3) Becomes known or available to the receiving party without restriction from a source other than the disclosing party, provided that such source has an unqualified right to disclose such information without restriction;
- (4) Becomes a part of the public domain after disclosure without breach of this Agreement by the receiving party;
- (5) Subsequent to disclosure is independently developed by agent(s) or employee(s) of the receiving party without knowledge of the disclosure;
- (6) Has been in the possession of the receiving party longer than three (3) years;
- (7) Is required by law, including the Tennessee Public Records Act, to be disclosed; or
- (8) Is required to be disclosed if necessary for defense of the receiving party in any suit or claim brought as a result of the study.

6. EXPORT CONTROL. SPONSOR acknowledges that the export of goods and/or technical data from the United States may require some form of export control license from the U.S. Government. SPONSOR agrees that it will not disclose, export or re-export any materials or technical data received under this Agreement to any countries for which the U.S. Government requires an export license, unless the Provider has obtained prior written authorization first from the U.S. Office of Export Control or other authority responsible for such matters. SPONSOR agrees that it is responsible for any fees or expenses associated with obtaining an Export License, if required. UNIVERSITY neither represents that a license shall not be required nor that, if required, it shall be issued

7. PUBLICATION. The UNIVERSITY may publish the results of scientific investigations involving this study, provided that confidential and/or proprietary information of the SPONSOR not publicly known is not disclosed and that the SPONSOR is provided a copy of the manuscript thirty days prior to submission for publication so that it may offer comments thereon. SPONSOR shall have the right to delay publication for a period not to exceed ninety (90) days after receipt of such manuscript to allow time for filing any appropriate patent applications. Should SPONSOR fail to make a written request for delay in publication within thirty (30) days after receipt of any manuscript from the UNIVERSITY, the UNIVERSITY shall be free to publish the manuscript as submitted and UNIVERSITY shall incur no liability to SPONSOR thereafter.

8. INDEPENDENT CONTRACTOR. The UNIVERSITY's relationship to the SPONSOR in the performance of this Agreement is that of an independent contractor.

9. INDEMNIFICATION. THE SPONSOR shall hold harmless and indemnify any and all of UNIVERSITY, its agents, officers, employees, students, and professional staff from and against any and all claims and suits arising out of this study or any act or omission of the SPONSOR involving the manufacture or distribution of any product

involved with this Agreement, provided such injury is not the result of negligence or improper action or omissions on the part of the indemnitee. The indemnification shall include but not be limited to reimbursement of all costs, including attorney fees, incurred in the defense of the claim or suit and any judgment or settlement. It is understood that the administration of any substance provided for in the protocol shall not constitute negligence or malpractice for the purposes of this Agreement.

10. **LIMITATION OF LIABILITY ON BEHALF OF THE UNIVERSITY.** The UNIVERSITY is self-insured under the provisions of the Tennessee Claims Commission Act (T.C.A. 9-8-301 *et seq.*), and its liability to SPONSOR and to third parties for the negligence of the UNIVERSITY and its employees is subject to the tort provisions of that Act. Accordingly, any liability of the UNIVERSITY for any damages, losses, or costs arising out of or related to acts performed by the UNIVERSITY or its employees under this agreement is governed by the provisions of said Act.

Notwithstanding anything in this agreement to the contrary, any provisions or provisions of this agreement will not apply to the extent that it is (they are) finally determined by a court of competent jurisdiction, including appellate review if pursued, to violate the laws or Constitution of the State of Tennessee.

11. **NEGATION OF WARRANTIES BY THE UNIVERSITY.** Although the UNIVERSITY will use reasonable efforts to perform the research as set forth in Section 1 (Statement of Work), the UNIVERSITY makes no warranties, either express or implied, as to the results of such research or the merchantability or fitness for a particular purpose of the research. The UNIVERSITY shall not be liable for any direct, consequential, or other damages suffered by the SPONSOR or others resulting from the use of the research.

12. **KEY PERSONNEL.** MD, Principal Investigator, is considered to be essential to the work performed under this contract. Substitutions for the Principal Investigator or substantial changes in his/her level of efforts will not be made without the prior written approval of SPONSOR.

13. **PRE-EXISTING INTELLECTUAL PROPERTY OF THE PARTIES.** Neither party claims by virtue of this Agreement any right, title, or interest in (a) any issued or pending patents owned or controlled by the other party or (b) any invention, process, or product arising out of the other party's previous research or development, whether or not patentable.

14. **USE OF PARTIES' NAMES.** Neither party to the Agreement shall use the name of the other party in any form of publicity without the written permission of that party.

15. **TERMINATION.** Performance under this agreement may be terminated by either party upon sixty (60) days' written notice. Upon termination, the SPONSOR shall reimburse the UNIVERSITY for all costs and non-cancellable commitments incurred in the performance of the research, such reimbursement not to exceed the total estimated project costs specified in Section 3.

16. **MODIFICATION.** This agreement constitutes the sole, full, and complete agreement by and between the parties with regard to the subject of this Agreement; and no amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing, signed by the parties, and attached hereto.

17. **NOTICES AND OTHER COMMUNICATIONS.** With the exception of research funds paid by SPONSOR under the provisions of Section 3, all notices and other communications between the parties shall be deemed sufficiently given when hand-delivered or sent by prepaid United States mail or other recognized carrier, addressed as follows:

If to SPONSOR:

If to UNIVERSITY:

Linda Seely  
University of Tennessee  
Research Administration, Clinical Trials

