

STANDARD CLINICAL TRIAL AGREEMENT

This Agreement is entered into by and between _____, hereinafter called the Sponsor, and the Board of Regents of the University of Wisconsin System, hereinafter called the University. In anticipation of benefits to each party, the Sponsor and the University agree as follows:

1. SCOPE OF WORK

The University will perform the project set forth in the appended Exhibit A (the Project).

Any additional work not identified in Exhibit A, but indicated during the course of the Project, will be separately negotiated and funded in appropriate amounts to be agreed upon in writing by the Sponsor and the University.

2. PROJECT DIRECTION

The Project will be directed by _____ who will be accountable to the University as Principal Investigator. A change of Principal Investigator will require University and Sponsor agreement in writing.

3. PERIOD OF PERFORMANCE

The project will be conducted during the period _____ through _____, and may be extended by mutual agreement of the parties.

4. PAYMENTS

The Sponsor agrees to reimburse the University \$ _____ per patient studied and other associated costs, in accordance with the appended BUDGET (Exhibit B). Check(s), payable to the Board of Regents of the University of Wisconsin System, shall be sent to:

Principal Investigator
Principal Investigator Address
University of Wisconsin
Madison, WI (Zip-code)

For identification purposes, each payment shall include the title of the Project and the name of the Principal Investigator.

5. 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 the authority to make any statement, representation, commitments, or action which would bind the other without the other party's prior written authorization.

6. NOTICES

All notices to either party by the other regarding this Agreement shall be delivered to the individuals identified below:

University: Research and Sponsored Programs
750 University Avenue, 4th Floor
Madison, WI 53706-1490
ATTN: Diane Barrett
FAX: 608-262-5111

Sponsor:

7. CONFIDENTIAL INFORMATION

Unless otherwise required by law, the University will maintain in confidence proprietary or trade secret information disclosed or submitted to the University by the Sponsor which is designated in writing as confidential information at the time of disclosure (Confidential Information).

Confidential Information does not include information which at the time of receipt:

- (a) is generally available in the public domain or thereafter becomes available to the public through no act of the University; or
- (b) was independently known prior to receipt thereof or was discovered independently by an employee of the University who had no access to the information supplied by Sponsor under this Agreement; or
- (c) was made available to the University as a matter of lawful right by a third party.

The University retains the right to refuse to accept any information which is not considered to be essential to the completion of the project.

The obligations of the University under this paragraph shall survive and continue for one (1) year after termination of this Agreement.

8. PUBLICATION

The University and its employees have an obligation to assure that research results are made known to the general public when in the opinion of the Principal Investigator and the University it is appropriate to do so. The University will provide a sixty (60) day review period prior to publication to afford the Sponsor the opportunity to identify and prevent disclosure of any Confidential Information that may have been inadvertently included in a proposed release. If the Project is part of a multi-center trial, University agrees that the first publication is anticipated to be a joint publication covering all centers. However, if a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of the Project at all participating sites, the University is free to publish separately.

9. PATENTS and INVENTIONS

Except as required under 35 USC secs. 200-212 or other cases where there is a co-mingling of funds which require assignment to the University because of statutory or contracted obligations to a third party, and subject to a right reserved to the Board of Regents of the University of Wisconsin System to make and use any such invention, discoveries, and know-how for educational or research purposes, the University warrants that it shall retain no ownership over any invention, patentable or otherwise, discoveries, know-how, patents or patent application in such inventions which are made during and as part of the project being funded under this Agreement. Such ownership rights shall remain the exclusive property of the inventor(s) who is under no obligation to assign said rights to the University, except as set forth above. The University shall retain the right to use data generated, as a result of this study, for educational and research purposes.

10. LIABILITY

The Sponsor agrees to hold harmless the University from any loss, claim, damage, or liability of any kind, arising out of or in connection with this Agreement. To the extent authorized by secs. 893.82 and 895.46(1), Wis. Stats., the University agrees to hold harmless the Sponsor, its officers, agents and employees from any and all liability including claims, demands, losses, costs, damages and expenses of every kind and description (including death), or damages to persons or property arising out of or in connection with or occurring during the course of this agreement where such liability is founded upon or grows out of the acts or omissions of any of the officers, employees or agents of the University.

11. INSURANCE

University warrants and represents that it has adequate liability coverage, such coverage being applicable to officers, employees, and agents while acting within the scope of their employment by University. The University may request proof of insurance from Sponsor at any time.

12. PUBLICITY

Neither party shall use the name of the other party in connection with any products, promotion, or advertising without the prior written approval of the named party.

13. TERMINATION

This Agreement may be terminated by either party at any time prior to its full term of performance provided that a written notice is given to the other party thirty (30) days in advance. In the event of termination by the Sponsor, the University will be reimbursed for all non-cancelable costs and commitments incurred in performance of the study through the effective date of the termination.

14. GOVERNING LAW

This Agreement is made in accordance with and shall be governed and construed under the laws of the State of Wisconsin.

15. WAIVER & SEVERABILITY

Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, and the same shall remain at all times in full force and effect. If any part of this Agreement is held unenforceable, the rest of the Agreement will remain in full force and effect.

16. ASSIGNMENT

Neither party shall assign or transfer any of its rights or obligations under this Agreement without the written consent of the other party.

17. MISCELLANEOUS

This Agreement is the entire understanding between the parties relative to this project. This Agreement may be changed only by written modification signed by both parties.

This Agreement shall take precedence over any conflicting administrative language contained in the protocol (Exhibit A).

APPROVED FOR THE Sponsor:

BY

DATE

(NAME AND TITLE)

APPROVED FOR THE UNIVERSITY:

BY

DATE

(NAME AND TITLE)

CONCURRENCE BY THE PRINCIPAL INVESTIGATOR:

BY

DATE