CONTRACT FOR INSTITUTIONAL REVIEW BOARD SERVICES

THIS AGREEMENT, made and entered into this the ___ day of __________, 1999, by and between Shriners Hospitals for Children, hereinafter "Shriners" and the University of Kentucky, an independent agency of the Commonwealth of Kentucky, hereinafter "UK":

WITNESSETH:

WHEREAS, UK holds a Multiple Project Assurance from the United States Department of Health And Human Services that regulates the manner in which the Institutional Review Boards, hereinafter "IRB" conduct review and oversight of human subjects research and is also bound by Food and Drug Administration regulations;

WHEREAS, UK is bound by the Code of Federal Regulations, 45 CFR 46 Protection of Human Subjects; 21 CFR 50 Protection of Human Subject; and 21 CFR 56 Institutional Review Boards and any applicable state laws; and

WHEREAS, Shriners desires to contract for the services of UK to provide IRB services for research activities conducted at Shriners in Lexington, Kentucky, which involve human subjects.

NOW, THEREFORE, for and in consideration of the mutual promises and representations set forth herein, the parties agree as follows:

1. UK agrees to serve as a provider of IRB review for research activities that involve human subjects and which activities are conducted at or sponsored by Shriners in Lexington, Kentucky.

2. UK agrees to provide technical assistance and consultation to potential investigators who intend to conduct their investigations at Shriners and are employed by Shriners and/or are designated agents of Shriners during the IRB preparation and application process to ensure that all requirements are met.

3. Shriners and its investigators agree to abide by all policies and procedures governing conduct of research involving human subjects as set forth by UK IRB.

4. UK agrees to make available to Shriners a copy of the UK IRB guidelines and IRB criteria for application and approval. Shriners agrees to copy and disseminate guidelines to its investigators.

5. Shriners and its investigators agree to make research related records available for review by the UK IRB and appropriate institutional officials as necessary to conduct review. These research related records include, but are not limited to, contracts, research study files, the relevant medical records of patients who are study subjects, and any other material relevant to research studies reviewed by the IRB.
6. UK agrees to hold protocols, research and patient records and other information provided or made available by Shriners confidential to the extent allowed by law and agrees to disclose such information only as necessary to conduct appropriate review and oversight.

7. Shriners acknowledges that it and its investigators bear full responsibility for performance of all research covered by this contract, including full responsibility for complying, as applicable, with the Code of Federal Regulations, 45 CFR 46 Protection of Human Subjects, 21 CFR 50 Protection of Human Subject, and 21 CFR 56 Institutional review Boards and any applicable state laws.

8. Shriners agrees to implement a policy that outlines for individuals conducting research at its facilities the requirement that research that involves human subjects must be submitted to an IRB for review. Shriners is responsible for ensuring that individuals conducting research in this facility comply with that policy. Shriners agrees to establish policies and procedures to ensure that all parties at Shriners affected by the research are notified and comply with all applicable federal regulations including, but not limited to, regulations involving investigational drugs and devices which may affect Pharmacy and Technology Services.

9. Shriners agrees to appoint a physician who is a Shriners employee to serve as a member of the UK IRBs. This individual will serve in the capacity of a regular member and must attend meetings of the IRBs.

10. CK agrees to communicate official IRB actions dealing with noncompliance related to Shriners studies to the Shriners designated institutional official who is responsible for the oversight and implementation of this contract. Shriners investigators agree to acknowledge responsibility for protecting human subjects in method deemed appropriate by UK IRB.

11. Each of the parties hereto is an equal opportunity employer and provider of service and each party agrees that it will comply with all applicable laws regarding discrimination with respect to services or employment.
12. All notices anticipated by the within agreement shall be deemed received three (3) days after any such notice is placed in the United States mail, postage prepaid and addressed to:

FOR SHRINERS:

Chief of Staff
Shriners Hospital for Children
1900 Richmond Road
Lexington, KY 40502-1298

With a copy to

Legal Department
Shriners Hospitals for Children
P.O. Box 31356
Tampa, FL 33631-3356

FOR UK:

Fitzgerald Bramwell, Ph.D.
Vice President, Research and Graduate Studies
University of Kentucky
207 Administration Building
Lexington, KY 40506

13. Shriners shall maintain a policy of insurance or self insurance of not less than One Million Dollars ($1,000,000.00) per claim and Three Million Dollars ($3,000,000.00) aggregate per policy year or such other minimum amount as may be required from time to time by UK. The policy of insurance shall provide that such insurance shall not be canceled, modified or permitted to lapse without thirty (30) days prior written notice to UK. Upon request, Shriners will provide evidence of such insurance in a form acceptable to UK.

14. Shriners shall defend and indemnify UK, its agents and employees, from claims resulting from Shriners' actions, including failure to comply with an approved protocol.

15. UK as an agency and instrumentality of the Commonwealth of Kentucky is vested with sovereign immunity and does not carry general liability insurance for itself, agents, officers, employees or students. UK is subject to the provision of the Kentucky Board of Claims. KRS 44.070 et seq for the recovery of tort claims made against UK, its agents, officers, or employees. UK does maintain commercial excess general liability insurance for itself, its agents, officers, employees and students.

16. The effective date of the within agreement shall be July 1, 1999 through and including June 30, 2000 and shall be automatically renewed for successive annual periods subject to the renegotiation of charges made by UK to Shriners for the provision of services. Each party to the within agreement may terminate said agreement by the giving of ninety (90) days prior written notice.

17. No amendments to the within contract shall be effective unless in writing and signed by the parties hereto.
18. UK and Shriners each agree to notify the other in the event of any lawsuit, which is threatened. Further, each party agrees to promptly notify the other in the event of communication from the United States Department of Health and Human Services and/or the Food and Drug Administration and/or other regulatory agency concerning any investigative protocol or research activity of Sooners.

Date ____________

John D. VerMaas
President
Shriners Hospitals for Children
PO Box 31356
Tampa, FL 33631-3356

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