101816

# CLINICAL RESEARCH AGREEMENT

**This Clinical Research Agreement** ("Agreement") made this 7th day Nov; 2007, ("The effective date") is entered into between Shelby County Health Care Corporation d/b/a Regional Medical Center at Memphis ("The Med") and The University of Tennessee, an educational corporate agency of the State of Tennessee, with offices at 62 S. Dunlap Street, Suite 300, Memphis, TN 38163. ("The University").

**WHEREAS**, The University is engaged in research and educational activities, including clinical research studies for the purpose of evaluating the safety and efficacy of products, devices and medically related matters.

**WHEREAS**, the Med operates a medical facility as well as provides out-patient services in Memphis, Shelby County, Tennessee and such facilities are suitable for the conduct of clinical research studies and

**WHEREAS,** The University desires that The Med provide certain hospital and out-patient services required in conjunction with clinical research studies conducted by The University.

**NOW, THEREFORE**, the parties have agreed to the following:

## 1.0 CLINICAL TRIALS COMMITTEE

The parties hereby agree to form and staff a clinical trial committee, comprised of an equal number of representatives. The committee shall coordinate the activities between The University and The Med relative to the implementation and administration of clinical trials initiated and conducted by The University in conjunction with services to be provided by The Med. The clinical trials committee shall have general over-sight, and coordination for compliance with appropriate rules, regulations and authorities relative to clinical investigation.

## 2.0 THE UNIVERSITY'S RESPONSIBILITES

2.1 **Approval.** Prior to the initiation of each clinical research study and/or amendment thereto, The University shall submit a written application, in accordance with the policies and procedures of The Med's office of Medical Research.

2.2 **Procedure**. The University shall pursuant to The Med's policies and procedures promptly identify the services necessary for the clinical research study and the specific services to be provided by The Med and required by the study Sponsor. The University shall include a Sponsor's protocol with each application and such additional documents as reasonably requested by The Med for its review regarding the scope and procedures of the study. The Med shall act upon the proposed research application within thirty (30) days from date of submittal. The University shall promptly inform The Med of any changes or amendments to the protocol or to said study should it affect the

services to be provided by The Med. The term "Sponsor" shall include entities initiating research clinical studies as well as providing financial or material assistance for said studies.

2.3 The University shall obtain the consent of each individual participant of the clinical research study, copies of which shall be included in the medical records and available to The Med. Upon conclusion of the study relative to said individual The Med will be advised of that party's termination, removal, or completion.

2.4 The University shall provide any necessary training, education or preparation for Med staff to perform all of their respective responsibilities pursuant to the protocol, applicable regulations and this Agreement, if they are different from the professional services normally performed by The Med.

2.5 The University shall ensure that all investigators and their research coordinators that shall participate in the protocol at The Med meet the qualifications required by The Med to perform the services to be provided. The University shall cause each investigator to comply with all federal, state and local laws, rules and regulations, including those that provide additional protection for human subjects, any requirements of The University's institutional review board overseeing the study, and The Med's policies and procedures for the conduct of clinical research. The Med shall notify The University immediately of any change in The Med's policies and procedures that will affect the conduct of a clinical research study, and no such changes shall be applicable to existing studies unless approved by both parties.

## 3.0 POLICIES AND PROCEDURES

3.1 The Med shall prepare policies and procedures for the administration of clinical research studies, copies of which shall be provided to The University.

## 4.0 RECORDS

4.1 The parties shall maintain proper clinical and medical records specifically identifying the nature of the clinical research study and any services, supplies or care rendered or dictated by said clinical research study within said records.

## 5.0 REIMBURSEMENT

5.1 **Contract for Study-Specific Services**. A written contract between The University and The Med shall be executed for each new clinical research study for which The Med will be providing services. That contract will set forth the specific services to be performed by The Med and the amount The Med will be charging for each specific service. The University shall reimburse The Med for services reimbursed by the funding Sponsor in the amount set forth in Paragraph 5.2.

5.2 **Calculation of Amounts for Services to be Provided by The Med**. The amount to be paid for specific services provided by The Med, and for which The University is reimbursed by the funding Sponsor, shall be determined by applying the amount from the CMS (Center for Medicare Services) fee schedules for the specific service, and adding ten percent (10%) to the CMS scheduled amount for that service. The CMS rates to be used will be those in effect as of the date the service agreement between The Med and The University for a particular study is executed, and those rates shall be neither increased nor decreased during the course of that study, regardless of any subsequent modification of the CMS fee schedules. The University shall provide information necessary to identify and document the research services provided by The Med for the research subject and for which The Med is to bill The University.

## 6.0 TERM AND TERMINATION

6.1 **Term.** This Agreement shall begin upon the date of the signatures of both parties to this agreement and continue until termination as set forth below.

6.2 **Termination With or Without Cause**. Notwithstanding anything in this agreement to the contrary, this agreement may be terminated with or without cause, by either party upon thirty (30) days prior written notice to the other.

6.3 **Survival of Certain Rights and Obligations**. Termination of this Agreement shall not affect (i) those rights and obligations provided in any provisions of this Agreement which must survive to give effect to their terms; (ii) those rights and obligations which shall be accrued as a result of the operation of this Agreement and (iii) any existing studies.

## 7.0 INDEMNIFICATION / LIABILITY

7.1 **The Med**. The Med will be responsible for the actions of its employees pursuant to the limitations and to the extent of the Governmental Tort Liability Act T.C.A. 29-20-101, et seq.

7.2 **The University**. The University will be responsible for the actions of its employees pursuant to and to the extent allowed by applicable laws of the State of Tennessee, specifically Tennessee Code Annotated 9-8-301, et seq. To the extent the funding Clinical Trial Study Sponsor has agreed to indemnify and hold The University harmless for claims for personal injury, including death, arising out of or connected with the performance of the activities of the Clinical Research Study or resulting from a subject's participation in the Clinical Study, The University shall request that The Med be included as an additional indemnitee to be covered by said indemnification agreement. The University shall promptly notify The Med if the study Sponsor declines to include The Med as an additional indemnitee.

## 8.0 CONFIDENTIALITY OF PROPRIETARY INFORMATION

The Med agrees to maintain the appropriate confidentiality of all research related information or data, including but not limited to protocols, data, discoveries, study results, inventions, and any other proprietary information The Med may have access to through any study that is subject to this agreement. The Med shall not disclose this information to any person or entity, other than The University or the study's Sponsor, except as required by law. Research materials or research information developed by the study shall be the sole and exclusive property of The University, or such other entity as The University shall determine.

## 9.0 HIPAA COMPLIANCE

Parties agree that each shall comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and shall use and disclose Protected Healthcare Information (as defined by HIPAA), obtained through a study that is subject to this Agreement, solely consistent with the applicable subject consent form/authorization, or as otherwise provide by law.

## 10.0 OWNERSHIP OF RESEARCH DATA / INVENTIONS

The University shall retain the unrestricted right to use the study results for its own academic, clinical, and research purposes and to fulfill its obligations and exercise its rights herein. The Med shall make no claim to research data, inventions or discoveries arising under or resulting from studies that are subject to this Agreement. All such research data, inventions or discoveries, and all rights thereto, shall be owned by and the sole property of The University or such other entity as The University shall determine.

## 11.0 CONFIDENTIALTY

The parties agree that their respective employees, agents and services shall be reasonably informed of the necessity of confidentiality of information or data acquired or generated through studies subject to this Agreement.

## 12.0 ACCESS TO RECORDS

The Med agrees to allow The University and the study Sponsor/funding agency and government regulatory agencies or their respective representatives reasonable access to relevant medical records generated under this Agreement, subject to applicable laws and subject consent forms.

## 13.0 INDEPENDENT RELATIONSHIPS

13.1 **Independent Contractors**. Nothing in the Agreement shall be construed or be deemed to create a relationship between or among The Med and The University of employer and employee or principal and agent or any relationship other than that of independent parties contracting with each other at arms length solely for the purpose of carrying out the provisions of this Agreement.

13.2 **No Inducement to Refer**. Nothing contained in this Agreement shall require The University to admit or refer any patients to The Med. The parties enter into this Agreement with the intent of conducting their relationship in full compliance with

applicable federal, state, and local law, including the federal anti-kickback statute (42 U.S.C §1320a-7b) and the Stark Law (42 U.S.C. §1395nn). Notwithstanding any unanticipated effect of any of the provisions herein, neither party will intentionally conduct itself under the terms of this Agreement in a manner to constitute a violation of these provisions.

13.3 **Severability.** To the extent allowed by law, each provision of this Agreement is intended to be severable. If any term or provision hereof shall be determined by a court of competent jurisdiction to be illegal or invalid for any reason whatsoever, such provision shall be severed from this Agreement and shall not affect the validity of the remainder of this Agreement.

13.4 **Governing Law**. The interpretation and enforcement of this Agreement will be governed by the laws of the state of Tennessee, without regard to any conflicts of law provisions contained therein.

13.5 **Force Majeure**. Either party shall be excused for failures and delays in performance of its respective obligations under this Agreement due to any cause beyond the control and without the fault of such party, including without limitation, any act of God, war, riot or insurrection, law or regulation, strike, flood, fire, explosion or inability due to any of the aforementioned causes to obtain necessary labor, materials or facilities. This provision shall not, however, release such party from using its diligent efforts to avoid or remove such cause and such party shall continue performance hereunder with diligence whenever such causes are removed. Upon claiming any such excuse or delay for non-performance, such party shall give prompt written notice thereof to the other party, provided that failure to give such notice shall not in any way limit the operation of this provision.

13.6 **Remedies: No Waiver**. Subject to any period of limitations, no delay or omission by either party to exercise any right, power or remedy shall impair such right, power or remedy or be construed to be a waiver of or an acquiescence to any breach or default. A waiver by either party of any breach or default hereunder shall not constitute a waiver of any subsequent breach or default.

13.7 **Authorization for Agreement**. The execution and performance of this Agreement by The Med and The University have been duly authorized by all necessary laws, resolutions, and corporate or partnership action, and this Agreement constitutes the valid and enforceable obligations of The University and The Med in accordance with its terms.

13.8 **Assigment**. Neither party may assign this Agreement without the prior written approval of the other, which consent shall not be unreasonably withheld.

13.9 **Successor in Interest**. All of the rights, benefits, duties, liabilities, and obligations of the parties hereto shall inure to the benefit of and be binding upon the parties and their permitted successors and assigns.

13.10 **Amendments**. Any amendments to this Agreement will be effective only if in writing and signed by all the parties.

13.11 **Entire Agreement**. This Agreement constitutes the entire agreement of the parties with respect to the subject matter hereof.

13.12 **Headings**. The headings of the Sections and Articles of this Agreement are inserted for convenience of reference only and shall not in any manner affect the construction or meaning of anything herein contained or govern the rights or liabilities of the parties hereto.

13.13 **Notices**. All notices, requests, and communications required or permitted hereunder shall be in writing and shall be sufficiently given and deemed to have been received upon personal delivery or delivery by overnight courier or, if mailed, upon the first to occur of actual receipt or seventy-two (72) hours after being placed in the United States mail, postage prepaid, registered or certified mail, receipt requested, addressed to the parties as follows:

**To The University**:

Research Administration Clinical Trials
910 Madison Avenue, Suite 823
Memphis, Tennessee 38163
(901) 448-3303

**To The Med**:

Attn: CEO

With a copy to:

Notice of a change in address of one of the parties shall be given in writing to the other party as provided above, but shall be effective only upon actual receipt.

## 14.0 DUTY TO COOPERATE

The parties acknowledge that their mutual cooperation is critical to the ability of the other to perform its duties hereunder successfully and efficiently. Accordingly, each party agrees to cooperate with the other fully in performance of this Agreement.

**15.0 COUNTERPARTS**

This Agreement may be executed in exact counterparts and when so executed by the parties hereto shall be effective in accordance with the terms hereof.

**IN WITNESS WHEREOF**, the parties have executed this Agreement on the day and year first written above.

For The Med:

By: Mary E. Whitaker
Print Name: Mary E. Whitaker
Title: V.P. Legal Affairs

For The University

By: OCT 22 2007
Print Name: Anthony A. Ferrara
Title: Vice Chancellor
Finance & Operations