UT# 700 345

MASTER CLINICAL RESEARCH STUDY SITE AGREEMENT

THIS **MASTER CLINICAL RESEARCH STUDY SITE AGREEMENT** ("Master Agreement") is entered into as of the 14th day of May, 2009 ("Effective Date"), by and between UT Medical Group, Inc., with its principal office and place of business located at 66 North Pauline Street, Suite 101, Memphis, Tennessee 38105 ("UTMG"), and The University of Tennessee, an educational agency of the State of Tennessee, with offices at 62 S. Dunlap Street, Suite 300, Memphis, Tennessee 38163 ("The University").

BACKGROUND

A. The University is engaged in research and educational activities, including clinical research studies, for the purpose of evaluating the safety and efficacy of investigational drugs, devices, and other health products.

B. UTMG is a nonprofit, public benefit corporation, organized under the laws of the State of Tennessee and exempt from Federal income taxation under section 501(c) (3) of the Internal Revenue Code of 1986, as amended. UTMG is the group medical practice of the faculty physicians at The University of Tennessee Health Science Center, College of Medicine, and operates exclusively for charitable, educational, and scientific purposes.

C. UTMG operates several primary care and specialty medical clinics in the Memphis, Shelby County, Tennessee area that serve as study sites for research studies ("UTMG Study Sites").

D. The University wishes to obtain and UTMG is willing to provide certain of its facilities, equipment, and personnel in conjunction with clinical research studies conducted by The University, pursuant to the terms and conditions of this Master Agreement.

TERMS AND CONDITIONS

1. REQUEST PROCESS AND STUDY SPECIFIC AGREEMENTS.

1.1. The University shall submit a completed request for resources needed to conduct a research study in the form attached hereto as Exhibit A ("the Request") to UTMG's Director, Office of Clinical Research ("the Director") not less than thirty (30) days prior to the initiation of any clinical research study by The University at any UTMG Study Site. The Request shall include, at a minimum, a description of the UTMG facilities, equipment, and personnel needed for participation in the specific study.

1.2. The Director shall review The University's Request and shall respond to The University's Assistant Vice-Chancellor, Research Administration or her/his designee concerning the approval or disapproval of the Request (i.e., Request

· Page 1 of 12

approved, Request disapproved pending receipt of additional information) within five (5) business days of receipt of the Request.

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1.3. In the event UTMG agrees with The University's request, the parties shall enter into a study specific agreement ("Study Specific Agreement") under this Master Agreement prior to conducting a study at UTMG. An executed Study Specific Agreement, along with this Master Agreement, shall constitute the agreement of the parties in relation to a specific study. A Study Specific Agreement sample form, which may be modified by mutual agreement of the parties for specific studies, is attached hereto as Exhibit B.

1.4. Each Study Specific Agreement shall be a unique agreement and shall stand alone with respect to any other Study Specific Agreement provided, however, that:

A. If any provision of a Study Specific Agreement is in direct conflict with this Master Agreement so that the provisions of both cannot be given effect, the terms of the Study Specific Agreement shall govern the specific issue; and

B. The Study Specific Agreement shall use the form attached as Exhibit B and incorporate all the Standard Terms and Conditions of the University not already contained in this Master Agreement.

1.5. The University shall provide a copy of the Institutional Review Board ("IRB") termination letter to the Director promptly upon the conclusion of each study governed by this Master Agreement. In addition, The University shall notify the Director immediately in the event it becomes aware of any research subject's termination or removal from a study, or in the event of the subject's completion of participation in a study prior to study conclusion.

1.6. Notwithstanding any provision of this Master Agreement or any Study Specific Agreement that may appear to be to the contrary, the services to be provided by UTMG under this Master Agreement shall not include the services of any physician in the care of any patient, regardless of such patient's status as a study subject. Any medical professional service provided to any individual by a physician within the scope of any study that is the subject of any Study Specific Agreement shall be provided solely by The University and its employed physicians in their capacity as clinical researchers, and not by UTMG. Any medical professional service provided to a patient by UTMG or any of its physician employees or contractors shall be outside of the scope of this Master Agreement or any Study Specific Agreement.

2. **RESPONSIBLITIES OF THE PARTIES.**

2.1. The University shall obtain and document the informed consent of each research subject enrolled in a study conducted through The University at a UTMG Study Site, copies of which documentation shall be included in the subject's UTMG clinical record and available to UTMG.

2.2. The parties agree that any study conducted by The University at a UTMG Study Site shall be performed under the supervision and direction of The University's principal investigator as identified for that study and such performance shall be in accordance with the applicable protocol and other study documents. Research procedures conducted pursuant to an IRB approved study and to which the patient has consented to participate shall be the responsibility of the University's principal investigator.

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2.3. The University and UTMG acknowledge that studies shall not be conducted at a UTMG Study Site until IRB approval has been received, including at a minimum, approval of the protocol, informed consent documentation, and study recruitment documents (if applicable). Any amendments to the protocol, consent form, or recruitment documents shall be approved by the IRB prior to their use. The University agrees to provide UTMG copies of the final protocol, final informed consent, and final budget.

2.4. The University will notify the Director of any UTMG staff who are deemed "key personnel" on a Study and are required to complete training in protection of human subjects (including Collaborative Institutional Training Initiative "CITI" or similar courses) prior to any involvement with human subjects. UTMG agrees to require UTMG staff so identified to complete all necessary training, education, or preparation to perform their respective responsibilities required pursuant to the protocol, applicable regulations, applicable Study Specific Agreement, and this Master Agreement. If training adequate to meet the University's requirements is not available through UTMG, the University will make such training available. UTMG also agrees to ensure that all UTMG personnel involved in any Study have completed HIPAA training.

2.5. The University shall ensure that all University investigators, research coordinators, and other research personnel participating in a study conducted at a UTMG Study Site meet minimum educational qualifications. Minimum educational qualifications are CITI training according to their category, which is defined by title/group (e.g., administrator, department chair, principal investigator, key study personnel, resident, or student). HIPAA training is required of all University personnel in clinical trials. Documentation of minimum educational requirements is required by UTMG prior The University shall require each University to the performance of research. investigator, research coordinator, and other research personnel to comply with all relevant federal, state, and local laws, rules, and regulations, including but not limited to those that provide additional protection for human subjects and any requirements of The University's IRB overseeing the study. UTMG shall notify The University immediately of any change in UTMG's policies and procedures that affect the conduct of a clinical research study, and no such change shall be applicable to existing studies unless approved by both parties.

3. COMPENSATION.

3.1. The University shall compensate UTMG for services provided in accordance with the terms of the applicable Study Specific Agreement. The applicable

Study Specific Agreement shall be based on and consistent with the study budget agreed upon by The University and UTMG as contained in the Study Specific Agreement. The University shall have no obligation to make payments in absence of an executed Study Specific Agreement.

3.2. All UTMG professional services shall be compensated at a rate equal to one hundred ten percent (110%) of the applicable Medicare fee schedule in effect at the study's inception, or where no Medicare rate is available, at a negotiated rate. Such rates shall be established at the study's inception and shall not be adjusted during the course of the study, regardless of changes in Medicare or other market rates, unless the parties mutually agree to an amendment.

4. ACCESS, RECORDKEEPING, AND REPORTING.

4.1. UTMG shall retain possession of all medical records. The University shall have the right to access and to make copies of medical records of UTMG consistent with the IRB-approved informed consent documentation and 45 C.F.R. § 512(i) on reasonable notice during regular business hours.

4.2. UTMG agrees to allow The University and the study Sponsor or funding agency and government regulatory agencies or their respective representatives reasonable access to relevant medical records generated under a Study Specific Agreement, subject to applicable laws and informed consent documentation.

4.3. The University agrees that research-related documentation placed in a UTMG medical record will be clearly identified as research related.

4.4. The University shall maintain all research records acquired or generated in the course of any study governed by this Master Agreement in accordance with prudent record keeping procedures and as required by law.

4.5. UTMG and The University shall require their employees and agents who provide services hereunder or who have access to information or data required or generated hereunder are bound by the provisions of this Agreement.

5. TERM AND TERMINATION.

5.1. This Master Agreement shall begin upon the Effective Date and continue until terminated as set forth below. Each Study Specific Agreement shall take effect as of the effective date designated in the Study Specific Agreement.

5.2. Either party may terminate this Master Agreement at any time, with or without cause, upon thirty (30) days advance written notice to the other party.

5.3. Notwithstanding anything in this Master Agreement to the contrary: (a) any Study Specific Agreement that has a term extending beyond the effective date of any termination of this Master Agreement with or without cause shall remain in effect

and shall be deemed to incorporate all of the terms and conditions of this Master Agreement in effect immediately prior to such expiration or termination; and (b) any Study Specific Agreement may be terminated in such manner as may be provided therein.

6. INDEMNIFICATION AND INSURANCE.

6.1. UTMG agrees to maintain, throughout the term of this Master Agreement, at its sole expense, professional and general liability insurance coverage to insure itself and its officers, directors, and employees against any third party claim or cause of action arising out of the performance of this Master Agreement. Such professional liability insurance coverage shall have limits of not less than One Million Dollars (\$1,000,000) per occurrence, Three Million Dollars (\$3,000,000) annual aggregate, and general liability insurance coverage with limits of not less than One Million Dollars (\$1,000,000) combined single limit.

Indemnification by Sponsor. To the extent the funding Sponsor has agreed 6.2. to indemnify and hold University harmless for claims for personal injury, including death. arising out of or connected with the performance of the activities of the Study or resulting from a subject's participation in the Study, The University shall request that UTMG be included as an additional indemnitee to be covered by said indemnification agreement. The University shall promptly notify UTMG if the study Sponsor declines to include UTMG as an additional indemnitee or if no indemnification is available from the Sponsor. The University will extend its good faith efforts to obtain indemnification and will promptly notify UTMG if a study Sponsor is not willing to provide indemnification for UTMG. In such case, UTMG and The University will discuss the potential liability issues to facilitate a determination by UTMG of its consent for the conduct of such study in UTMG facilities. UTMG will not unreasonably withhold consent. In any instance in which UTMG withholds consent. The University may appeal such decision to UTMG's President and Chief Executive Officer. The decision of UTMG's President and Chief Executive Officer may be appealed to the UTMG Board of Directors.

6.3 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.* UTMG acknowledges that any and all claims against The University under the terms of this Master Agreement shall be submitted to the Claims Commission of the State of Tennessee. Damages recoverable against The University shall be expressly limited to claims paid by the Claims Commission pursuant to Tenn. Code. Ann. §§ 9-8-301, *et seq.*

7. CONFIDENTIAL INFORMATION.

7.1. UTMG agrees to maintain the confidentiality of all research-related information or data, including but not limited to protocols, data, discoveries, study results, inventions, and any other proprietary information UTMG may have access to through any study that is subject to this Master Agreement ("Confidential Information"). UTMG shall not disclose this information to any person or entity, other than The University or a 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. The obligation of nondisclosure and nonuse shall not apply to the following:

A. Information at or after such time that it is or becomes publicly available through no fault of UTMG;

B. Information that is already independently known to UTMG or independently developed by UTMG without use of or reliance upon information provided by The University;

C. Information at or after such time that it is disclosed to UTMG on a non-confidential basis by a third party with the legal right to do so;

D. Information required to be released by a court or any other governmental entity with jurisdiction, provided that UTMG notifies The University prior to making such release of Confidential Information and provides The University with a copy of the request, adequate time to contest such requirement, and works in good faith with The University to ensure that disclosure is limited in scope and content to that which is reasonably necessary;

E. Information necessary to facilitate proper medical care of a subject.

7.2. In the event that UTMG finds it necessary to disclose Confidential Information to a proper authority in order to permit UTMG to defend against an allegation of fraud, UTMG and The University shall agree to a mutually satisfactory way to disclose such Confidential Information as necessary for this limited purpose.

8. HIPAA COMPLIANCE. The parties agree that each of them shall comply with the regulations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), governing the privacy and security of health information. Study data collected in a particular study will include Protected Health Information ("PHI") as that term is defined in the privacy regulations (45 C.F.R. Parts 160 and 164) enacted pursuant to the HIPAA Privacy Standards. UTMG and The University shall treat all information regarding diagnosis, history, or treatment that allows unique identification of an individual's PHI, as that term is defined by 45 CFR §160.103, as confidential information. The parties shall comply with the Privacy Standards and shall use and disclose PHI obtained through a study, that is subject to this Master Agreement, solely consistent with the applicable subject consent form/authorization unless otherwise required by law.

9. OWNERSHIP OF RESEARCH DATA AND INVENTIONS. Any and all inventions, discoveries, innovations, or improvements, whether patentable or not, made developed, conceived, obtained, or reduced to practice by UTMG as a result of a study shall be communicated to The University. UTMG understands and agrees that UTMG shall have no ownership, license, or access rights in, or to, such regulatory filings based solely upon the inclusion of such findings therein, nor shall it acquire any interest whatsoever in the study drug or device as a result of a study performed in a UTMG

Study Site. UTMG effectively vests in The University any rights UTMG's personnel might have otherwise in the results of their work, and authorizes The University to assign those rights to such other persons as The University shall determine.

10. NOTICE. Any notice, requests, and communications required or permitted under the terms of this Master Agreement shall be sufficient if given in writing and sent by United States certified mail, postage prepaid, return receipt requested or hand-delivered or sent by nationally recognized carrier, to the addresses set forth below, or such other address as is subsequently specified by written notice hereunder:

NOTICE TO THE UNIVERSITY:

Deborah L. Smith, Ed.D. Assistant Vice Chancellor for Research Office of Research Administration The University of Tennessee 910 Madison Avenue, Suite 823 Memphis, Tennessee 38163 (901) 448-5587

NOTICE TO UTMG:

Steven H. Burkett President and CEO 66 North Pauline Street, Suite 101 Memphis, Tennessee 38105 (901) 448-6936

With a copy to: Manager, Contract Administration UT Medical Group, Inc. Office of Clinical Research 66 North Pauline Street, Suite 300 Memphis, Tennessee 38105 (901) 448-6070

11. GENERAL PROVISIONS.

11.1. <u>Independent Contractors</u>. UTMG and The University are independent legal entities. Nothing in this Master Agreement shall be construed to create the relationship of employer and employee, or principal and agent, or any relationship other than that of independent parties contracting with each other solely for the purposes of carrying out the terms of this Master Agreement. UTMG warrants that no part of the total contract amount provided herein shall be paid directly or indirectly to any officer or employee of The University or the State of Tennessee as wages, compensation, or gifts in exchange for acting as officer, agent, employee, subcontractor, or consultant to UTMG in connection with any work contemplated or performed relative to this Master Agreement or any Study Specific Agreement.

11.2. <u>No Inducement to Refer</u>. Nothing contained in this Master Agreement shall require The University to admit or refer any patients to UTMG. The parties enter into this Master 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 Master Agreement in a manner to constitute a violation of these provisions.

11.3. <u>Non-Discrimination</u>. No person shall be excluded from participation in, be denied benefits of, or otherwise be subjected to discrimination in the performance of this Master Agreement on the basis of disability, age, race, color, ethnicity, national origin, religion, gender, veteran status, or any other category protected under Federal or state law.

11.4. <u>Compliance with Laws.</u> UTMG and The University agree they will comply with all applicable Federal and state laws and regulations in the performance of this Master Agreement.

11.5 <u>Debarment and Exclusion</u>. Each party certifies that it is not debarred under subsections 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act and that it will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Master Agreement. Each party also certifies that it is not excluded from any federal health care program, including Medicare and Medicaid. During the term of this Master Agreement and for three years after its termination, each party will notify the other party promptly if either of these certifications needs to be amended in light of new information.

11.6. <u>Illegal Immigrants.</u> In compliance with the requirements of Chapter 878, Public Act of 2006 of the State of Tennessee, for any contract for goods or services purchased by The University, UTMG hereby attests that UTMG shall not knowingly utilize the services of an illegal immigrant in the performance of this Master Agreement or any Study Specific Agreement and shall not knowingly utilize the services of any subcontractor who will utilize the services of an illegal immigrant in the United States in the performance of the Master Agreement or any Study Specific Agreement.

11.7. <u>Severability</u>. This Master Agreement will be deemed severable, and the unenforceability of any one or more provisions will not affect the enforceability of any other provisions or the remainder of this Master Agreement as a whole. In addition, if any provision of this Master Agreement, for any reason, is declared to be unenforceable, the parties will substitute an enforceable provision that, to the maximum extent possible in accordance with applicable law, preserves the original intentions and economic positions of the parties.

11.8 <u>Force Majeure</u>. Either party shall be excused for failures and delays in performance of its respective obligations under this Master 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.

11.9. <u>Remedies: No Waiver</u>. Subject to any period of limitations, no delay or omission by either party to exercise any right, power, or remedy will operate as a waiver of such right, power, or remedy, and no waiver will be effective unless it is in writing and signed by the waiving party. If either party waives a right, power, or remedy, such waiver will not waive any successive or other right, power, or remedy such party may have under this Master Agreement.

11.10. <u>Authorization for Agreement</u>. The execution and performance of this Master Agreement by UTMG and The University have been duly authorized by all necessary laws, resolutions, and corporate or partnership action, and this Master Agreement constitutes the valid and enforceable obligations of The University and UTMG in accordance with its terms.

11.11. <u>Assignment</u>. Neither party may assign this Master Agreement without the prior written approval of the other party, which consent shall not be unreasonably withheld.

11.12. <u>Successor in Interest</u>. 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 respective successors and permitted assignees.

11.13. <u>Amendments</u>. Any amendments or changes to this Master Agreement will be effective only if in writing and signed by authorized individuals of the parties.

11.14. <u>Entire Agreement</u>. This Master Agreement represents the entire understanding of the parties with respect to the subject matter hereof. Any prior agreements, promises, negotiations, oral or written, relating to the services expressly set forth herein are of no force or effect.

11.15. <u>Headings</u>. The Section headings or captions used in this Master Agreement are inserted for the convenience of reference only, and will not in any way be construed to modify or restrict any of the terms or provisions hereof.

11.16. <u>Duty to Cooperate</u>. 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 Master Agreement.

11.17. <u>Counterparts</u>. This Master Agreement may be executed in exact counterparts and it is recognized by the parties that each counterpart is an original, but that all counterparts together constitute one and the same instrument.

11.18. <u>Governing Law</u>. The interpretation and enforcement of this Master Agreement will be governed by the laws of the State of Tennessee, without regard to any conflicts of law provisions contained therein.

IN WITNESS WHEREOF, the parties hereto have executed this Master Agreement in duplicate by proper persons thereunto duly authorized.

THE UNIVERSITY OF TENNESSEE

Title: Vice-Chancellor Business and Finance

UT MEDICAL GROUP, INC. ("UTMG")

By: Dtum 162

Name: Steven H. Burkett

Title: President and CEO

MAY 2 0 2009 Date:

Narae: Anthony Ferrara

By:

Date: _____5/14/09

EXHIBIT A TO MASTER CLINICAL RESEARCH STUDY SITE AGREEMENT

Request to Conduct a Clinical Research Study at a UT Medical Group, Inc. Facility

(attached)

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UT MEDICAL GROUP, INC. Administration ATTN: Office of Clinical Research 66 North Pauline Street, Suite 300 Memphis, Tennessee 38105 901-448-6070 • Fax: 901-448-1512

REQUEST FOR APPROVAL TO CONDUCT RESEARCH IN A UT MEDICAL GROUP FACILITY

Instructions: All research activities undertaken in a UT Medical Group, Inc. (UTMG) facility must be reviewed and approved prior to initiation of research. This Form is not required when the research is conducted through the UTMG Office of Clinical Research. All requested information and documentation must be submitted for a Request to be a considered.

Submission Date:					
Desired Start Date of Research:		Approximate Rese	arch End Date:		
I. STUDY					
Protocol Title:					
Protocol No.:		Sponsor Name:	· · · · · · · · · · · · · · · · · · ·		
Type of Study (check all that apply): Drug(s). Investigational New Drug (IND) No.: Drug Trial Phase: I II III III III IIII IIII IIII IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII					
In addition to access to a UTMG facility, list any UTMG equipment or materials that may be used for study:					
In-addition to access to a UTMG facility, list any UTMG personnel that may be used for study:					
Has the appropriate departmental Director of Operations been contacted regarding the study?					
II. PRINCIPAL INVESTIGATOR					
Name:					
Position and/or Title:	Organizat	ion through which re	search being conducted:		
Mailing Address:					
Email:	Telephone Number		Fax:		
PART III. FACILITIES (facilities where					
Family Medicine - 1301 Primary Parkway Family Medicine - 1951 Highway 51 North, Covington					
Medicine - 1325 Eastmoreland, Suite	es 360 & 365	Medicine - 7945	5 Wolf River Blvd., Suite 120		
Medicine (Harbor of Health) - 718 Harbor Bend Road					
Г и OB/GYN - 880 Madison Ave., Suite 3D01		OB/GYN - 880	Madison Ave., Suite 3E01		

OB/GYN - 7945 Wolf River Blvd., Suite 320

PARTIII. FACILITIES (facilities where any sto	udy services	and procedures w	/III/be performed)		
C Ophthalmology - 930 Madison Ave., Suite 200		Ophthalmology	- 7945 Wolf River Blvd, Suite 250		
. L. Utolaryngology - 777 Washington Ave., Suite	e P110	Otolaryngology	- 7945 Wolf River Blvd, Suite 220		
Pediatrics - 777 Washington Ave., Suite P11	0	Pediatrics - 777	7 Washington Ave., Suite 240		
Pediatrics - 777 Washington Ave., Suite P35			45 Wolf River Blvd, Suite 250		
Psychiatry - 135 North Pauline St., 6 th Floor					
Surgery - 1325 Eastmoreland, Suite 220		Surgery - 1325	Eastmoreland, Suite 310		
Surgery - 7945 Wolf River Blvd., Suite 280		Surgery (Plastic	c) - 7945 Wolf River Blvd., Suite 290		
Surgery - 50 Humphreys Center, Suite 30		<u>.</u>			
Urology - 7945 Wolf River Blvd., Suite 350		``````````````````````````````````````			
PARTIV. STUDY COORDINATOR					
UTMG employee? Ves No		<u>If no, employee of</u>			
Mailing Address: Email: Telepho	one Number:	· · · · · · · · · · · · · · · · · · ·	Fax:		
PARTY. INSTITUTIONAL REVIEW BOARD					
Name of Institutional Review Board (IRB):		IRB No.:			
IRB submission date:		Expected IRB review date:			
Has the IRB granted approval of the Informed Consent Form? Yes No					
PART VI. SUBJECT RECRUITMENT					
			ocedures that will be used for potential study subjects at the UTMG		
PARTVIL BILLING INFORMATION					
Will the Sponsor pay for all services and/or procedures: Yes No Not Applicable					
If no, is the Sponsor requiring submission of billin	g informatior	n to third party payor	s? 🗌 Yes 🗌 No 🗌 Not applicable		

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VIII. ATTACHMENTS

iollowing documents must be submitted with the Request for Approval to Conduct Research in a UT Medical Group Facility

Cover Letter. The Cover Letter should clearly state the role of UTMG in the study and any special arrangements that must be made. The Cover Letter can also be used to clarify information presented in the Request.

Informed Consent Form, draft and final when available

IRB Approval Letter, when available

Investigator Curriculum Vitae (CV) or resume and professional license

NOTE: Final approval will be withheld until the IRB Approval Letter and final informed Consent Form have been received.

REQUIRED SIGNATURES:

By signing this Form, I certify that: (1) the information provided is complete and accurate to the best of my knowledge, (2) I accept responsibility for the scientific conduct of the project, and (3) I agree to provide additional information to the Office of Clinical Research upon request.

Pl Signature

Date Printed Name

Internal Use Only		
Date Received:	Received by (printed name):	

EXHIBIT B TO MASTER CLINICAL RESEARCH STUDY SITE AGREEMENT

Sample Study Specific Agreement

(attached)

STUDY SPECIFIC AGREEMENT

This STUDY SPECIFIC AGREEMENT ("Study Specific Agreement") is entered into as of the date of the last signature ("Effective Date"), by and between UT Medical Group, Inc. ("UTMG"), and The University of Tennessee ("The University").

<u>BACKGROUND</u>. The University and UTMG are parties to a Master Clinical Research Study Site Agreement effective May 14, 2009 ("Master Agreement"). Under the Master Agreement, The University and UTMG are executing this Study Specific Agreement to contract for the following Study.

1. <u>THE STUDY</u>. UTMG agrees to allow The University to perform the Study described below at a UTMG Study Site.

STUDY TITLE AND PROTOCOL NUMBER: «Study_Title» «Study_Number» INVESTIGATOR'S NAME: «PI_Name»

2. COMPENSATION

COMPENSATION SECTION WILL VARY FROM STUDY TO STUDY

All checks shall be made payable to the entity identified on the Federal Tax Form W-9 provided by UTMG. UTMG represents and warrants that such entity identified is the appropriate entity to receive payments under this Study Specific Agreement.

Mailing address for checks (if different from mailing address on Federal Tax form W-9):

Controller Attention: Research Contracts Receivable UT Medical Group, Inc. 70 North Pauline Street Memphis, TN 38105 Tax ID# 62-1162462

3. <u>TERM: TERMINATION</u>. This Study Specific Agreement shall continue until the Study is completed or until terminated as provided in the Master Agreement.

4. <u>INCORPORATION BY REFERENCE</u>. This Study Specific Agreement is made expressly subject to and incorporates by this reference the terms and conditions of the Master Clinical Research Study Site Agreement entered into between the parties on May 14, 2009, as the same may be amended from time to time ("the Master Agreement"). No oral or written agreement of the parties shall be construed in such manner as to contradict the terms and conditions of the Master Agreement, and any such language that may appear contradictory to

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the Master Agreement shall be void and unenforceable unless and until included in a signed, written amendment to the Master Agreement.

All defined terms in the Master Agreement shall have the same meaning when used in this Study Specific Agreement.

The University' Standard Terms and Conditions are incorporated within and attached hereto as Exhibit A.

5. <u>NOTICES</u>. Notices applicable to this Study Specific Agreement shall be sent to:

If to The University Department of Research Administration The University of Tennessee 910 Madison Avenue, Suite 823 Memphis, Tennessee 38163 Phone: (901) 448-3303

If to Institution: Steven Burkett President and CEO UT Medical Group, Inc. 66 North Pauline Street, Suite 101 Memphis, TN 38105 Phone: (901) 448-6936

With a copy to: Office of Clinical Research UT Medical Group, Inc. 66 North Pauline Street, Suite 300 Memphis, TN 38105 Phone: (901) 448-6977

6. <u>ENTIRE AGREEMENT</u>. This Study Specific Agreement represents the entire and integrated agreement between The University and UTMG and supersedes all prior negotiations, representations or agreements, either written or oral, regarding the Study.

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The University of Tennessee ("The University")	UT MEDICAL GROUP, INC. ("UTMG")
Ву:	By:
Name:	Name: <u>Steven H. Burkett</u>
Title:	Title: President and CEO
Date:	Date:

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Exhibit A

STANDARD TERMS AND CONDITIONS

- 1. The University is not bound by this Contract until it is approved by the appropriate University official(s) indicated on the signature page of this Contract.
- 2. This Contract may be modified only by a written amondment which has been executed and approved by the appropriate parties as indicated on the signature page of this Contract
- The Contractor shall not assign this Contract or enter into a subcontract for any of the services performed under this Contract without obtaining the prior written approval of the University.
- 4. Unless otherwise indicated on the reverse, if this Contract provides for reimbursement for travel, meals or lodging, such reimbursement must be made in accordance with University travel policies.
- 5. The Contractor warrants that no part of the total Contract smount shall be paid directly or indirectly to an employee or official of the State of Tennesses as wages, compensation, or gifts in exchange for acting as officer, agant, employee, subcontractor, or consultant to Contractor in connection with any work contemplated or performed relative to this Contract, and that no employee or official of the State of Tennessee holds a controlling interest in the Contractor. If the Contractor is an Individual, the Contractor contractor is that he/she is not presently employed by the University or any other agency or institution of the State of Tennessee; that he/she has not retired from or terminated such employment within the past six months; and that he/she will not be so employed during the term of this Contract.
- 5. The Contractor shall maintain documentation for all charges against the University under this Contract. The books, records and documents of the Contractor, insofar as they relate to work performed or monay received under this Contract, shall be maintained for a period of three (3) full years from the date of the final payment, and shall be subject to audit, at any reasonable time and upon reasonable notice, by the University or the Comptroller of the Treasury, or their duly appointed representatives. These records shall be maintained in accordance with generally accepted accounting principles.
- 7. No person on the grounds of disability, age, race, color, religion, sex, national origin, veteran status or any other classification protected by Federal and/or Tennessee State constitutional and/or statutory law shall be excluded from participation in, or be denied benefits of, or be otherwise subjected to discrimination in the performance of this Contract. The Contractor shall, upon request, show proof of such non-discrimination, and shall post in conspicuous places, available to all employees and applicants, notice of nondiscrimination.
- 8. The Contractor, being an independent contractor, egrees to carry adequate public liability and other appropriate forms of insurance, and to pay all taxes incident to this Contract. The University shall have no liability except as specifically provided in this Contract.
- 9. The Contractor shall comply with all applicable Federal and State laws and regulations in the performance of this Contract
- 10. This Contract shall be governed by the laws of the State of Tennessee, which provide that the University has liability coverage solely under the terms and limits of the Tennessee Claims Commission Act.
- 11. The Contractor shall avoid at all times any conflict of interasts between his/her duties and responsibilities as a Contractor and his/her interests outside the scope of any current or future Contracts. The following principles define the general parameters of a conflict of interests prohibited by the University:
 - A Contractor's outside interests shall not interfere with or compromise his/her judgment and objectivity with respect to his/her duties and responsibilities to the University.
 - b. A Contractor shall not make or influence University decisions or use University resources in a manner that results in:
 - Financial gain outside any current or future Contracts for either the Contractor or his/her relatives or
 - Unfair advantage to or favored treatment for a third party outside the University.
 - c A Contractor's outside financial interests shall not affect the design, conduct, or reporting of research.

The Contractor certifies that he/she has no conflicts of interests and has disclosed in writing the following:

- a. Any partners or employees of the Contractor who are also employees of the University.
- b. Any relatives of the Contractor's partners or employees who work for the University.
- c. Any outside interest that may interfere with or compromise his/her judgment and objectivity with respect to his/her responsibilities to the University.
- 12. If the Contractor falls to perform properly its obligations under this Contract or violates any term of this Contract, the University shall have the right to terminate this Contract immediately and withhold payments in excess of fair compensation for completed sarvices. The Contractor shall not be relieved of liability to the University for damages sustained by breach of this Contract by the Contractor.
- 13. It is understood by the Contractor that the University will possess all rights to any creations, inventions, other intellectual property, and materials, including copyright or patents in the same, which arise out of, are prepared by, or are developed in the course of the Contractor's performance under this Contract. The Contractor and the University acknowledge and agree that the Contractor's work under this Contract shall belong to the University as "work-made-for-hire" (as such term is defined in U.S. Copyright Law).
- 14. For personal, professional, and consultant services, the Contractor shall submit brief, periodic progress reports to the University as requested.
- 15. In compliance with the requirements of Chapter 878, Public Acts of 2006 of the State of Tennessee, for any contract for goods or services purchased by the University, the Contractor hereby attests that the Contractor shall not knowingly utilize the services of an illegal immigrant in the performances of this Contract and shall not knowingly utilize the services of any subcontractor who will utilize the services of an illegal immigrant in the United States in the performance of the Contract.