

CLINICAL RESEARCH SERVICES AGREEMENT

This Clinical Research Services Agreement is entered into and effective this ____ day of _____, 200_, by and between Jewish Hospital & St. Mary's HealthCare, a Kentucky non-profit corporation ("JHSMH" or the "Hospital"), and _____ ("Principal Investigator" or "PI").

A. Principal Investigator conducts business in the area of clinical research in accordance with his/her agreement with _N/A ("Sponsor");

B. Principal Investigator desires to conduct a clinical trial, a portion of which is to be performed at the Hospital, and JHSMH desires to render clinical services to participants in such trial, said trial being entitled: _____
(the "Study");

C. _____ has agreed to conduct the Study in the capacity of Principal Investigator.

NOW, THEREFORE, in consideration of the mutual promises set forth in this Agreement, the parties agree as follows:

1. IRB Approval of the Study.

1.1 The Study will be undertaken in accordance with the terms of Protocol No. _____ . This Protocol is subject to the review and approval of the Institutional Review Board (IRB) designated by JHSMH. As reviewed and approved by the IRB, this Protocol shall be made a part of this Agreement.

1.2 Changes to the Protocol may be made (i) in accordance with the procedures outlined in the Protocol, or as may be agreed to in writing by the Principal Investigator and the Sponsor. Changes to the Protocol are subject to prior review and approval of the IRB as required by applicable laws.

1.3 _____ will serve as the Principal Investigator and will supervise the conduct of the Study.

1.4 The Principal Investigator and the Hospital shall comply with the Protocol and with all applicable laws, rules, regulations and other governmental requirements in the performance and documentation of the Study.

1.5 Principal Investigator shall use the Informed Consent Form approved by the IRB to obtain informed consent from all subjects who participate in the Study prior to their participation. Principal Investigator will not allow any patient to participate in the Study prior to receiving IRB and Hospital approval for the Study and prior to the research subject completing and signing the Informed Consent Form.

2. Hospital Obligations and Financial Considerations.

2.1 The Hospital agrees to provide in connection with the Study the clinical services that are set forth in the MIRA form, the study budget, and the study contract and subcontract pertaining to the Study which are incorporated into this Agreement by reference (the “Clinical Services”). The Principal Investigator shall designate in the appropriate form prior to the commencement of the Study whether each Clinical Service is standard of care (“Clinical Care Services”) or research related (“Research Related Clinical Services”) and the estimated Hospital cost associated with each service. JHSMH support personnel in the research area shall assist the Principal Investigator in obtaining the estimated Hospital costs.

2.2 For each Clinical Service designated as Research Related Clinical Services, the Principal Investigator will identify the source of reimbursement for the Research Related Clinical Service or the President of Hospital or his designee shall agree in writing to write-off the Hospital charges associated with the Research Related Clinical Services.

2.3 The parties acknowledge that in some instances third party payors, including federal payors may not reimburse for Research Related Clinical Services without first granting pre-authorization for the services. The Principal Investigator, through either their Study coordinators (“PI’s Coordinators”) or coordinators employed by JHSMH (“JHSMH Coordinators”), will identify which Research Related Clinical Services must have pre-authorization, obtain such authorization, and indicate the payor, contact name and date authorized on the initial notification of enrollment form before ordering any Research Related Clinical Services to be provided at the Hospital. Principal Investigator acknowledges that if he fails to obtain such pre-authorization, JHSMH may, at discretion, cancel the procedure.

3. The Term.

The term of this Clinical Research Services Agreement shall begin on the date set forth above and shall be coterminous with the Study, including extensions approved by the IRB and follow-up.

4. Billing Compliance.

Principal Investigator shall identify the name of each subject enrolled in the Study that will have an encounter of any type in the Hospital and provide this information to the Hospital. Principal Investigator, or either the PI’s Coordinator, must notify the Hospital of all subject encounters during which the Hospital provides Research Related Clinical Services (inpatient or outpatient) by close of next business day after each unscheduled encounter, and one week prior to all scheduled encounters. The Hospital shall conduct random audits on Studies to verify that Principal Investigator is providing appropriate notice to the Hospital. Notwithstanding the preceding, if the Principal Investigator uses a JHSMH Coordinator, then the JHSMH Coordinator shall provide such information and notice to the Hospital and the Hospital, and not the Principal Investigator, is responsible for accuracy of information filed by the JHSMH Coordinator. Notice can be given to the Center for Advanced Medicine by completing and faxing the notification form that can be found online.

5. Confidential Information.

5.1 In furtherance of the conduct of the Study, it may be necessary or desirable for the parties hereto to disclose proprietary, trade secret and/or other confidential information (“Confidential Information”) to one another. All such Confidential Information shall remain the property of the party disclosing same. All parties hereto agree that any such Confidential Information disclosed to him/her or, as to the Principal Investigator and the Hospital, to its employees, agents and contractors, shall be used only in connection with the legitimate purposes of this Agreement, shall be disclosed only to those who have a need to know it and are obligated to keep same in confidence, and shall be safeguarded with care; provided, however, that the disclosing party marks the Confidential Information as such at the time of disclosure (or, if disclosed verbally, is reduced to writing and so marked within a reasonable period of time not to exceed fifteen (15) days thereafter).

5.2 The foregoing confidentiality obligations shall not apply when, after and to the extent the Confidential Information disclosed:

- (i) is now, or hereafter becomes, generally available to the public through no fault of the receiving party or its employees, agents or contractors;
- (ii) was already in the possession of the receiving party without restriction as to confidentiality at the time of disclosure as evidenced by competent written records; or
- (iii) is subsequently received by the receiving party from a third party without restriction and without breaching any confidential obligation between the third party and the disclosing party hereunder.

Notwithstanding the foregoing, patient identifiable information shall always be deemed Confidential Information.

5.3 Confidential Information may also be disclosed to the extent required by law, regulation, or court order (including without limitation the filing and prosecution of patent applications), provided that the party making such disclosure of the other party’s Confidential Information shall give maximum practicable advance notice of same and request such confidential treatment of such disclosure from the recipient thereof as may be afforded by law, regulation, or court order.

6. Reporting Requirements.

Principal Investigator is responsible to insure that all data, including Case Report Forms, resulting from this Study are furnished to Sponsor. Principal Investigator shall keep Sponsor advised of the status of the Study via periodic reports. The frequency of reports shall be agreed upon by Principal Investigator and Sponsor. In some cases Principal Investigator will utilize Jewish Hospital coordinators to prepare these reports.

7. Conflict of Interest.

Principal Investigator represents and warrants that he/she and all members of his/her immediate family (defined as spouse and children) have disclosed, developed and implemented a plan to manage any real or perceived conflict of interest in the execution of the Study (e.g., rights to patent or licensure income or fees, stock or other equity in companies which manufacture the drug being tested in the Study) or that conflicts with any other obligation to third parties. The Principal Investigator agrees to abide by the Hospital's conflict of interest policy and to have his/her conflict management plan approved by the appropriate Hospital committee.

8. Compliance with Legal Requirements and JHSMH Policies.

8.1 Principal Investigator shall comply with all applicable legal requirements and applicable JHSMH policies in performing the Study. JHSMH agrees to provide applicable JHSMH policies upon request by the PI.

8.2 Principal Investigator agrees to comply and cooperate with the implementation of any reasonable safety rules, programs or services that may be required by JHSMH with respect to the conduct of clinical trials at the Hospital.

8.3 Principal Investigator agrees to comply with JHSMH's policies and procedures for complying with the requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

9. Acknowledgements/Indemnification.

9.1 Principal Investigator agrees to indemnify and hold harmless JHSMH and its directors, employees and agents ("JHSMH Indemnitees") from any and all claims (whether fraudulent, groundless, false or not), for damages, losses, liabilities, penalties, fines or other sanctions and any costs (including, but not limited to, legal fees and expenses and costs of investigation) of whatsoever kind and nature ("Claims") which may be incurred by any of the JHSMH Indemnitees relating to or arising out of: (i) if the Principal Investigator utilizes his own coordinators, failure, either knowingly or through gross negligence, to notify JHSMH of subject encounters that are Research Related Clinical Studies; or (ii) failure, either knowingly or through gross negligence, of the Principal Investigator to verify that JHSMH Coordinators have been given correct notice of subject procedures/tests that are research related per section 4 of this Agreement.

9.2 JHSMH agrees to indemnify and hold harmless Principal Investigator and his employees and agents ("Principal Investigator Indemnitees") from any and all claims (whether fraudulent, groundless, false or not), for damages, losses, liabilities, penalties, fines or other sanctions and any costs (including, but not limited to, legal fees and expenses and costs of investigation) of whatsoever kind and nature ("Claims") which may be incurred by any of the Principal Investigator Indemnitees relating to or arising out of the negligent or willful misconduct, omissions or acts of the JHSMH, its directors, employees or agents in connection with the Study.

9.3 If requested to do so by the Hospital, Principal Investigator shall require Sponsor to issue a written statement regarding Sponsor's obligation to indemnify and hold harmless the

JHSMH Indemnitees against any and all Claims which may be brought against the JHSMH Indemnitees by reason of personal injury, illness or death to any person as a result of the administration of the procedures contained in the Protocol or otherwise arising out of or reasonably attributable to the activities to be carried out in this Study. If PI is associated with the University of Louisville, then PI shall coordinate this with the appropriate University of Louisville Office. The Sponsor's indemnification statement must be reviewed and approved by JHSMH.

The provisions of this Article 9 shall continue after termination of this Agreement.

10. Insurance.

10.1 Principal Investigator shall, at his/her own expense, obtain and maintain professional liability insurance coverage in the minimum amounts of \$1,000,000 per occurrence and \$3,000,000 annual aggregate covering the Principal Investigator providing Clinical Care Services or making clinical care decisions in connection with the Study ("the PI's Insurance Policy") and require all other individuals providing Clinical Care Services or making clinical care decisions in connection with the Study ("Key Personnel") to obtain and maintain an insurance policy in the same minimum amounts and liability coverage ("Key Personnel's Insurance Policy.") . Notwithstanding the above, if the Principal Investigator is conducting a Study that involves only retrospective review of data, the Principal Investigator is exempt from this requirement to obtain the PI's Insurance Policy and Key Personnel are similarly exempted.

10.2 Inability to obtain and maintain the PI's Insurance Policy and Key Personnel's Insurance Policy as required in Section 10.1 shall be cause for immediate termination of this Agreement. JHSMH shall not be required to provide any insurance covering the Principal Investigator or any other individual providing services on his/her behalf hereunder. If requested to do so by the Hospital, Principal Investigator shall furnish JHSMH with a copy of a certificate of insurance evidencing compliance with Section 10.1. Principal Investigator shall notify JHSMH of cancellation of the policy and any and all incidents, untoward occurrences, notices or claims made arising out of services provided in connection with the Study as soon as Principal Investigator becomes aware of this information and shall cooperate in any investigation and in the defense of any incidents, untoward occurrences, notices and claims.

10.3 If requested to do so, Principal Investigator shall cause Sponsor to provide JHSMH with a letter stating the insurance limits that Sponsor carries to cover the indemnification obligations set forth in Section 9.2 above. This letter and insurance limits must be reviewed and approved by JHSMH.

The provisions of this Article 10 shall continue after termination of this Agreement.

11. Warranties.

THE HOSPITAL MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AND HEREBY DISCLAIMS SUCH WARRANTIES, AS TO ANY MATTER WHATSOEVER INCLUDING, WITHOUT LIMITATION, THE CONDITION OF THE RESEARCH OR ANY INVENTION(S) OR PRODUCT(S), WHETHER TANGIBLE OR INTANGIBLE, CONCEIVED, DISCOVERED, OR DEVELOPED UNDER THIS AGREEMENT; OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY SUCH INVENTION OR PRODUCT. THE HOSPITAL SHALL

NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL, OR OTHER DAMAGES SUFFERED BY PRINCIPAL INVESTIGATOR OR ANY THIRD PARTIES RESULTING FROM THE USE OF THE RESEARCH OR ANY SUCH INVENTION OR PRODUCT.

The provisions of this Article 11 shall continue after the termination of this Agreement.

12. Independent Contractor.

Principal Investigator acknowledges and agrees that each shall be and act as an independent contractor and not as the agent or partner of, or joint venturer with, the Hospital for any purpose. No party, by virtue of this Agreement, shall have any right, power or authority to act or create any obligation, express or implied, on behalf of any other party to this Agreement.

13. Use of Name.

Principal Investigator agrees that he/she will not, under any circumstances, use the name of the Hospital in advertising, publicity, or otherwise, without the express written permission of an authorized representative of the Hospital.

14. Conflicts.

In the event there is a conflict with the terms of this Agreement, the Protocol or any other documents pertaining to this study, the terms of this Agreement shall govern except as to the conduct and design of the Study itself in which event the terms of the Protocol govern.

15. Notices.

All notices, requests and communications required or permitted hereunder, other than the notice required in Section 4, shall be in writing and deemed to have been received upon personal delivery or, if mailed, upon actual receipt or forty-eight (48) hours after being placed in the United States mail, postage prepaid, registered or certified mail, return receipt requested, addressed to the parties as follows:

As to the Hospital: Jewish Hospital & St. Mary's HealthCare
200 Abraham Flexner Way
Louisville, Kentucky 40202
Attn: _____

With a copy to: Jewish Hospital & St. Mary's HealthCare
200 Abraham Flexner Way
Louisville, Kentucky 40202
Attn: Kathleen M. Haddix
Vice President/General Counsel

As to Principal Investigator: _____

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 upon actual receipt.

16. Law Governing.

This Agreement shall in all respects be governed by, and construed in accordance with, the laws of the Commonwealth of Kentucky, including all matters of construction, validity and performance, without reference to principles of conflicts of laws.

17. Headings.

The headings of the various sections herein are for the convenience of reference only and shall not define or limit any of the terms or provisions hereof.

18. Counterparts.

This Agreement may be executed by the parties hereto in separate counterparts, each of which, when so executed and delivered, shall be an original, but all such counterparts shall together constitute but one and the same instrument.

19. Entire Agreement.

This Agreement, including the Protocol and any annexed Exhibit(s), sets forth the entire understanding between the parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, relating to the subject matter hereof. This Agreement may not be changed or supplemented, except by a writing executed by all parties to this Agreement.

20. Severability.

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, invalid or unenforceable for any reason whatsoever, such provision shall be severed from this Agreement and shall not affect the legality, validity or enforceability of the remainder of this Agreement.

21. Affirmative Action Plan.

The parties hereby incorporate the requirements of 41 CFR §§ 60-1.4(a)(7), 60-250.4 and 60-741.5, if applicable.

IN WITNESS WHEREOF, this Clinical Research Services Agreement is effective as of the date first herein set out and executed by duly authorized officers of the parties on the dates below:

JHSMH:

PRINCIPAL INVESTIGATOR:

Jewish Hospital & St. Mary's HealthCare

(Printed Name)

By: _____

Printed Name: _____

Signature

Title: _____

Date _____

Date: _____

CLINICAL RESEARCH SERVICES AGREEMENT
Attachment A
Institutional Administrative Fee
(when applicable)

Jewish Hospital and Investigators recognize that there are a number of administrative costs associated with clinical research studies. Therefore, Jewish Hospital has instituted an administrative fee to help to defray these expenses associated with the review and processing of clinical research studies. In cases where no sponsor funding is available, this fee may be waived. The fee varies with the extent of involvement of the JHSMH facility and Center for Advanced Medicine in the particular study.

The Institutional Administrative Fee is in addition to any procedure costs conducted at a JHSMH facility and separate from any fees associated with the use of a research coordinator from the Center for Advanced Medicine for a particular study (“JHSMH Coordinator”).

For assistance in determining the Institutional Administrative Fee when preparing a sponsor study budget, the investigator may contact Nancy K. Gentry, the JHSMH Research Office Manager by e-mail at nancy.gentry@JHSMH.org or by telephone at 560-8310.