AGREEMENT WITH ERLANGER HEALTH, INC.
FOR
FACILITIES, SERVICES, AND/OR RESOURCES PROVIDED IN THE COURSE OF HUMAN SUBJECT RESEARCH

THIS AGREEMENT (the "Agreement") is entered into by and between, and is effective as of the latest of the signature dates ("Effective Date"), **ERLANGER HEALTH, INC., a Tennessee non-profit entity, having a business address at 975 East Third Street** ("Erlanger") and _____, having a business address at _____ (the "Institution").

W I T N E S S E T H:

WHEREAS, the Institution has entered into a Clinical Trial Agreement (the "Clinical Trial Agreement") with _____ (the "Sponsor") to conduct a human subject research study titled _____ (the "Study");

WHEREAS, Institution desires to utilize certain Erlanger facilities, services and/or resources in the course of conducting the Study;

WHEREAS, Erlanger and Institution hereby enter into this Agreement for the purposes of delineating and memorializing responsibilities of the respective parties in connection with the Study.

NOW, THEREFORE, the parties hereby agree as follows:

1. **Term**. This Agreement shall commence as of the Effective Date and shall terminate upon the earliest occurrence of the: (i) termination of the Clinical Trial Agreement for any reason; or (ii) termination of this Agreement as set forth herein.

2. **Termination**.

(a) In addition to termination due to termination of the Clinical Trial Agreement, this Agreement may be terminated as follows:

(i)Either party may terminate this Agreement upon thirty (30) days advance written notice to the other party;

(ii) Erlanger may terminate this Agreement immediately, upon notice, in the event it determines, in its sole reasonable discretion, that termination is necessary to protect the interest, safety or welfare of Erlanger, its patients or its medical staff; or

(iii) Erlanger may terminate this Agreement immediately, upon notice, in the event Institution violates any term or condition of this Agreement.

(b) Should the Study be terminated pursuant to this provision, or should any patient in the study discontinue, the Institution is responsible for ensuring continuum of care in compliance with the set of documents setting forth the objections, design, methodology, statistical considerations and aspects related to the Study (the "Protocol").

3. **Responsibilities of Institution**. The Institution shall:

(a) Be responsible for all activities undertaken by Institution pursuant to this Agreement and the Clinical Trial Agreement and shall supervise the work of all persons who assist in performing the Study.

(b) Immediately notify the Sponsor and Erlanger in writing at such time as they become aware that the Institution shall be otherwise unable to complete the Study.

(c) Conduct the Study in strict accordance with the Protocol and other Study documents, which may be amended and/or revised from time to time by Sponsor.

(d) Notify Erlanger within one (1) business day when an individual is enrolled in the Study for participation (each, a "Subject" and collectively, "Subjects") or in the event of any change in status of a Subject and otherwise timely respond to inquiries from Erlanger as to Subject status.

(e) Not permit any Subjects to participate in the Study unless and until (i) the IRB has reviewed and approved the Protocol and the information to be provided to potential Subjects of the Study to secure their informed consent (the "Informed Consent Form"), (ii) a valid HIPAA authorization, and (iii) Institution has provided Sponsor and Erlanger with documents verifying such review and approval.

(f) Obtain the informed consent or if applicable re-consent of each Subject in accordance with applicable regulations under 21 C.F.R. parts 50 and 56 and/or 45 C.F.R. 46 et. seq. (hereafter "the Common Rule"), including, without limitation, the completion of an Informed Consent Form (such activities to be referred to collectively as "Informed Consent"). Institution shall maintain adequate documentation of the Informed Consent of each Subject.

(f) Monitor the Subjects in accordance with the Protocol and shall notify Sponsor, Erlanger and the IRB of any information concerning any serious or unexpected event, injury, toxicity or sensitivity reaction or any unexpected incidents, and the severity thereof, associated with the Study within twenty-four (24) hours of its first becoming aware of such information.

(g) Conduct the Study in compliance with all rules and regulations of Erlanger, the medical staff and appropriate state and other government authorities. Furthermore, any and all equipment or materials used by Institution in activities, operations or other matters performed in connection with the conduct of the Study shall have specifications that conform to the rules and regulations of Erlanger, its medical staff and appropriate state and other government authorities. Institution shall cause its employees, agents, and other personnel to comply with and observe such rules, regulations and the requirements of this paragraph.

(h) Comply with and cause its officers, agents, employees and contractors to comply with any and all applicable federal, state and local laws, statutes, rules, regulations, and guidelines including, but not limited to, the Federal Food, Drug, and Cosmetic Act, as amended, and regulations promulgated thereunder, the United States Food and Drug Administration ("FDA") regulations governing the protection of human subjects and regulations governing clinical investigators, the Common Rule and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA) and the regulations published thereunder. In furtherance of the foregoing, the parties agree that no individual shall, on the grounds of race, sex, color, creed, national origin, age or handicap status be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination by the parties.

(i) Provide advice and assistance to Erlanger and Erlanger's Institutional Review Committee (herein referred to as "IRC" or "IRB"), and/or the IRB of record and keep Erlanger and the IRB fully informed regarding all aspects of the Study being conducted by the Institution.

(j) Comply with all decisions of the IRB and shall maintain proper records and file all reports required by the IRB.

(k) Comply with and fulfill all of their responsibilities as set forth in the Clinical Trial Agreement and the Protocol.

(l) Comply with Erlanger's policies and procedures applicable to human subject research, including but not limited to the "Clinical Research Studies Conducted by Affiliated Outside Entities" Policy, which requires that in negotiating its Clinical Trial Agreement, Institution will include a facilities and administrative rate of 30% to cover Erlanger's indirect costs for all procedure and non-procedure line items. The minimum documentation Institution agrees to make available to Erlanger so that Erlanger can assess the feasibility of providing services and resources for the research at Erlanger would include the Clinical Trial Agreement, including the study budget, the study protocol, the complete coverage analysis, the informed consent document, the HIPAA authorization and if applicable documentation of a waiver of authorization. Other documentation and information may be deemed necessary and Institution agrees to provide such documentation reasonably requested by Erlanger.

4. **Responsibilities of Erlanger**. Erlanger shall provide the facilities, resources and/or services set forth on Exhibit A, incorporated herein by this reference, to the Institution for the purpose of conducting the Study, upon full execution of this Agreement and after Erlanger receives notice from Institution in accordance with Section 3(e)(ii) that the Study has been presented to and approved by the IRB.

5. **Financial Arrangement**. Institution shall pay Erlanger for services and resources provided by

Erlanger in connection with the Study in the amounts set forth on Exhibit A attached hereto. Erlanger shall submit an invoice to Institution identifying the services and resources provided by Erlanger and the amount owed for such services and/or resource. Institution shall pay the amount of the invoice within thirty (30) days from the date of the invoice. Any amount of the invoice not paid by Institution when due shall bear interest at the rate of one and one-half percent (1.5%) per month until paid in full. Institution and Erlanger each agrees not to seek reimbursement from any state or federal health care program or other third party payor for costs reimbursed by Sponsor pursuant to the Study.

6. **Representations and Warranties**. Institution represents and warrants that:

(a) Any amounts paid to Erlanger by Institution for services rendered by Erlanger in connection with the Study shall be consistent with fair market value and shall not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, TennCare or other federal or state health care program.

(b) Institution, including, but not limited to its officers, directors, employees and other personnel, are currently in good standing under and have never been suspended, excluded, barred or sanctioned by Medicare, Medicaid or any other state or federal health care program, nor have they ever been convicted of a criminal offense related to health care. Institution shall notify Erlanger immediately if any such action is proposed or taken against Institution or if they become the subject of an investigation that could lead to such action. Erlanger shall be entitled to terminate this Agreement immediately, without notice and without penalty or further obligation to Institution, upon notification by Institution or discovery by Erlanger, of any such action or investigation or at any time Erlanger discovers that the foregoing certification is or may be untrue.

(c) Institution, including, but not limited to its officers, directors, employees and other personnel, have never been and are not currently Debarred or Disqualified Persons, nor will they employ any Debarred or Disqualified Person. Institution and Principal Investigator further represent and warrant that neither it nor their officers, directors, employees and other personnel, have engaged in any conduct or activity that could render any of them a Debarred or Disqualified Person and that it has no notice that the FDA or other regulatory authority intends to seek disqualification or debarment. If during the term of this Agreement or the Clinical Trial Agreement, Institution or any of its personnel (i) comes under investigation by the FDA for debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity which could lead to any of them being rendered a Debarred or Disqualified Person, Institution shall immediately notify Erlanger. For purposes of this paragraph, "Debarred or Disqualified Person" means any person subject to limitations or any form of enforcement imposed upon clinical investigators by the United States Food and Drug Administration (FDA), the European Medicines Evaluation Agency (EMEA), or any Regulatory Authority or other recognized national, multi-national, or industry body, including but not limited to sections 306(a) and (b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 335a and 335b).

(d) Institution shall at all times during the term of this Agreement and the Clinical Trial Agreement be properly licensed, competent and qualified to conduct the Study.

(e) Institution shall retain at their sole cost and expense a sufficient number of properly licensed, competent personnel to discharge the duties of Institution under this Agreement and the Clinical Trial Agreement.

7. **Indemnity**. Institution shall indemnify, defend and hold harmless Erlanger, including, without limitation, Erlanger's agents, Members of the Board of Trustees, Officers, and employees, against all claims, losses, costs, damages and expenses (including, without limitation, reasonable attorneys' fees) relating to or arising out of (i) any negligent or intentional act or omission or any other wrongful act or conduct of Institution, its officers, agents, servants, employees or contractors, in the conduct of the Study or (ii) Institution's breach of or default under the provisions of this Agreement or the Clinical Trial Agreement.

8. **Insurance**. Institution shall, at their sole cost and expense, obtain and maintain appropriate workers' compensation coverage for their personnel employed to fulfill their obligations under this Agreement or under the Clinical Trial Agreement, if any, and shall carry professional liability or errors and omissions insurance covering Institution and all of its employed personnel, if any, in the minimum amounts of One Million Dollars ($1,000,000) per

occurrence and Three Million Dollars ($3,000,000.00) in the annual aggregate or greater if otherwise required by the Sponsor. Institution shall also maintain commercial general liability insurance, including blanket contractual liability, with minimum limits of One Million Dollars ($1,000,000) per occurrence and Three Million Dollars ($3,000,000) in the annual aggregate or greater if otherwise required by the Sponsor. The foregoing coverage shall provide protection for any act or omission which may result in a claim, because of an act or omission that occurred during a time period that this Agreement or the Clinical Trial Agreement was in force. All insurance shall be placed with a company or companies and under contracts acceptable to Erlanger. Upon request, Institution shall furnish Erlanger with copies of each insurance policy and shall furnish copies of all amendments and renewals to each policy so long as this Agreement or the Clinical Trial Agreement is in effect. Upon execution of this Agreement, Institution shall cause to be issued by such insurer(s) a certificate thereof reflecting such coverage and shall instruct and obtain the consent of such insurer(s) to provide prior written notice to Erlanger (equal to notice given to Institution) of the cancellation or proposed cancellation thereof for any cause or material reduction in coverage. Institution shall cause Erlanger to be added as an additional insured under any insurance policies acquired or maintained pursuant to this paragraph.

9. **Confidentiality**.

(a) In furtherance of this Agreement, it may be necessary or desirable for Erlanger to disclose business, financial, proprietary, trade secret, patient and/or other confidential information (hereinafter "Confidential Information") to Institution. All such Confidential Information shall remain the property of Erlanger. Institution agrees that any such Confidential Information disclosed to him or her, or to it or its employees, agents and/or 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 reasonable care.

(b) The foregoing confidentiality obligation 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 Institution or its employees, agents or contractors;

(ii) was already in the possession of Institution without restriction as to confidentiality at the time of disclosure as evidenced by competent written records; or

(iii) is subsequently received by Institution from a third party without restriction and without breaching any confidential obligation between the third party and Erlanger.

(c) Confidential Information may also be disclosed to the extent required by law. To the extent Institution discloses Confidential Information as required by law, he, she or it agrees to give maximum practical advance notice of same and request such confidential treatment of such disclosure from the recipient thereof as may be afforded by law. Institution shall not disclose the terms of this Agreement to any third party, except as required by law or with the permission of Erlanger.

(d) Institution knows and understand that use and disclosure of Protected Health Information is governed by the Health Insurance Portability and Accountability Act of 1996, and the rules and regulations published thereto, all as may be from time to time modified or amended (hereinafter referred to as “HIPAA”). Institution hereby agrees not to access, use or disclose Protected Health Information except in strict accordance with a valid HIPAA authorization or exception under HIPAA which may include a waiver of HIPAA Authorization, or other applicable HIPAA exception, and then only to the extent necessary to carry out the limited purpose of the access to, use or disclosure of such Protected Health Information and in accordance with the provisions of HIPAA and all applicable federal, state and local laws, rules and regulations. Institution shall indemnify and hold harmless Erlanger including, without limitation, Erlanger’s agents, members of the Board of Trustees, officers, employees and independent contractors, against all claims, losses, costs, damages and expenses (including, without limitation, attorneys’ fees), and all fines, penalties and interest, arising out of or relating to Institution’s breach of the provisions of this paragraph. As used herein, the term “Protected Health Information” shall have the meaning as set forth in HIPAA.

10. **Ownership of Medical Records**. Any hospital medical records generated pursuant to this Agreement by

Institution or otherwise, shall be the property of Erlanger.

11. **Relationship of the Parties**. Nothing contained in this Agreement shall be deemed nor construed as creating a relationship of employer and employee, principal and agent or a partnership or a joint venture between the Institution and Erlanger, it being understood and agreed that no provision contained herein nor any acts of the parties hereto shall be deemed to create any relationship between the Institution and Erlanger other than that of independent contractors. Institution understands and agrees that (i) Institution's personnel shall be deemed by the parties and shall be treated by Institution as employees of Institution for federal and state tax purposes, and, consistent with such treatment, Institution shall be responsible for and shall withhold on behalf of such personnel, any sums for income tax, unemployment insurance, Social Security, or any other withholding pursuant to any law or requirement of any governmental body relating to Institution or their personnel (the "Tax Obligations"); (ii) Erlanger will not withhold on behalf of Institution or their personnel any sums for Tax Obligations or make available to such personnel any of the benefits afforded to employees of Erlanger; (iii) all Tax Obligations are the sole responsibility of Institution; (iv) Institution shall provide to Erlanger within three (3) days of Erlanger's request proof acceptable to Erlanger in its sole discretion of payment of Tax Obligations; and (v) Institution shall jointly and severally indemnify and hold Erlanger harmless from and against any and all loss or liability arising out of or with respect to the Tax Obligations.

12. **Governing Law**. This Agreement shall be governed by an interpreted in accordance with the laws of the State of Tennessee. Hamilton County, Tennessee shall be the sole and exclusive venue for any litigation, special proceeding, or other proceeding between the parties that may be brought, arise out of, or in connection with or by reason of this Agreement or the Clinical Trial Agreement; provided, however, any judgment or settlement rendered in or agreed upon in any such litigation or proceeding may be enforced in any other jurisdiction.

13. **Intentionally Omitted.**

14. **Resolution of Claims.** If a dispute arises out of or relates to this Agreement, or the breach thereof, the parties agree to meet and attempt to resolve the issue by negotiation. If the dispute cannot be settled through direct negotiation, the parties agree to try in good faith to settle the dispute by mediation. Mediation shall be held before either party may resort to litigation.

15. **Entire Agreement**. This Agreement and all documents referenced herein supersede all previous contracts regarding the subject matter herein and constitute the entire agreement between the parties. No oral statements or prior written material not specifically incorporated herein shall be of any force and effect, and no changes in or additions to this Agreement shall be recognized unless incorporated herein by amendment as provided herein, such amendment or amendments to become effective on the date stipulated in such amendment or amendments.

16. **Notice**. Any notice, demand, or communication required, permitted, or desired to be given hereunder shall be deemed effectively given when mailed by prepaid certified mail, return receipt requested; delivered by hand or personal delivery or overnight courier service; or by facsimile or other electronic transmission, which date and time stamps such notices, addressed as follows:

STUDY SITE:

Erlanger Health, Inc.
975 E. Third Street
Chattanooga, Tennessee 37403
Attn: _____
Fax No.: _____

With a copy to:
Erlanger Health Legal Department
975 E. Third Street
Chattanooga, TN 37403
Attn: Stephanie Dawn
Fax No. (423) 778-7525

INSTITUTION:

or to such other address, and to the attention of such other person(s) or officer(s) as either party may designate by written notice.

17. **Amendments**. This Agreement may not be changed, amended or modified except in writing, signed by all parties.

18. **Successors and Binding Effect**. This Agreement shall be binding upon and shall inure to

the benefit of the parties and their respective legal representatives, successors and assigns.

19. **Assignment**. No assignment of this Agreement or the rights and obligations hereunder shall be valid without the specific written consent of all parties hereto. Any attempted assignment in violation of this provision shall be void and shall have no binding effect.

20. **Binding Effect.** Erlanger is not bound by this Agreement until it is approved by the appropriate Erlanger officials indicated on the signature page of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

INSTITUTION:

_____

By:_____

Name:_____

Title:_____

Date_____

ERLANGER:
Erlanger Health, Inc.

By: _____

Name: _____

Title:_____

Date_____ _____

EXHIBIT A

Reimbursement for services and resources provided by Erlanger in connection with the Study)

Guarantor will be:

Reimbursement to Erlanger through a mutually agreed upon methodology which such as check, ACH transfer, etc.: Payment will be issued by: _____ upon an invoice from Erlanger for the following services and resources.

Fixed Study Start-up: Non-negotiable and due within 30 days of executed contract (Total Cost)		
Fee Description:	**Amount:**	**Justification:**
Regulatory Preparation and Compliance Fee		Preparation and submission to central and local IRBs; internal review boards including, but not limited to, Protocol Review and Monitoring Committee, Radiation Committee, Clinical Trial Billing Compliance, Research Support Services Protocol review; Site Selection Visit, Site Initiation Visit, Scientific Review, Legal preparation and negotiation Principal Investigator (PI) protocol and feasibility review; PI legal documentation; meetings with budget and regulatory staff; Investigator meeting(s); Site Initiation Visit Protocol review; meeting with budget, regulatory and ancillary departments as required by protocol and in accordance with Erlanger Health System practices; Site Initiation Visit; Investigator meeting; source documentation development; electronic data capture training
Total		

Medicare Analysis		
Ancillary Fees: Non-negotiable and due within 30 days of executed contract (Total Cost not including 30% OH)		
Fee Description:	**Amount:**	**Justification:**
Investigational Drug Services Start-up Fee		[For Studies involving investigational product with or without placebo]: Protocol and Investigator Brochure review; IP receipt and inventory; dispensing procedures and staff training
IP Dispensation Fees		Per Dispensation

Annual Fees: Non-negotiable and due within 30 days of Invoice (Total Cost)		
Administrative Maintenance Annual Fee		[Assessed at time of **Continuing Review**]: Continuing regulatory and administrative maintenance, including, but not limited to, IRB continuing reviews, modifications, safety reports, filing, binder upkeep, regulatory documentation (1572, CVs FDs); monthly financials; invoicing; reconciliations
Investigational Drug Services Annual Maintenance Fee		[Assessed at time of **Continuing Review**]: Inventory controls/accountability; monitoring visits; internal drug audits; expired drug reviews
Annual Supply Fee		[Assessed at time **of Continuing Review**]: Any miscellaneous supplies required for the study that are not provided by the Sponsor, e.g. PPE, dry ice, etc

Study Closure Fees: Non-negotiable and due within 30 days of Invoice (Total Cost)		
Investigational Drug Services Closure Fee		[Assessed at time of **Study Closure with IRB**]: Final drug inventory, close-out and destruction or return of investigational product
Study Close-out Fee		Final close-out of all study related procedures and regulatory
Task Specific Fees: Non-negotiable and due within 30 days of Invoice (Total Cost)		
Local Initial IRB Fee		
Protocol Amendment Fee		Per Occurrence
IRB Continuing Review Fee		Annually
Local IRB Amendment (for each amend)		Per Occurrence
Local IRB Renewal Fee		Per Occurrence

Expectations – Things to Know:

Indirect Cost Rate – The current indirect cost rate (overhead) for Erlanger Institute for Clinical Research is 30% for industry-sponsored research and is non-negotiable. This rate applies to:

All new study budgets negotiated;
Amendments to existing study budgets that result from protocol amendments if the overhead rate is lower than 30%;
All procedure and non-procedure line items.

Fees are reviewed annually on July 1st and are subject to change.

Any questions should be directed to the Clinical Research Operations Director at 423-778-3902.

Subject specific services

Procedure Fees	Cost Center	CPT Code	Fee
_____			
_____			
_____			

Laboratory Fees

	Cost Center	CPT Code	Fee
_____			
_____			
_____			

Imaging Fees	Cost Center	CPT Code	Fee
_____			
_____			

Staff Resource Fees	Cost Center	CPT Code	Fee
_____			
_____			
_____			

The parties acknowledge and agree that above-related subject specific services are for Erlanger services that are not considered standard of care and are provided to Institution's research subjects for purposes of conducting the Study.

(Please attach the study schematic to list the study procedures required and the timepoints that they will be provided).