PREMISES USE AND INDEMNIFICATION AGREEMENT

This Premises Use and Indemnification Agreement (“Agreement”), made and entered into as of the date signed by the last party to sign below (the “Effective Date”), is by and between \_\_\_\_\_, having a business address at \_\_\_\_\_\_\_\_\_ (“Sponsor**”**), and OSF Healthcare System, an Illinois not-for-profit corporation (“OSF”), owner and operator of Saint Francis Medical Center, located at 530 N .E. Glen Oak Avenue Peoria, IL 61637 (“Hospital”)

**RECITALS**

# Sponsor conducts business in the research, development, and manufacture of pharmaceutical and healthcare products, including, among others, (the “Study Drug/Device”); and

# Sponsor has engaged \_\_\_\_\_\_\_ (“Principal Investigator”), a physician who participates in a medical practice in conjunction with \_\_\_\_\_\_\_ (“Research Institution”), which maintains its principal offices at \_\_\_\_\_\_\_\_ (“Institution”), under a separate Clinical Trial Agreement to conduct a clinical trial utilizing the Study Drug/Device. Principal Investigator wishes to conduct part or all of such clinical trial at Hospital because certain patients who may become participants in the Study may be seen by the Principal Investigator on the premises of and using the facilities of OSF.

Now, therefore, in consideration of the promises and covenants expressed herein, the parties agree as follows:

## Performance of Study.

### OSF acknowledges that the Study may be performed on its premises, using its facilities at Hospital, and that the Study shall conform to the following Protocol:

### OSF shall perform its duties, if any, for the Study as directed by the Principal Investigator in conformance with this Agreement, the rules, regulations and conditions of approval of the Institutional Review Board with jurisdiction over this Study, the Protocol through the verbal and written directions of the Principal Investigator, generally accepted standards of good clinical and medical practices and all applicable laws, rules, and regulations, including without limitation, HIPAA. Principal Investigator and OSF agree that any obligations imposed on Principal Investigator under the referenced Clinical Trial Agreement which require the involvement of OSF shall be discussed and agreed upon by Principal Investigator and OSF prior to the conduct of the Study at OSF under this Agreement.

### Sponsor shall provide, without cost, sufficient amounts of the Study Drug/Device to allow Principal Investigator to carry out the Study. Study Drugs/Devices furnished for the Study will be used solely under the Protocol, and may not be used for any other purposes. All unused drug/device supplies shall be returned to Sponsor at the conclusion of the Study, unless written authorization to destroy them is given by Sponsor. OSF shall follow Sponsor’s instructions related to disposition of the clinical trial materials and OSF shall comply with all laws and regulations applicable to any destruction or disposition of the materials at OSF. OSF shall not release any Study drug/device to any third party (including without limitation any governmental agency, any other investigator or any other third party) without the prior written express approval from Sponsor, except in cases where OSF is required by law to release the Study drug/device to a regulatory agency acting within the scope of its regulatory authority, in which case, OSF will immediately notify Sponsor of such action.

## Ownership of Study Data; Confidentiality; Publication.

### OSF shall have no right or interest in any data, inventions or discoveries arising as a result of the Study. For the sake of clarity, Study Data does not include non-Study medical records belonging to OSF. In addition, all information relating to the Study which is received from Sponsor or Principal Investigator, directly or indirectly, by OSF, its employees, representatives, or agents, shall remain confidential and shall not be used for any purpose other than the conduct of the Study, nor disclosed to any third party, except (i) as required by law, provided that OSF gives Sponsor prompt and reasonable notification prior to such disclosure so as to enable Sponsor to obtain appropriate confidential protection of such information, (ii) as allowed for by the patient’s particular informed consent, provided such consent form shall have been previously approved by Sponsor and/or Principal Investigator, and/or (iii) as such may be approved by the prior written consent of Sponsor.

### With the exception of personal and confidential patient medical records which are not part of the Study data, all CRFs and any other reports and data generated during the course of this Study (the “Study Data”) are the sole property of Sponsor and may be used by Sponsor for any purpose whatsoever. OSF agrees not to provide the Study Data to any third party nor use the Study Data (except as required to perform its obligations hereunder) without Sponsor’s prior written consent.

### OSF shall not publish nor make any presentation concerning the Study without the prior written permission of Sponsor.

## Monitoring of Study; Inspections.

### OSF agrees to permit representatives of Sponsor (or any of its authorized representatives), the FDA, and/or other regulatory authority to examine at any reasonable time during normal business hours (i) the facilities where Study is conducted, (ii) medical records regarding research subjects (for the purpose of verifying the accuracy of Study data), and (iii) any other relevant information necessary to confirm that Study is being conducted in conformance with the Protocol, the terms of this Agreement, FDA regulations and applicable legal requirements. Such access will be subject to Sponsor’s representatives complying with OSF’s reasonable rules and regulations.

### OSF shall immediately notify Sponsor and the Principal Investigator of any intended or actual examination or inspection by any governmental agencies or other authorized third parties.

## Compensation.

### Compensation.

#### All payments due to Principal Investigator for performance of the Study at OSF, including without limitation, all laboratory and other facilities, equipment, supplies (other than the Study Device), physicians and clinical support staff required for the proper and complete conduct of the Study will be made to Principal Investigator, pursuant to a separate agreement between those parties. OSF acknowledges and agrees that, except for the Facility and Administration Fee described in Part “b.” of this Section, no payments will be made by Sponsor to OSF for any work, activities, use, services or any other obligations assumed for work performed under this Agreement by or on behalf of OSF relating in any manner to the conduct of the Study. OSF hereby waives any claim against Sponsor for such obligations.

#### Institution shall pay a one time non-refundable Facility and Administration Fee of One Thousand Five Hundred Dollars ($1,500.00) to OSF upon execution of this Agreement.

## Termination.

### This Agreement may be terminated and/or further enrollment of subjects in a Study may be suspended:

#### Immediately by any party upon notice to all other parties, if such party reasonably believes a termination is necessary: (i) to protect the safety or welfare of the Study subjects, or (ii) any applicable state or federal law or regulation, such as, without limitation, those governing clinical trials;

#### by any party upon notice to all other parties for a breach of a material provision hereof by any other party; provided the aggrieved party shall have first provided the defaulting party with a notice of such material breach and the defaulting party shall have failed to cure such breach within thirty (30) days following receipt of written notice thereof from the aggrieved party;

#### by Sponsor, upon thirty (30) days prior written notice, (i) if Sponsor believes there are scientific reasons for such termination, as solely determined by Sponsor, (ii) if the purpose of the Study has for any reason become obsolete or no longer has any validity or purpose, or (iii) for any other reason which Sponsor deems appropriate; or

#### by written mutual agreement.

### Upon receipt of any notice of termination or suspension, OSF and Principal Investigator agree that no additional Study subjects will be enrolled in the Study. Any Study subjects already enrolled in the Study will be phased-out as deemed appropriate by Sponsor and Principal Investigator.

## Indemnification.

### Indemnification. Sponsor will indemnify and hold harmless OSF, OSF’s IRB, its affiliated corporations, and its and their respective directors, trustees, officers, employees and agents (individually an “Indemnitee” and collectively, the “Indemnitees”), from and against any and all amounts paid or payable by an Indemnitee to a Study subject resulting from actions, suits, proceedings, claims, demands, assessments, judgments, costs and expenses (individually a “Claim” and collectively, “Claims”), including without limitation, legal fees and expenses, incident to any of the foregoing or incurred in enforcing this indemnity, asserted or initiated by or on behalf of the Study subject, which Claim is based upon personal injury (including death) to such Study subject and which injury is sustained as a direct result of the administration of the Study Drug/Device in accordance with the Protocol, except to the extent any such Claim, is attributable to:

#### the failure of Principal Investigator, the Institution, any other Institution personnel, OSF or any other OSF personnel involved in the performance of the Study to adhere to the terms of the Protocol or any written or oral instructions (including, without limitation, package inserts, where appropriate) relative to the use of any drug or device used in the performance of the Study, or comply with applicable FDA or other governmental requirements; or

#### any negligent or wrongful act or omission, malpractice, willful malfeasance, or breach of any a material representation or warranty given by Principal Investigator, the Institution, any other Institution personnel, OSF or any other OSF personnel (including employees, agents or independent contractors) involved in the performance of the Study.

OSF understands that the sole liability of Sponsor to any Indemnitee will be the indemnification described above.

Further, the provisions of subparagraphs (b) and (d) of Section 6.2 entitled Conditions shall apply only in the event that Sponsor has indemnification responsibility under Section 6.1 entitled Indemnification.

### Conditions. It is a condition precedent to Sponsor’s indemnification obligations under Section 6.1 above that each Indemnitee seeking indemnity hereunder must:

#### promptly notify Sponsor of the assertion of any Claims against it/him/her;

#### authorize and permit Sponsor to conduct and exercise sole control of the defense and disposition (including all decisions relative to litigation, appeal or settlement) of such Claims; provided, however, Sponsor shall: (i) not enter into any settlement which admits fault by an Indemnitee without Indemnitee’s prior written consent, which consent shall not be unreasonably withheld; (ii) not settle or dispose of a claim or suit of a criminal nature without prior written permission of the Indemnitee and (iii) utilize competent attorneys experienced in such claims and lawsuits.

#### fully cooperate with Sponsor regarding any such Claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Sponsor’s obligations hereunder; and

#### not compromise or settle any claim or action, nor make any admission prejudicial to the defense of such claim, without the prior express written approval of Sponsor.

Subject to the foregoing, each Indemnitee may participate in any such Claims at its/his/her own cost and expense. In the event any notice is not timely received or is otherwise prejudicial to Sponsor’s ability to timely or adequately defend such Claim, the Sponsor’s obligations under Section 6.1 are null and void.

### Patient Reimbursement. Sponsor agrees to pay for the cost of reasonable and customary medical treatment of any illness or injury sustained by a Study subject as a direct and sole result of the administration of the Study Device in accordance with the Protocol (except to the extent such costs are covered by the Study subject’s insurance or other third-party coverage); provided, however, that Sponsor’s obligations under this Section 6.3 shall not apply to the extent that any such costs or such illness or injury is attributable to:

#### the failure of Principal Investigator, the Institution, any other Institution personnel, OSF or any other OSF personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written or oral instructions (including, without limitation, package inserts, where appropriate) relative to the use of any product(s) used in the performance of the Study, or comply with applicable FDA or other governmental requirements;

#### any negligent or wrongful act or omission, willful malfeasance or malpractice, of Principal Investigator, the Institution, any other Institution personnel, OSF or any other OSF personnel involved in the performance of the Study;

#### the Study subject’s primary disease or any concurrent disease not directly and solely caused by the administration of the Study Device in accordance with the Protocol; and/or

#### the Study subject’s failure to comply with written information, instructions, or warnings contained in the Informed Consent executed by such subject or communicated to the Study subject by any Study personnel.

OSF shall provide prompt written notice, no later than ninety (90) days, to Sponsor of the Subject injury or a potential subject injury. Sponsor shall not reimburse OSF or any third party for any injury claims received or notice of potential injury claims received after ninety (90) days from the date of the subject injury. The compensation provided to Study-subjects in this Section 6.3 shall be the sole and exclusive form of compensation of any type provided by Sponsor to the Study subjects for injuries related to this Study.

## General Provisions.

### Debarment Certification. OSF hereby certifies to Sponsor that OSF has not used, and will not use, the services of any person debarred under the Generic Drug Enforcement Act of 1992, as amended (GDEA) in any capacity, in connection with any of the services performed under this Agreement. This certification applies in respect of officers, agents and employees of OSF, as well as third parties with whom either party may subcontract. OSF agrees to notify Sponsor promptly in the event any person so used ever becomes debarred under the GDEA. Upon request by Sponsor, OSF agrees to provide a list of persons used to perform any services in connection with the Study who were or are convicted under the GDEA.

### Survival. The rights and obligations under Section 2 (Ownership of Study Data; Confidentiality; Publication), Section 3 (Monitoring of Study; Inspections), Section 4 (Compensation), Section 5 (Termination), and Section 6 (Indemnification), as well as any other terms which by their intent or meaning are intended to so survive, shall survive indefinitely the termination of this Agreement. No termination hereunder shall constitute a waiver of any rights or causes of action that any party may have based upon events occurring prior to the termination date.

### Miscellaneous Contract Language.

#### This Agreement constitutes the entire Agreement between the parties and contains all of the terms and conditions between the parties with respect to the subject matter hereunder. OSF and Sponsor shall be entitled to no benefits or services other than those specified herein. This Agreement supersedes any and all other agreements, either written or oral, between the parties with respect to the subject matter hereof.

#### This Agreement shall be construed and interpreted in accordance with the laws of the State of Illinois, and Peoria County, Illinois shall be the sole and exclusive venue for any proceeding as between the parties in connection with this Agreement. It may only be amended, modified or terminated by an instrument signed by the parties. This Agreement shall inure to the benefit of and be binding upon the parties, their successors, and assigns, provided that neither this Agreement nor any right or interest of OSF arising herein shall be voluntarily or involuntarily sold, transferred or assigned without written consent of Sponsor, and any attempt at assignment is void.

#### The parties are independent contractors under this Agreement. Nothing in this Agreement is intended nor shall be construed to create an employer/employee relationship or a joint venture relationship between the parties, or to allow any party to exercise control or direction over the manner or method by which any of the parties perform services herein. The waiver by either party of a breach or violation of any provision of this Agreement shall not operate as, or be construed to be, a waiver of any subsequent breach of the same or other provisions hereof. Notices required herein shall be considered effective when delivered in person, or when sent by United States certified mail, postage prepaid, return receipt requested and addressed to:

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| --- | --- |
| OSF:  Michael Cruz, MD  President  Saint Francis Medical Center  530 N.E. Glen Oak Avenue  Peoria, Illinois 61637  USA | Sponsor: |

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

#### It is understood and agreed that neither party to this Agreement shall be legally liable for any negligent or wrongful act, either by commission or omission, chargeable to the other, unless such liabilities imposed by law and that this Agreement shall not be construed as seeking to either enlarge or diminish any obligations or duty owed by one party against the other or against a third party. The invalidity or unenforceability of any particular provision of this Agreement shall not affect the other provisions hereof, and this Agreement shall be construed in all respects as if such invalid or unenforceable provision were omitted. The section titles and other headings contained in this Agreement are for reference only and shall not affect in any way the meaning or interpretation of this Agreement.

#### This Agreement is a result of negotiations between the parties, none of whom have acted under any duress or compulsion, whether legal, economic or otherwise. Accordingly, the parties hereby waive the application of any rule of law that otherwise would be applicable in connection with the construction of this Agreement that ambiguous or conflicting terms or provisions should be construed against the party who (or whose attorney) prepared the executed Agreement or any earlier draft of the same.

IN WITNESS WHEREOF, the parties caused this Agreement to be executed by their duly authorized representatives as of Effective Date.

OSF: SPONSOR:

OSF HEALTHCARE SYSTEM,

SAINT FRANCIS MEDICAL CENTER

By: By:

Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dated: Dated:

Read and Acknowledged: Investigator and/or Investigator’s Employer/Medical Group

PRINCIPAL INVESTIGATOR

By:

Printed Name:

Title:

Date: