**STATEMENT OF AGREEMENT FOR CONTRACT RESEARCH ORGANIZATION (CRO) BETWEEN THE UNIVERSITY OF TEXAS COMPONENT (UNIVERSITY) AND CONTRACT RESEARCH ORGANIZATION**

**1 INTRODUCTION**

This Agreement is made this day of , 19 between The University of Texas {component} (“University”), a component of The University of Texas System (“System”), and Contract Research Organization, {address} (“CRO”) to conduct a clinical Study and evaluation (“Study”). University and CRO agree as follows:

**2 PROTOCOL**

The scope and nature of the clinical Study to be performed will be in accordance with {name of sponsor} (“Sponsor”), protocol number {protocol number} entitled {protocol title}, which has been provided to University. This protocol fully details the clinical research activities and responsibilities to be undertaken.

**3 COMPLIANCE WITH LAWS**

As required by federal law, the Study will be conducted in accordance with the conditions specified in the Statement of Investigator, Form FDA 1572 which has been completed, signed, and returned to the Department of Clinical Research Services of CRO. Furthermore, University agrees to comply with any and all other federal, state, and local laws applicable to the conduct of the Study.

**4 TERM OF AGREEMENT**

The clinical Study will be supervised by Dr. (“Principal Investigator”) under the supervision of University as an independent contractor and will be initiated on or about {start date}. The Study, involving approximately {# of patients} patients per site, will be completed in a time period of approximately {length of Study}; therefore, the patient enrollment termination date is anticipated to be {termination date}. Entry of the first patient at University’s site is expected to occur within twelve (12) weeks of the initiation visit. If the first patient has not been entered by this time, CRO/Sponsor reserve the right to terminate the Study at University’s site, with full recovery of all Study materials.

**5 REIMBURSEMENT**

[As negotiated.]

**6 CONFIDENTIAL INFORMATION**

***[If Sponsor is a company with which we have a Universal agreement, use the Confidential Information provision from the Universal; if not, use the following:]***

The parties may wish, from time to time, in connection with work contemplated under this Agreement, to disclose confidential information to each other (“Confidential Information”). Each party will use reasonable efforts to prevent the disclosure of any of the other party’s Confidential Information to third parties for a period of three (3) years from receipt thereof, provided that the recipient party’s obligation shall not apply to information that:

* 1. is not disclosed in writing or reduced to writing and so marked with an appropriate confidentiality legend within thirty (30) days of disclosure;
	2. is already in the recipient party’s possession at the time of disclosure thereof;
	3. is or later becomes part of the public domain through no fault of the recipient party;
	4. is received from a third party having no obligations of confidentiality to the disclosing party;
	5. is independently developed by the recipient party; or
	6. is required by law or regulation to be disclosed.

In the event that information is required to be disclosed pursuant to subsection f., the party required to make disclosure shall notify the other to allow that party to assert whatever exclusions or exemptions may be available to it under such law or regulation.

**7 CLINICAL DATA**

All clinical data, including case report forms and other relevant information generated as a result of the Sponsor sponsored Study, will be promptly and fully disclosed to and produced for the inspection of the Sponsor clinical monitor and/or the CRO monitor upon request.

**8 PUBLICATIONS**

***[If Sponsor is a company with which we have a Universal agreement, use the Publications provision from the Universal; if not, use the following:]***

University reserves the right to publish the results of the Study. University will, however, notify Sponsor and will submit a draft of the manuscript to Sponsor for comments at least sixty (60) days prior to submission for publication or oral presentation. Sponsor shall notify University in writing within thirty (30) days of receipt of such draft whether such draft contains information deemed to be confidential under the provisions of Section , or information that if published within thirty (30) days would have an adverse effect on a patent application in which Sponsor owns full or part interest, or intends to obtain an interest from University pursuant to this Agreement. In the latter case Sponsor has the right to request a delay and University agrees to delay said publication for a period not exceeding ninety (90) days. In any such notification, Sponsor shall indicate with specificity to what manner and degree University may disclose said information. University shall have the final authority to determine the scope and content of any publication, provided that such authority shall be exercised with reasonable regard for the commercial interests of Sponsor. It is the intent of the parties that no publication will contain any of confidential information disclosed by Sponsor without Sponsor’s prior written permission. Information related to Sponsor’s experimental drugs will not be transmitted to nonscientific journals, newspapers, radio or television without Sponsor’s written consent.

***[If the Study is multisite, use the following:]***

University reserves the right to publish the results of the Study, with due regard to the protection of Sponsor’s confidential information. University will submit the manuscript of any proposed publication to Sponsor at least thirty (30) days before publication, and Sponsor shall have the right to review and comment upon the publication in order to protect Sponsor’s confidential information. Upon Sponsor’s request, publication will be delayed up to sixty (60) additional days to enable Sponsor to secure adequate intellectual property protection of property of Sponsor that would be affected by said publication. University acknowledges that the Study is part of a multi-center study, and that an independent, joint publication is anticipated to be authored by investigators in the multi- center study, including University’s investigator. Therefore, University agrees not to independently publish the results of the Study before the publication of the multi- investigator paper; but in no event shall University be so restricted after the expiration of eighteen (18) months from completion of University’s performance of the Study.

**9 INVENTIONS**

***[If Sponsor is a company with which we have a Universal agreement, use the Inventions provision from the Universal; if not, use the following:]***

Title to all inventions and discoveries made by University resulting from the research performed hereunder shall reside in University; title to all inventions and discoveries made by Sponsor resulting from the research performed hereunder shall reside in Sponsor; title to all inventions and discoveries made jointly by University and Sponsor resulting from the research performed hereunder shall reside jointly in University and Sponsor. Inventorship shall be determined in accordance with U.S. Patent law.

After consultation with Sponsor regarding the advisability of filing patent applications, University shall file appropriate United States and foreign patent applications for wholly or jointly owned University inventions. University will provide Sponsor, on a confidential basis, a copy of any such application filed and any documents received or filed during prosecution thereof and will provide Sponsor the opportunity to comment thereon. On any application on which an employee of Sponsor is named as a co-inventor, Sponsor will cooperate in obtaining execution of any necessary documents by its employees.

University agrees to grant to Sponsor an option to negotiate an exclusive, worldwide, royalty-bearing license to make, use or sell under any invention or discovery owned wholly or partly by University and made or conceived and reduced to practice during the term of this Agreement or within six (6) months thereafter and directly resulting from the performance of the research hereunder, with right to sublicense with accounting to University. Sponsor shall have three (3) months from disclosure of any invention or discovery to notify University of its desire to enter into such a license agreement, and a license agreement shall be negotiated in good faith within a period not to exceed six (6) months from Sponsor’s notification to University of its desire to enter into a license agreement, or such period of time as to which the parties shall mutually agree. If Sponsor and University fail to enter into an agreement during that period of time, Sponsor shall have a right of first refusal with respect to any terms generally more favorable offered by University to a third party for a period of one (1) year thereafter. In the event Sponsor elects to exercise its option to negotiate a license in accordance with the procedures detailed above, it shall be obligated to pay all expenses, including attorney’s fees, incurred in searching prior art, obtaining search opinions, preparing applications, filing, prosecuting, enforcing or maintaining a patent or patent application with respect to the licensed invention in any country in which the patent or application is filed.

**10 INDEMNIFICATION**

Sponsor shall indemnify University as set forth in the Indemnification Letter attached hereto as EXHIBIT A.

***[If Sponsor is a company with which we have a Universal agreement, Exhibit A should set forth the Indemnification provision from the Universal; if not, use the following:]***

Sponsor agrees to indemnify and hold The University of Texas System (“System”), the University, their Regents, officers, agents and employees harmless from any liability, loss or damage they may suffer as a result of claims, demands, costs or judgments against them arising out of the activities to be carried out pursuant to the obligations of this Agreement, including, but not limited to, the use by Sponsor of the results obtained from the activities performed by University under this Agreement; provided, however, that any such liability, loss or damage resulting from the following Subsections “a” or “b” is excluded from this Agreement to indemnify and hold harmless: a. the negligent failure of University to substantially comply with any applicable FDA or other governmental requirements; or

b. the negligence or willful malfeasance of any Regent, officer, agent or employee of University or System.

**11 TERMINATION**

CRO/Sponsor may terminate University’s involvement in the Study prior to its completion by written notification for any of the following reasons:

* 1. if available data indicate that it is not safe to continue to administer the Study drug to patients;
	2. if University defaults on any material term of this Agreement;
	3. if CRO’s agreement with Sponsor is terminated;
	4. by agreement, in writing, between CRO and University;
	5. if the entry of valid patients in the Study is too slow to meet the agreed time scheduled;
	6. if a sufficient number of patients have been enrolled across all Study sites to complete the needs of the Study, even though the Study termination date has not arrived; or
	7. adherence to the protocol is poor or data recording is chronically inaccurate or incomplete.

University may terminate this Agreement prior to completion of the Study by written notification upon Sponsor/CRO’s material default of its’/their obligations hereunder; provided that University shall allow Sponsor/CRO thirty (30) days from the date of notification to cure such default.

**12 MISCELLANEOUS**

This Agreement shall be binding upon the parties, their legal representatives, successors and assignees; may not be amended except by written instrument signed by the parties; and supersedes all prior written and oral agreements and representations between the parties with respect to the subject matter hereof. All obligations contained herein as to which performance is required after termination shall survive termination.

**13 AGREEMENT**

This Agreement shall be construed and the rights of the parties determined in accordance with the laws of the State of Texas.

In witness whereof, the parties hereto have executed this Agreement by their duly authorized representatives.

**CONTRACT RESEARCH ORGANIZATION**

By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
{name}
{date}

**THE UNIVERSITY OF TEXAS AT {component}**

By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
{name}
{date}

**Read and Understood:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
{Primary Investigator}