**CLINICAL TRIAL RESEARCH AGREEMENT**

No. \_\_\_\_\_\_\_\_\_\_

This Agreement is entered into by and between the University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ hereinafter called "Institution," and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_a corporation with its principle office and place of business at, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, hereinafter called "Sponsor."

**WITNESSETH**

WHEREAS, the research program contemplated by this Agreement is of mutual interest and benefit to the Institution and to the Sponsor, and will further the Institution's instructional and research objectives in a manner consistent with its status as a tax-exempt educational institution.

WHEREAS, Sponsor Protocol No. \_\_\_\_\_\_\_\_\_\_\_\_\_ which will guide the performance of this Agreement has been written by the Sponsor and accepted by the Institution and the Institution warrants it is fully able to perform the research program in a professional, competent manner with strict adherence to its terms and the Institution will utilize its best efforts to do so.

NOW THEREFORE, the parties hereto agree as follows:

**1. SCOPE OF WORK**

The Institution shall exercise its best efforts to carry out the research ("Research") set forth in the Protocol entitled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [name of protocol] and attached here as Exhibit A ("Protocol") in accordance with this Agreement. As of the date of execution of this Agreement, the Protocol consists of \_\_\_\_\_\_\_ pages and is dated \_\_\_\_\_\_\_\_\_\_.

**2. PRINCIPAL INVESTIGATOR**

Institution's Principal Investigator is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ who will be responsible for the direction of the Research in accordance with applicable Institution policies which Institution warrants and represents are not inconsistent with the terms of this Agreement, the Protocol, generally accepted standards of good clinical practice all applicable local, state and federal laws and regulations governing the performance of clinical investigations and in accordance with Article 24. If for any reason, the above named individual is unwilling or unable to continue to serve as Principal Investigator and a successor, acceptable to both the Institution and the Sponsor, is not available, this Agreement shall be terminated as provided in Article 14.

**3. PERFORMANCE PERIOD**

The effective period of this Agreement will be from \_\_\_\_\_\_\_\_\_\_ through \_\_\_\_\_\_\_\_\_\_ unless otherwise terminated in accordance with Article 14. The effective period may be extended by mutual agreement as provided in Article 15.

**4. RECORDKEEPING, REPORTING AND ACCESS**

A. The Sponsor's authorized representative(s), and regulatory authorities to the extent required by law, may, during regular business hours, arrange in advance with the Principal Investigator and Institution to:

(1.) examine and inspect the Institution's facilities required for performance of the Research; and

(2.) inspect and copy all data and work products relating to the Research.

B. Institution shall cooperate with any regulatory authority and allow them access to applicable records and data.

C. The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(1.) preparation and maintenance of complete, accurately written records, accounts, notes, reports and data of the Research;

(2.) preparation and submission to Sponsor of all original case report forms ("Case Reports") for each patient or subject participating in the Research ("Research Subject") as provided in the Protocol; and

(3.) All Case Reports will be delivered to Sponsor by Institution in a timely manner throughout the performance of Study, and in no event later than ten (10) working days after the date of termination of the Agreement or on which Sponsor reasonably requests delivery of data.

(4.) [**OPTIONAL**] Preparation of a final written report ("Final Report") including a complete summary of the study acceptable to the Sponsor. The Final Report will be submitted to the Sponsor promptly following completion of the Research, with the last Case Reports.

C. All data and Case Reports relating to the Research shall be owned by the Sponsor and the Institution. The Sponsor may use or transfer the same for any lawful purpose in a manner not inconsistent with this Agreement with no further payment to the Institution. The Institution may use the data it generates hereunder in accordance with this Agreement and for the educational and research purposes of a university. The Sponsor may transfer its ownership rights; the Institution's ownership rights cannot be transferred and cannot be used to transfer title to the data.

**5. COST AND PAYMENT**

A. As consideration for performance under the terms of this Agreement, Sponsor shall pay the Institution up to a total sum of $\_\_\_\_\_\_\_\_\_\_\_ based upon $\_\_\_\_\_\_\_\_\_\_ per completed, evaluable Case Report form. The total sum assumes enrollment of \_\_\_\_\_\_\_\_\_\_\_ (\_\_\_\_\_\_) evaluable Research Subjects in accordance with the scope of work set forth in the Protocol. The payment noted above includes all applicable overheads due any party or entity.

B. Payment shall be made to the Institution according to Schedule A appended hereto and incorporated herein by reference. All costs outlined on Schedule A shall remain firm for the duration of the Research, unless otherwise agreed in writing by the Institution and Sponsor.

C. Checks will be made payable to:

"The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_"

Checks will reference this Agreement number, the Principal Investigator, and the protocol title and will be sent to:

The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
[Address]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tax Identification Number \_\_\_\_\_\_\_\_\_\_\_\_\_

D. Partial payment for Research Subject(s) who do not complete the Protocol and/or are lost to follow up will be made in accordance with Schedule B appended hereto and incorporated herein by reference.

**NOTE: In the case of agreements that are not negotiated on a per Research Subject basis, the following alternate wording replaces A in Article 5.**

A. As consideration for performance under the terms of this Agreement, Sponsor shall pay the Institution the total sum of $\_\_\_\_\_\_\_\_ as set forth in the budget attached as Schedule A. Payment includes all applicable overheads due any party or entity.

B. The Institution reserves the right to re-allocate funds between budget categories.

**6. CONFIDENTIAL INFORMATION**

A. The Institution and the Principal Investigator shall not disclose or use for any purpose other than performance of the Research, any and all trade secrets, privileged records or other confidential or proprietary information (collectively "Information") disclosed to the Institution pursuant to this Agreement. Such Information shall be disclosed to the Institution hereunder in writing, or if disclosed orally or in other than documentary form shall be reduced to writing within thirty (30) days thereafter. Information which is not in oral or written form, such as but not limited to data tapes, shall be designated in writing as confidential within thirty (30) days after disclosure. The obligation of non- disclosure shall not apply to the following:

(1.) Information at or after such time that it is or becomes publicly available through no fault of the Institution;

(2.) Information that is already independently known to the Institution as shown by its prior written records, provided that the Institution so advises the Sponsor promptly upon the Institution's discovery that the Information is already independently known to the Institution; or

(3.) Information at or after such time that it is disclosed to the Institution on a non-confidential basis by a third party with the legal right to do so.

B. The obligations of the Institution under this Article shall survive and continue for year(s) after termination of this Agreement. (NOTE: The number of years will be determined on the basis of the Protocol and by negotiation between the Sponsor and the Institution.)

C. In the event the Sponsor shall come into contact with Research Subjects' medical records, the Sponsor shall hold in confidence the identity of the patient and shall comply with all applicable law(s) regarding the confidentiality of such records.

D. In the event the Institution finds it necessary to disclose Information to a proper authority to permit the Institution to defend its research against an allegation of fraud, the Institution shall first notify the Sponsor and the Institution and Sponsor shall agree to a mutually satisfactory way to disclose such Information as necessary for this limited purpose.

E. Institution agrees to hold the results of the Research in confidence, subject to its rights under Article 7.

**7. PUBLICATIONS**

The Institution shall have the right, consistent with academic standards, to publish the results of Research provided such publication does not contain Sponsor's Information. Prior to submission for publication or presentation, the Institution will provide the Sponsor thirty (30) days for review and comment upon the manuscript or other material for such publication. Expedited reviews for abstracts or poster presentations may be arranged if mutually agreeable to the Sponsor and the Institution or Principal Investigator. The Sponsor shall be permitted to advise as to the implications of timing of the publication if the same clinical trials set forth in Protocol are still in progress at other sites. In addition, if requested in writing and with reasonable justification, the Institution will withhold such publication an additional sixty (60) days to allow for filing a patent application or taking such other measures as Sponsor deems appropriate to establish and preserve its proprietary rights. Notwithstanding the foregoing, Institution agrees that if the Research is part of a multicenter study, the first publication of the results of the Research shall be made in conjunction with the results from the Investigators at the other study centers. The manner in which the publication will be generated will be negotiated between Sponsor and Principal Investigators prior to initiation of Research.

**8. PATENTS AND INVENTIONS**

A. "New Invention or Discovery" shall mean any invention or discovery conceived or reduced to practice during and as a part of the Research performed pursuant to this Agreement by Institution's Principal Investigator faculty, staff, employees, or students or jointly by such an individual or individuals with one or more employees of the Sponsor. Here and throughout this Agreement, the terms "conceived" and "reduced to practice" shall be given the meaning of those terms as they appear in 35 USC Section 102(g). New Inventions or Discoveries made solely by Institution's Principal Investigator, faculty, staff, employees, or students shall be the sole property of the Institution or its designated patent agent, in accordance with the Institution's patent policy. New Inventions or Discoveries made jointly by Institution's faculty, staff, employees, or students with one or more employees of the Sponsor shall be owned jointly by the Institution and the Sponsor.

B. The Institution or its designated patent agent, consistent with the Institution's patent policy, will offer Sponsor the first opportunity to enter into a royalty- bearing license agreement to practice such New Invention or Discovery, by exercise of the option provided for in Article 8.C. Such license shall be exclusive and worldwide except for those countries in which patents are valid and enforceable for which Sponsor does not reasonably assume out-of-pocket costs associated with obtaining and maintaining Letters Patent therein. All remaining terms of the license, including payment to the Institution of a reasonable royalty, shall be established in good faith negotiation by the parties.

C. The Institution shall promptly notify Sponsor, in writing, of any New Invention or Discovery. The notice shall provide a full written description of new invention or discovery. Sponsor shall have ninety (90) days after such notice to exercise the option to obtain the license identified in Article 8.B with respect to the identified New Invention or Discovery by written notification to the Institution. A failure by the Sponsor to timely notify the Institution shall be deemed a waiver of the Sponsor's option but only with respect to the identified New Invention or Discovery and not to other New Inventions or Discoveries subject to this Agreement.

D. If the Sponsor exercises the option, the parties shall immediately enter into negotiations on such terms of the license as are not already established by this Agreement. If a license has not been executed within one-hundred eighty (180) days of Sponsor's exercise of the option, the Institution may, upon giving the Sponsor thirty (30) days' notice, declare the negotiations deadlocked. In that event, and if agreement on all terms is not reached within that thirty (30) day notice period or by an appropriate method of alternate dispute resolution requested by one of the parties, the Sponsor's option with respect to the disclosed New Invention or Discovery shall be deemed waived by Sponsor, and the Institution shall be free to seek another potential licensee. However, if within six (6) months thereafter the Institution desires to offer a license under the New Invention or Discovery to a third party on terms more favorable to the licensee than those last offered Sponsor, the Institution must first offer the license to Sponsor on the more favorable terms. If Sponsor does not accept the offer within thirty (30) days, the Institution may proceed as it pleases with such third party.

E. The parties mutually acknowledge that the United States Government, as a matter of statutory right under 35 USC Sections 200-212, holds or may hold a non-exclusive license and certain other rights under patents on inventions made as a consequence of research whose funding includes funds supplied by the United States Government. The Institution and the Principal Investigator each warrant that to the extent each is aware of any funding supplied by the United States Government, the details of such funding, if any, are set forth in an Attachment to this Agreement. In the event either becomes aware of such funding in the future, the details of such funding shall be provided immediately to the Sponsor. In the event the United States Government has such rights or in the future is found to have such rights with respect to all or any New Inventions or Discoveries, any license contemplated under this Agreement, even if termed "exclusive" license, shall be understood to be subject to the rights of the United States Government, without any effect on the parties' remaining obligations, as set forth in the license or in this Agreement.

F. The right of publication by the Institution or its faculty, staff, employees or students, as indicated in Article 7, shall not be affected by license to any New Invention or Discovery.

**9. USE OF THE INSTITUTION'S OR SPONSOR'S NAME (ADVERTISING)**

A. The Institution and the Sponsor will obtain prior written permission from each other before using the name, symbols and/or marks of the other in any form of publicity in connection with the Research. This shall not include legally required disclosure by the Institution or Sponsor that identifies the existence of the Agreement. Further, Sponsor's use of the name, symbols and/or marks of Institution, or names of Institution's employees, shall be limited to identification of Institution as the Research site and the Research staff as participants in the Research.

B. The Sponsor will not use, nor authorize others to use, the name, symbols, or marks of the Institution in any advertising or publicity material or make any form of representation or statement in relation to the Research which would constitute an expressed or implied endorsement by the Institution of any commercial product or service without prior written approval from the Institution.

**10. APPLICABLE LAW**

This Agreement shall be governed by the laws of the State of [State of Institution or Sponsor, as negotiated].

**11. NOTICE**

Any notice required or permitted herein shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) received by Registered or Certified Mail, postage prepaid, return receipt requested, or received by facsimile and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

|  |  |
| --- | --- |
| **If to Sponsor:** | **If to Institution:** |
| For Administrative Matters: | For Technical Matters: |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Sponsor's Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Principal Investigator |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Address | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Institution Address |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ City              State             Zip Code | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ City              State               Zip Code |
| For Technical Matters: | For Administrative Matters: |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Sponsor's Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Grant or Administrative Officer |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Address | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Address |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ City              State             Zip Code | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ City              State                Zip Code |

**12. INDEMNIFICATION**

A. Sponsor shall defend, indemnify and hold harmless the Institution, the Principal Investigator, The University of Texas System, their Regents, officers, agents and employees from any and all liabilities, claims, actions or suits 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 of the Research, provided however:

(1.) that the Research is conducted in accordance with the Protocol and all written instructions delivered by Sponsor concerning administration of the Research study drugs or devices and Good Clinical Practice regulations, and in a manner required of a reasonable and prudent clinical investigator or physician;

(2.) that such loss does not arise out of the negligence or willful malfeasance of any Indemnitee, or any other person on the Institution's property, exclusive of the Sponsor's employees;

(3.) that the Sponsor is notified within ten (10) working days of any complaint, claim or injury relating to any loss subject to this indemnification;

(4.) that the Sponsor, subject to the statutory duty of the Texas Attorney General, has sole control over the defense and settlement of any such complaint or claim(s);

(5.) that the Sponsor, subject to the statutory duty of the Texas Attorney General, shall have the right to select defense counsel and to direct the defense or settlement of any such claim or suit.

B. The Sponsor shall provide a diligent defense against or settlement of any claims brought or actions filed with respect to the subject of the indemnity contained herein, whether such claims or actions are rightfully or wrongfully brought or filed. The Sponsor shall have the right to settle claims at the Sponsor's sole expense.

C. Any liability, loss or damage resulting from negligence or willful malfeasance by the Principal Investigator, other Institution investigators, the Institution, or their Regents, officers, agents and employees is excluded from this agreement to indemnify, defend and hold harmless. Deviations from the terms of the Protocol that may arise out of necessity do not per se constitute negligence or willful malfeasance provided that Institution shall promptly notify Sponsor of any such deviations.

D. The Institution and the Principal Investigator shall reasonably cooperate with the Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement. In the event a claim or action is or may be asserted, the Institution shall have the right to select and to obtain representation by separate legal counsel. If the Institution exercises such right, all costs and expenses incurred by Institution for such separate counsel shall be borne by Institution.

E. Sponsor warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Unless the Sponsor is self-insured, upon request the Sponsor will provide evidence of its insurance and will provide to the Institution, thirty (30) days prior, written notice of cancellation of its coverage.

F. The Institution will maintain during the performance of this Agreement the following insurance or self-insurance in amounts no less than that specified for each type:

(1.) bodily injury or death insurance and liability insurance with limits of not less than $500,000 per occurrence and $250,000 per person;

(2.) property damage liability insurance with limits of not less than $100,000 per occurrence and $100,000 per accident; and

(3.) Worker's Compensation Insurance in the amount required by the law of the State in which the Institution's workers are located.

G. Upon request, the Institution will provide evidence of its insurance or self-insurance and unless the Institution is self-insured, will provide to the Sponsor thirty (30) days prior, written notice of any cancellation in its coverage.

**13. SUBJECT INJURY**

The Sponsor shall reimburse for reasonable and necessary medical expenses incurred by Research Subjects as a direct result of the treatment of adverse reactions from study drugs or devices following their administration or use in accordance with the Protocol, provided such expenses are not covered by the Research Subject's medical or hospital insurance coverage and are in no way attributable to the negligence or misconduct of any agent or employee of the Institution. No other compensation of any type will be provided by the Sponsor to the Research Subjects.

**14. TERMINATION**

A. This Agreement may be terminated by either party, upon immediate prior notice, if any of the following conditions occur:

(1.) if the authorization and approval to perform the Research in the United States is withdrawn by the U.S. Food and Drug Administration;

(2.) if animal, human and/or toxicological test results, in the opinion of either the Sponsor or the Institution, support termination of the Research;

(3.) if the emergence of any adverse reaction or side effect with the drug administered or the device employed in the Research is of such magnitude or incidence in the opinion of either the Sponsor or the Institution to support termination.

B. This Agreement may be terminated by either party, upon ten (10) days prior written notice, if any of the following conditions occur:

(1.) If either party fails to comply with the terms of the Agreement after receipt of written notice, with opportunity to cure, from the other party.

(2.) If the Principal Investigator is unwilling or unable to continue to serve and a successor acceptable to both the Institution and the Sponsor is not available.

C. This Agreement may be terminated by either party for any other reason, other than those listed in 14 A (1), (2), (3), 14 B (1), (2), above, upon thirty (30) days prior written notice.

D. Upon the effective date of termination, there shall be an accounting conducted by the Institution, subject to verification by the Sponsor. Within thirty (30) days after receipt of adequate documentation therefore, the Sponsor will make payment to the Institution for:

(1.) all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and

(2.) reasonable non-cancelable obligations properly incurred for the Research by the Institution prior to the effective date of termination; unless the Sponsor objects to any charge, in which case, the parties shall use best efforts to resolve expeditiously any disagreement.

E. The Institution will credit or return to the Sponsor any funds not expended or obligated by the Institution in connection with the Research prior to the effective termination date of the notice of termination.

F. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Research Subjects into the Protocol and shall cease conducting procedures on Research Subjects already enrolled in the Protocol as directed by the Sponsor, to the extent medically permissible.

G. Termination of this Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination. The rights and duties under Articles 4, 6, 7, 8, 9, 10, 11, 12, 13, 23 and 24 survive the termination or expiration of this Agreement.

H. [OPTIONAL] If this Agreement is terminated prior to completion, Institution shall furnish Sponsor an acceptable Investigator's report for the Research completed.

**15. AMENDMENTS**

This Agreement and the Protocol may only be extended, renewed or otherwise amended by the mutual written consent of parties hereto.

**16. ENTIRE AGREEMENT**

This Agreement represents the entire understanding of the parties with respect to the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern.

**17. SEVERABILITY**

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

**18. INTEGRATION**

The Protocol and Schedules are incorporated in this Agreement by reference.

**19. ASSIGNMENT**

Neither party hereto may assign, cede or transfer any of its rights or obligations under this Agreement without the written consent of the other party, which consent may not be unreasonably withheld; provided, however, without such consent either party may assign this Agreement in connection with the transfer or sale of all or substantially all of its assets or business or its merger or consolidation with another company. The Sponsor may assign this Agreement in whole or in part to any corporate affiliate without consent of the Institution.

This Agreement shall inure to the benefit of and be binding upon each party signatory hereto, its successors and permitted assigns. No assignment shall relieve either party of the performance of any accrued obligation which such party may then have under this Agreement.

**20. INDEPENDENT CONTRACTOR**

A. In the performances of all services hereunder, the Institution shall be deemed to be and shall be an independent contractor and, as such, shall not be entitled to any benefits applicable to employees of the Sponsor.

B. Neither party is authorized or empowered to act as agent for the other for any purpose and shall not on behalf of the other enter into any contract, warranty or representation as to any matter. Neither party shall be bound by the acts or conduct of the other.

**21. NO TRANSFER OF PROPRIETARY RIGHTS NOT SPECIFIED**

It is agreed that neither the Sponsor nor the Institution transfers to the other by operation of this Agreement any patent right, copyright right, or other proprietary right of either party, except as specifically set forth herein.

**22. CHANGES TO THE PROTOCOL**

If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between the Sponsor and the Institution. If such changes affect the charge for the Research, the Institution will submit to the Sponsor a written estimate for approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice relating to the safety of Research Subjects requires a deviation from the Protocol, such standards will be followed. In such case, the party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the party.

**23. DELIVERY TO THE SPONSOR OF UNUSED MATERIALS**

Upon termination or completion of the Research, all unused compounds, drugs, devices, Case Reports, whether or not completed, and other related materials that were furnished to the Institution by or on behalf of the Sponsor shall be returned to the Sponsor at the Sponsor's expense.

**24. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE**

The Institution shall perform the Research in conformance with generally accepted standards of good clinical practice, with the Protocol, instructions provided by Sponsor and with all applicable local, state and federal laws and regulations governing the performance of clinical investigations including but not limited to the Federal Food, Drug and Cosmetic Act and regulations of the Food and Drug Administration. The Institution shall retain all records resulting from the Research for the time required by applicable federal regulations (the Sponsor will notify the Institution of the FDA Application filing and approval status), and to allow for inspection of all such records including the Research Subjects medical records. The Informed Consent form signed by the Research Subjects shall provide for access to the Research Subjects medical records by the Sponsor and by agencies such as the FDA.

**25. WAIVER**

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

**CLINICAL TRIAL RESEARCH AGREEMENT**

**No. \_\_\_\_\_\_\_\_\_\_\_**

**Sponsor Protocol No. \_\_\_\_\_\_\_\_\_\_\_\_**

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

|  |  |
| --- | --- |
| University of Texas \_\_\_\_\_\_\_\_\_\_\_\_  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                 Name  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Licensee  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                 Name  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

PRINCIPAL INVESTIGATOR:

Read and Understood:

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
      [Name]Principal Investigator

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**SCHEDULE A**

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**SCHEDULE B**

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**SCHEDULE C - BUDGET**

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**ADDENDUM to the   
CLINICAL TRIAL RESEARCH AGREEMENT ("AGREEMENT") between  
THE UNIVERSITY OF TEXAS ("UNIVERSITY") and  
("SPONSOR")**

Sponsor and Institution have agreed to the following modifications to the Agreement:

1. Section 4.C. shall be amended in full to read as follows:

C. All data and Case Reports relating to the Research shall be owned by the Sponsor and the Institution. The Sponsor may use or transfer the same for any lawful purpose in a manner not inconsistent with this Agreement with no further payment to the Institution. The Institution may use the data it generates hereunder in accordance with this Agreement and for the education and research purposes of a university. The Sponsor may transfer its ownership rights; the Institution's ownership rights cannot be transferred and cannot be used to transfer title to the data.

2. Section 6.A. shall be amended by the deletion in line 4 of the words "or developed by."

3. Section 6.D. shall be amended by the substitution in line 3 of the word "misconduct" for the word "fraud".

4. Section 7 shall be amended by the substitution in line 2 after the word "not" of the words "contain Sponsor's Information" for the words "constitute a violation of Article 6".

5. Section 8.D. shall be amended by the substitution in line 7 after the word "by" of the words "an appropriate method of" for the words "arbitration or".

6. Section 12.A. shall be amended in full to read as follows:

A. Sponsor shall defend, indemnify and hold harmless the Institution, the Principal Investigator, The University of Texas System, their Regents, officers, agents and employees, from any and all liabilities, claims, actions or suits 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 of the Research, provided however:

7. Section 12.A.(4). and (5.) shall be amended by the addition in line 1 after the word "Sponsor" of the words ", subject to the statutory duty of the Texas Attorney General,".

8. Section 12.C. shall be amended by the addition in line 2 after the word "other of the word "Institution" and by the substitution in line 3 of the word "Regents" for the word "trustees".

9. Section 12.F.(1.) shall be amended by the substitution in line 2 of the amount $500,000 for the first appearance of the amount of $1,000,00, and the substitution of the words "$250,000 per person" for the words "$1,000,000 per accident;".

Section 12.F.(2.) shall be amended by the substitution in line 2 of the amounts "$100,000" for both the first and second occurrences of the amounts of "$500,000".

(11/91)