

CLINICAL TRIAL AGREEMENT (DRAFT)

This Clinical Trial Agreement ("Agreement") is entered into by and between _____ with principal offices located at _____ (hereinafter referred to as "Sponsor") and the Rosalind Franklin University of Medicine and Science, with principal offices located at 3333 Green Bay Road, North Chicago, Illinois 60064-3095 (hereinafter referred to as "RFUMS") is effective as of the date of full execution.

WHEREAS, Sponsor desires to have a clinical trial investigation supervised by and conducted at RFUMS; and

WHEREAS, RFUMS has expertise in, and has the facilities for, conducting clinical trial investigations; and

WHEREAS, the clinical trial contemplated by this Agreement is of mutual benefit to RFUMS and to Sponsor, and will further RFUMS's educational and research objectives in a manner consistent with its status as a non-profit, tax-exempt, educational institution;

NOW THEREFORE, in consideration of the covenants and agreements stated herein, the parties agree as follows:

1. SCOPE OF WORK

- A. RFUMS shall use procedures that protect the rights and welfare of the participants in the human research project and exercise its reasonable best efforts to carry out the clinical trial investigation ("Study") of "... ("Study Material") set forth in Protocol Number _____, entitled "_____" ("Protocol"), which is attached hereto as Exhibit A and incorporated herein by reference, and any subsequent amendments to the Protocol, in accordance with this Agreement. Sponsor represents to and assures RFUMS that the manufacture and/or formulation of any investigational or unlicensed test articles conform to federal regulations.
- B. RFUMS's principal investigator is _____ ("Principal Investigator"), who will be responsible for the direction of the Study in accordance with applicable RFUMS policies and the Protocol. If for any reason, he/she is unwilling or unable to continue to serve as Principal Investigator and a successor, acceptable to RFUMS and Sponsor, is not available, this Agreement shall be terminated as provided in Article 13, herein.
- C. The Study will be conducted in accordance with the Statement of Investigator (FDA Form 1572) (if applicable), with the Protocol, and with all applicable laws, rules, regulations and guidelines relating to the conduct of human subject research and clinical investigations, including, without limitation, 45 CFR Part 46 and 21 CFR Parts 50, 54, 56, and 312 (hereinafter, "Applicable Laws").

2. AGREEMENT TERM

The term of this Agreement shall be from the day of full execution until _____ ("Agreement Period"), unless mutually agreed otherwise by the parties hereto in writing.

3. STUDY DATA AND RESULTS

Principal Investigator shall provide Sponsor, in writing, with all requested data and results directly arising from performance the Study, at such intervals as Sponsor shall reasonably request. Sponsor shall have free access to the laboratory and clinical data which is generated as a direct result of performing the Study as contemplated in the Protocol, *provided that*, the confidentiality of all Study subjects shall be maintained in accordance with any and all Applicable Laws and RFUMS's institutional policies. The case report forms to be completed by RFUMS and delivered to Sponsor shall be the sole property of Sponsor and, subject to Sponsor's confidentiality obligations under Article 7, Sponsor may use without restriction all information contained therein. Study records, including either the original or a copy of patient informed consent forms, shall be retained in accordance with the requirements of Applicable Laws (e.g., when applicable, 21 CFR 312.62).

In Studies where the Sponsor bears any level of responsibility for Study monitoring, the Sponsor shall promptly report to the RFUMS Principal Investigator any and all findings that could affect the safety of Study subjects or their

willingness to continue participating in the Study, that could influence the conduct of the Study, or that could alter the IRB's approval to continue the Study.

In Studies where the safety or medical care of Study subjects could be directly affected by the Study results, the Sponsor shall communicate the Study results to the RFUMS Principal Investigator, who will then communicate such information to the Study subjects.

To the extent required by federal law, RFUMS and the Sponsor agree to comply with the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. Section 1320d ("HIPAA") and any current and future regulations promulgated there under, including without limitation, the federal privacy regulations, the federal security standards, and the federal standards for electronic transactions, all collectively referred to herein as "HIPAA Requirements." The parties agree not to use or further disclose any Protected Health Information or Individuality Identifiable Health Information, other than as permitted by HIPAA Requirements and the terms of this Agreement.

4. INSPECTIONS

In the event regulatory agencies and/or representatives of Sponsor wish to inspect a Study site either during or after conclusion of the Study, RFUMS agrees to allow such inspections at mutually agreeable times, and if reasonably requested, assist the inspectors and representatives in their activities; provided, however, such inspections shall be allowable for a period of time not to exceed two (2) years following any FDA approval (e.g., marketing approval and labeling approval) or the conclusion of the Study, whichever occurs last.

5. DEBARMENT CERTIFICATION

RFUMS hereby certifies that it has not been and is not currently debarred under Section 306(a) or 306(b) of the Federal Food, Drug and Cosmetic Act.

6. PAYMENTS

A. Sponsor agrees to pay RFUMS a maximum of \$_____ for this Study (based on _____ Study subjects accrued). Payments are to be made as follows:

B. All Payments required hereunder shall be made payable to :

Rosalind Franklin University of Medicine and Science
Attn: Dora Espinosa, Director Office of Sponsored Research
3333 Green Bay Road, Room 1.325
North Chicago, Illinois 60064-3095

Taxpayer ID# 36-2181973

7. CONFIDENTIAL INFORMATION

A. The parties agree not to disclose or to use for any purpose other than performance of the Study any and all trade secrets, privileged records or other confidential or proprietary information (collectively "Confidential Information") disclosed to the other party pursuant to this Agreement. To be deemed "Confidential Information," such information must have been disclosed in writing and clearly marked as "confidential", or if graphic or oral, reduced to writing within thirty (30) days of disclosure and clearly marked as "confidential". The obligation of non-disclosure and non-use shall not apply to the following:

- (1) Information that is publicly available or later becomes publicly available through means other than the unauthorized disclosure by recipient;
- (2) Information that is in the possession of recipient at the time of disclosure as evidenced by recipient's contemporaneous written records;
- (3) Information that is disclosed to the recipient by a third party without recipient's knowledge of a breach of a duty to the disclosing party;
- (4) Information necessary to obtain IRB approval of the Study or information which must be included in the Study subject's written information summary and/or informed consent form;
- (5) Information that is independently developed without use of disclosing party's confidential information as evidenced by recipient's contemporaneous written records;

- (6) Information ordered disclosed by any governmental authority or otherwise by any statute, regulation or decree (after providing the disclosing party with reasonable notice of such requirement to divulge and with an opportunity to obtain a protective order);
- (7) Information that is published or otherwise disclosed in accordance with the Publications section of this Agreement, Article 8.

- B. The obligations of non-disclosure and non-use under this Article shall survive and continue for three (3) years following expiration or termination of this Agreement.
- C. In the event Sponsor shall come into contact with a Study Subject's medical records, said Sponsor shall hold in confidence the identity of the Study subject and shall comply with all applicable law(s) and institutional policies regarding the confidentiality of such records.

8. PUBLICATION/PRESENTATIONS

RFUMS shall have the right, consistent with academic standards, to publish the data and/or results of the Study.. Prior to such intended publication, RFUMS will provide a period of fifteen (15) days for presentational materials and abstracts or a period of thirty (30) days for manuscripts for the Sponsor to review and comment. The Sponsor acknowledges its responsibility to evaluate such intended publications for their accuracy, to ascertain whether Confidential Information is being inappropriately released, to provide the Principal Investigator with information which may not yet have been available to him/her, and to provide input from co-authors regarding content and conclusions of the publication or presentation. If requested in writing and with reasonable justification, RFUMS will withhold publication for an additional thirty (30) days to protect the potential patentability of any invention described therein.

Notwithstanding the foregoing, RFUMS agrees that if the Study is part of a multi-center study, the first publication of the results of the Study shall be made in conjunction with the results from the Investigators at the other study centers as a multi-center publication unless specific written permission is obtained in advance from Sponsor to publish separate results. Sponsor shall advise as to the implications of timing of the publication in the event clinical trials are still in progress at sites other than at the RFUMS.

If the above described collaborative multi-center publication or presentation does not occur within twelve (12) months following completion of the Study, RFUMS shall have access to all data from all sites and shall be free to publish its results in accordance with this Article 8. The one-year delay in publication or presentation shall be waived if the Principal Investigator has a good faith belief that the publication and presentation should not be delayed for reasons of public health, safety, or public welfare.

9. INVENTIONS AND PATENTS

Except as prohibited by federal or state law:

- A. RFUMS agrees to notify Sponsor in writing of any invention made by RFUMS hereunder within thirty (30) days after receipt of an invention disclosure from the inventor. If the work performed by RFUMS personnel during the Study results in an invention, the inventorship shall be determined according to US Patent Law. If RFUMS personnel are legally determined to be inventors, they shall assign their rights to RFUMS according to RFUMS policy.
- B. In consideration of the compensation and indemnification provided to RFUMS hereunder, RFUMS shall grant to Sponsor a royalty-free, exclusive, worldwide license to make, sell, or use any invention relating to the use of Study Materials as described by the Protocol in Exhibit A. This license shall not apply to inventions relating to novel uses of Study Materials falling outside the scope of the Protocol.
- C. During the term of this Agreement and for a period of twelve (12) months thereafter, Sponsor shall have an option to acquire a royalty bearing worldwide, exclusive license, including the right to sublicense, to make, use and sell Study Materials under all of RFUMS's right, title and interest in all intellectual property rights relating to novel uses of the Study Materials. Any such option shall be exercisable for a period of one hundred and eighty (180) days after RFUMS notifies Sponsor in writing of each invention or discovery resulting from the Study.

- D. Patent applications shall be filed jointly in the names of Sponsor and RFUMS, if jointly invented, or solely in the name of Sponsor or RFUMS if solely invented. Except as provided below, each party shall bear the full responsibility and expense of all filing, prosecution, and maintenance costs for all patent applications and issued patents relating to the subject matter of which it owns the entire right, title, and interest as set forth above. Any joint patent application or any patent application considered necessary by Sponsor to protect its proprietary position shall be prepared and filed by Sponsor at its expense. If Sponsor elects not to file or maintain an application or patent in any country, which application or patent arises from the Study, Sponsor shall promptly notify RFUMS and RFUMS shall have the right to file or maintain these applications or patents.
- E. Except as expressly set forth herein, neither party claims by virtue of this Agreement any right, title, or interest in any issued or pending patents owned or controlled by the other party or any invention, process, or product arising out of the other party's previous research or development, whether or not patented or patentable.

10. INDEMNIFICATION

- A. Sponsor agrees to indemnify, defend and hold harmless, and pay all reasonable legal or other costs or losses incurred by the Principal Investigator and RFUMS, its trustees, officers, agents, employees, students, and affiliates involved in the Study ("Indemnitees"), from and against any and all claims, damages, liabilities, losses, costs, expenses (including reasonable attorney fees) and legal actions ("Claim") arising out of any activities carried out pursuant to this Agreement and the Protocol including death, property damage and the use by Sponsor of the Study's results.
- B. Sponsor's indemnification shall not apply to the extent that such claim is attributable to the negligence or willful misconduct of the Indemnitees.
- C. No change in the Protocol shall be made by RFUMS or Principal Investigator, except pursuant to Applicable Laws and RFUMS policies relating to the safety of research subjects that require a deviation from the Protocol (hereinafter, "Deviation"), in which case RFUMS shall promptly notify Sponsor of the facts necessitating such Deviation as soon as the facts are known to RFUMS. Such a Deviation shall not be considered negligence, recklessness or willful misconduct and shall not preclude Sponsor's indemnification obligations hereunder.
- D. RFUMS will promptly notify Sponsor in writing upon learning of any Claim subject to this indemnification. RFUMS will cooperate in assisting Sponsor in presenting a defense, if so requested. Sponsor agrees to pay all out-of-pocket expenses for this cooperation.
- E. Sponsor agrees that it maintains a policy or program of general liability insurance or self-insurance, in amounts not less than \$3,000,000 per occurrence and \$5,000,000 aggregate for bodily injury, including death and property damage. Sponsor agrees to provide RFUMS evidence of such coverage at RFUMS's request. Sponsor will provide to RFUMS thirty (30) days prior written notice of any cancellation in its coverage.

11. SUBJECT INJURY

Sponsor agrees to provide compensation or reimbursement to a Study Subject directly for the reasonable costs of all reasonably necessary diagnostic procedures and medical treatment for any research-related injury, which is defined as any injury directly resulting from a research procedure, including but not limited to the use of an experimental item.

12. PUBLICITY

Neither party shall use the name of the other party or of the Principal Investigator, any staff member, employee or student of the other party or any adaptation thereof, nor issue any public statement about this Agreement, including its existence, without the prior written permission of the other party, except as required by law. Such prior permission shall not be unreasonably withheld. The parties agree that in order for RFUMS to satisfy its reporting obligations, it may identify Sponsor as the Study sponsor and the amount of funding received.

13. TERMINATION

- A. Either party may terminate this Agreement at any time in its sole discretion upon thirty (30) days prior written notice to the other party, except when the reason for termination concerns patient safety, in which case the Study may be terminated immediately.
- B. In the event of early termination of the Study: (1) all unused Study Materials shall be returned to Sponsor at the sole expense of Sponsor and Sponsor shall reimburse RFUMS for all actual costs and non-cancelable obligations reasonably incurred prior to the date of termination; and (2) the final payment for such Study will be calculated based on the number of evaluable completed subjects, with a prorated allowance for those still in the Study but only partially completed at the time of discontinuation less any amounts already paid by Sponsor. If the amount already paid by Sponsor exceeds total the amount payable to RFUMS for a Study under this Agreement, then the difference must be returned to Sponsor within sixty (60) days of the date of termination.
- C. Sponsor shall also reimburse RFUMS for all additional costs incurred after the termination date required to fulfill regulatory requirements; provided however, that Sponsor shall not pay any such costs incurred after thirty- (30) days from the date of termination.
- D. In the event of termination of this Agreement prior to completion of a Study, RFUMS and Principal Investigator shall use all reasonable efforts to minimize further costs.
- E. In the event of termination of this Agreement prior to the completion of a Study, RFUMS shall be free to publish its results in accordance with the provisions of Article 8.

14. NOTICE

Whenever any notice is to be given pursuant to this Agreement, it must be in writing and sent to the address set forth below, or such other address as is subsequently specified in writing. Such notices shall be deemed given on the date of receipt.

If to Sponsor:
XXX

**If to Rosalind Franklin University:
For Administrative (Contract) Matters:**

For Medical/Scientific Matters:

Office of Sponsored Research
3333 Green Bay Road, Room 1.113
North Chicago, IL 60064
Attn: Dora Espinosa
(847) 578-8524

Principal Investigator
XXX
XXX

15. APPLICABLE LAW

This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of Illinois. In the event of a dispute hereunder, the parties agree to submit to the exclusive jurisdiction of the state courts of, and the federal courts sitting in, the State of Illinois.

16. INDEPENDENT CONTRACTORS

It is understood and agreed that in connection with their performance under this Agreement and any Letter Agreement, RFUMS and Principal Investigator (and their respective agents and employees) shall be acting as independent contractors and not agents or employees of Sponsor.

17. COUNTERPARTS

This Agreement may be executed in counterparts, each of which shall be deemed an original, but each of which shall constitute one and the same instrument.

18. SURVIVAL

The provisions of Articles 3, 6, 7, 8, 9, 10, 11, 12, 14 and 21 shall survive the expiration or termination of this Agreement.

19. ASSIGNMENT

Neither party shall assign its rights or obligations hereunder to any third party without the prior written consent of the other party.

20. ORDER OF PRECEDENCE

In the event of a conflict or inconsistency between the terms of this Agreement and the terms of the Protocol, the terms of this Agreement shall govern.

21. NEGATION OF WARRANTY

Except as expressly stated herein, RFUMS MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, RESULTS OF THIS STUDY OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF SUCH RESULTS, OR ANY PRODUCT OR PROCESS BASED THEREON. EXCEPT AS EXPRESSLY STATED HEREIN, RFUMS SHALL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL, OR OTHER DAMAGES SUFFERED BY SPONSOR OR OTHERS AS A RESULT OF THE STUDY.

22. ENTIRE AGREEMENT

This Agreement represents the entire understanding of the parties with respect to the subject matter hereof. The invalidity or enforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof. The terms and conditions herein constitute the entire Agreement between the parties and supersede all prior oral or written agreements on the subject matter hereof. Said terms and conditions may not be waived or amended, except by a written instrument duly executed by both parties hereto.

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

SPONSOR

RFUMS

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

Read and Understood:

By: _____

Name: _____

Title: Principal Investigator

Date: _____