TEMPLATE
UCONN HEALTH CENTER
CLINICAL RESEARCH AGREEMENT

This Agreement is made by and between:

The_____ (state business or entity type) having a business address at_____,

and

The University of Connecticut Health Center, an agency of the State of Connecticut, having a business address at 263 Farmington Avenue, Farmington, Connecticut, 06030.

RECITALS:

Whereas, the _____ and the University of Connecticut Health Center herein referred to "UConn Health" have a desire to investigate the (state purpose and description)_____and

Whereas (Principal Investigator) of the University of Connecticut Health Center (UConn Health) has filed an Investigational New Drug Application (IND) with the United States Food and Drug Administration (FDA) pertaining to the purpose; and

Whereas, the (name of funding agency) has the ability to supply funding to support the Purpose; and

Whereas, the (name of funding agency) and UConn Health agree to work collaboratively to achieve the Purpose under the terms and conditions set forth in this agreement.

1.0 DEFINITIONS:

"Sponsor-Investigator", hereafter "Sponsor" refers to UConn Health and (Principal Investigator), described *infra*, as the Principal Investigator and all its applicable subsidiaries, business entities, and constituents involved in this Study. Pursuant to 21 C.F.R. §312.50, "Sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND, maintaining an effective IND with respect to the investigations, and ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug."

"**Institution**" refers to UConn Health, and its Investigator(s) and employees.

Principal Investigator" refers to _____(name of investigator), the principal researcher conducting and managing the research, as well as the author of the protocol, and the holder of the Investigational New Drug "IND." The project and all work assignments shall be carried out under the direction of _____ (investigator name), hereinafter referred to as the Investigator, while employed by Institution and by others (e.g. technicians, graduate students, postdoctoral fellows, nurses, staff assistants, hereinafter collectively referred to as Personnel) as assigned by the Investigator.

"Funding Agency" refers to the_____ who will provide the following:_____

"Materials" refers to_____supplied by Sponsor to the Principal Investigator for use in the study.

"Study" refers to the project entitled_____ "project name"

"**Subject**" includes, but not limited to, any participant who signs a consent form to participate in the study described herein and/or receiving the applicable intervention, specifically those receiving the Materials and those for whom tests will be conducted by the Investigator and his/her employees at Institution or by the Agency.

"Party" may include either the Institution (UConn Health) or Sponsor or Funding Agency. The term "**parties"** may be used as a collective term to include both the Institution and the Sponsor.

"Agreement" refers to the clinical trial agreement which sets forth the terms and conditions of the study entitled:

IT IS AGREED:

2.0 Description of Study and Scope of Services

A. Institution agrees to undertake certain research (hereinafter referred to as the Study) specifically described in the attached protocol (Appendix A) which by reference is incorporated into this Agreement and such other work as may be mutually agreed upon in a duly executed amendment to this Agreement

Number of subjects:

Study Population:

Investigational drug:

The description and payment of services will be described in the budget, attached herewith to
this Agreement as Exhibit _____.

B. The Funding Agency, will conduct the following services:

3.0 Duration

The investigation covered by this Agreement shall begin on _____the "Effective Date" and continue until the study has been completed or termination of the study pursuant to Section 14.

4.0 Facilities

Institution agrees to furnish such available facilities as it shall determine necessary for the work to be done on this project except for that which may be awarded as part of this Agreement. During the term of this Agreement, Institution and the Principal Investigator will permit, upon reasonable notice and at reasonable times, representatives of Funding Agency to observe research facilities used for and research performed by the Principal Investigator pursuant to this Agreement. Inversely, Funding Agency agrees to furnish such available facilities as it shall determine necessary for the work to be done on this project except for that which may be awarded as part of this Agreement. During the term of this Agreement, Funding Agency and the will permit, upon reasonable notice and at reasonable times, representatives of Sponsor to observe research facilities used for and research performed by the Funding Agency pursuant to this Agreement.

5.0 Payment

Funding Agency agrees to pay Institution the accordance with the attached budget (Attachment X). Payments are to be made as follows:

Payee Name:
University of Connecticut Health Center

Checks made payable to:
263 Farmington Avenue
Farmington, CT 06030-5335
Attn: David Larkin
Tax ID No. 52-1725543

Telephone: 860-679-8816
Fax: 860-679-4014

6.0 Funding Agency

The Principal Investigator shall furnish written reports on the progress of the work on dates mutually agreed upon and a final report on the entire Project within ninety (90) days after termination of this Agreement. Pursuant to 21 C.F.R. § 312.33, the Investigator must submit a yearly report to the Food and Drug Administration (FDA). Specifically, 21CFR §312.33, which includes, but not limited to the following mandates: "[a] sponsor shall within 60 days of the anniversary date that the IND went into effect, submit a brief report of the progress of the investigation that includes: (a) Individual study information. A brief summary of the status of each study in progress and each study completed during the previous year. "

7.0 Publications

The data and information accruing from the project may be published by the Sponsor-Investigator, but Funding Agency shall be provided with a copy of any proposed publication prior to submission and shall have thirty (30) days for

review of patentable items deemed confidential and proprietary as defined in Article 8.0.authorship of articles will be in compliance with the guidelines of the International Committee of Medical Journal Editors (ICMJE).

7.2 Funding Agency shall not disclose to others or publish any information disclosed to the Funding Agency by Sponsor which is confidential within the meaning of Article 8.0 without the prior written approval of the Sponsor.

8.0 Confidentiality

Institution agrees to hold in confidence all information "Confidential Information" which Funding Agency may wish to disclose to Principal Investigator in writing and marked "CONFIDENTIAL" under this Agreement except:

a. information which at the time of disclosure is in the public domain;
b. information which after disclosure is published or otherwise becomes part of the public domain through no fault of the Investigator; or
c. information which was in the possession of the Investigator at the time of disclosure and was not acquired from the Sponsor under an obligation of confidence;
d. information which is required to be disclosed by law.
e. information that was independently developed by the Institution

9.0 Intellectual Property

Each Party shall retain all right, title and interest in or to its materials, patents, patent applications, intellectual property and confidential information in existence as of the effective date of this Agreement and shall be free to utilize such materials, patents, patent applications, intellectual property and confidential information in its sole discretion and without limitation. Except and only to the extent necessary for the performance of the Study, neither Party is granted any license, express or implied, under or to any materials, patents, patent applications, intellectual property and confidential information of the other Party.

9.1 Inventions

For the purposes of this Agreement, an "Invention" is any invention or discovery, whether patentable or non-patentable, that is invented in the course of the Study. Inventorship of Inventions will be determined in accordance with principles of U.S. patent law. In the case of a non-patentable Invention, inventor ship will be determined under such principles by treating such Invention as if it were patentable. If an Invention is made solely by one or more Institution inventors, that Invention shall be the property of Institution. If an Invention is made solely by one or more Funding Agency inventors, that Invention shall be the property of Funding Agency. In the event that an Invention is made by at least one inventor from Institution and at least one inventor from Funding Agency, the Invention shall be jointly owned by Institution and Funding Agency.

9.2 Patents and Licensing

In the case of solely-owned Inventions, the preparation, filing and prosecution of patent applications and any licensing or other commercialization activities pertaining thereto will be at the owner's sole discretion and expense. The Parties agree to confer to reach a mutually acceptable course of action with regard to the patenting and licensing of any jointly owned Inventions.

10.0 Agents

Funding Agency and Sponsor agree that the Principal Investigator and Personnel are acting as employees of Institution/Sponsor.

11.0 Use of Name

No advertising or publicity matter having or containing any reference to Institution shall be used by Funding Agency except as approved by the Associate Vice President for Research Administration and Finance, Institution, in writing. Institution shall not use the name of Funding Agency in any advertising or publicity matter except as approved, in writing, by Sponsor.

Notwithstanding the preceding restrictions, Institution/Sponsor may disclose the sponsorship, title, duration and total budget of this project in Institution's "Annual Report of Research and Scholarly Activity," and in such other reports as may be required by the Institution's Board of Trustees or by the Board of Governors of Higher Education.

12.0 Amendments

All amendments to this Agreement must be in writing and signed by both parties.

13.0 Termination

13.1 Either party may terminate this Agreement by giving thirty (30) days written notice to the other party, unless thirty (30) days is not practical or reasonable to terminate subjects from the study.

13.2 Upon termination of this Agreement, unexpended funds appropriated by Funding Agency to Institution/Sponsor shall be returned to Funding Agency except for outstanding, unpaid commitments that cannot be canceled or otherwise terminated.

14.0 Indemnification

Funding Agency agrees to indemnify, defend, and hold harmless UConn Health (Institution), its trustees, officers, agents, and employees, against any third party claims, suits, or judgments which may be made or instituted against them or any of them by reason of personal injury (including death) to any person or damage to property arising out of or connected with the performance of activities to be carried out pursuant to

and in accordance with this Agreement. As a part of the indemnification described herein, Funding Agency agrees to pay all legal and other costs or losses incurred by Principal Investigator and Personnel, as investigator(s) in this study, and Institution as the host Institution, against any claim or legal cause of action brought against Investigator, Personnel, and Institution arising out of the use by Funding Agency , or by any party acting on behalf of or under authorization from Funding Agency , sale or other disposition by Funding Agency , or by any party acting on behalf of or under authorization from Funding Agency of products made as a result of work conducted under this Agreement, provided, however, Funding Agency will not be responsible for any liability resulting from any loss or damage resulting from:

a. a failure to adhere to the terms of the protocol or Agency's written instructions relative to the use of the investigational drug;
b. failure to comply with any applicable FDA or other governmental requirements; or
c. negligence or willful malfeasance by Institution , its trustees, officers, agents, and employees is excluded from this Agreement to indemnify, defend, and hold harmless.

15.0 Applicable Law

This Agreement shall be governed by and construed according to the laws of the State of Connecticut.

16.0 Sponsors

This Agreement shall be binding upon and inure to the benefit of the respective parties and their successors. The parties hereto have caused this Agreement to be executed by duly authorized representatives effective as of the later date indicated below.

17.0 Clinical Trial Materials and Record Retention

Materials furnished for this Study will be used solely under the Protocol and may not be used for any other purposes. Funding Agency shall render any necessary special instructions to Institution regarding the handling of the Materials supplied. Parties shall be responsible for compliance with all laws and regulations (21CFR 312.62) applicable to any destruction or disposition of clinical trial materials. Funding Agency warrants that the materials provided do not infringe on any patent, copyright, trademark, or other proprietary rights. Sponsor also warrants that the materials provided are fit for a particular purpose

18.0 Insurance

Funding Agency shall maintain in full force and effect throughout the performance of the Study professional liability insurance in amounts appropriate

to cover its liability for any damage which may be caused as a result of fault or negligence regarding the provision or distribution of Materials and any third-party claims against Funding Agency pertaining to faulty materials or negligence in handling. Institution/Sponsor is a constituent unit of the University of Connecticut. As such, it is an agency of the State of Connecticut and is self-insured in an amount limited only by the ability of the State of Connecticut to satisfy any judgment arising from the operations of the Institution. Upon request, the Institution will provide a letter issued by the Connecticut Assistant Attorney General of the State of Connecticut's self-insurance.

19.0 Conflict of Interest

All parties involved in this Study will readily disclose any actual or potential conflicts of interest.

20.0 Force Majeure

Neither party will be liable for any failure to perform under this Agreement due to fire, flood, storm, earthquake, epidemic, war, national emergency, national disaster, interruption of transportation, or other causes beyond its reasonable control. In the case of a force majeure event, the affected party will promptly notify the other party of the event and how long any non-performance is expected to last.

21.0 Severability

In the event that any one or more of the provisions contained herein shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this agreement, but this agreement shall be construed as if such invalid, illegal or unenforceable provisions had never been contained herein, unless the deletion of such provision or provisions would result in such a material change so as to cause completion of the transactions contemplated herein to be unreasonable.

22.0 Compliance with Law

All parties will comply with applicable state and federal guidelines, specifically 21 C.F.R. §312.57, 21 C.F.R. §312.58, and 21 C.F.R. §312.59.

FUNDING AGENCY:

_____
_____

Name: Date
Title:

UNIVERSITY OF CONNECTICUT HEALTH CENTER:

_____
_____

Name: Date
Title: Associate Vice President for Research Administration and Finance

_____
_____

Principal Investigator Name: Date
Title: