CLINICAL SUPPLY AGREEMENT

THIS AGREEMENT, effective as of date of last signature below, is made by and between The National Heart, Lung and Blood Institute of The National Institutes of Health, Bethesda, MD 20892 ("NHLBI"), and _____ (“Company”), having a principal place of business at _____.

WITNESSETH

WHEREAS, NHLBI has established relationships with a Coordinating Center and Clinical Centers (collectively, “Institutions” and each individually, “Institution”) in the [----name of study-------].

WHEREAS, Company has developed a proprietary therapeutic compound, _____ (“Clinical Material”), which exhibits efficacious properties, and has been found useful in treating one or more disease conditions;

WHEREAS, NHLBI has selected the Clinical Material for use in conducting a study entitled “_____” (“Study”) to evaluate the Clinical Material for treating or preventing _____;

WHEREAS, the parties desire to arrange for the supply to NHLBI of certain quantities of Clinical Material and placebo for use in the Study solely for the research purpose as set forth herein and under the terms and conditions in [-----name of protocol-----], and

WHEREAS the parties understand that the Coordinating Center and Clinical Centers will have responsibility for performing much of the work in connection with execution of the Study.

NOW, THEREFORE, in mutual consideration of the promises and covenants contained herein, the parties agree as follows:

1. Supply of Clinical Material and Placebo.

   (a) Company will supply Clinical Material and placebo at no charge and in the manner, packaging, timing and delivery as mutually agreed upon in a separate writing. It is agreed that the Clinical Material will be used as provided in the Study Protocol.

   (b) NHLBI may use the Clinical Material supplied hereunder solely for conducting the Study in accordance with the Protocol. Upon conclusion, or earlier termination, of the Study, all unused Clinical Material will either be (i) promptly returned by NHLBI to Company, or (ii) lawfully destroyed by NHLBI (or NHLBI will ensure its lawful destruction by the responsible investigator, with written certification of same to be provided to Company). At such time(s) as may be requested by Company, NHLBI will complete and forward to Company its standard reconciliation documentation evidencing receipt, use and return of the Clinical Material during the Study at such times as requested by Company.

2. Protocol Changes. The parties must review and approve the Protocol in writing prior to initiation of patient enrollment.

The parties may revise the Protocol by negotiation and agreement thereto. Such revisions shall be evidenced by a revised and approved Protocol, agreed to by both parties in writing.

Insofar as amendments to the Protocol may be required prior to submission to investigational site IRBs, NHLBI shall provide all Protocol amendments to Company for its review and written acceptance ten (10) days prior to NHLBI's submission to the investigational IRB, including without limitation any modifications to the previously accepted form of Informed Consent.

For all other Protocol amendments, NHLBI shall provide thirty (30)-days prior notice to Company. Company shall accept or reject any proposed Protocol amendments in writing.

3. Cross-Reference. NHLBI will be responsible for performance of the Study and will conduct the Study under Company's corresponding Investigational New Drug Application ("IND"). As such, for purposes of complying with relevant regulatory requirements, including without limitation, Company's safety reporting and other obligations as set forth in Paragraph 4, Company is the Study Sponsor. Company will provide NHLBI with such additional information regarding the Clinical Material as may be reasonably necessary to conduct such Study, including, but not necessarily limited to, certificates of analysis, information on proposed storage conditions, product identification methods and reference material required to run the methods, packaging specifications and repass dates for such Clinical Material; provided, however, that Company shall not be required to provide NHLBI with qualitative formulation information, except to the extent deemed necessary by Company in its sole discretion.

4. Conduct of the Study. It is agreed that performance of the Study, as well as the receipt of all necessary NHLBI/IRB approvals, are solely within the control of NHLBI and that, except as expressly provided in paragraph 2 of this Agreement, Company has no role and may not exercise any control in connection therewith. During the course of the Study, NHLBI will provide to Company general information regarding the overall progress of the operational aspects of the Study, such as, without limitation, the rate of recruitment, but not detailed data on performance that goes to the data and safety monitoring board.

The Study and Protocol will be conducted in accordance with Food and Drug Administration ("FDA") regulations governing studies with investigational drug products (specifically 21 CFR 312.30, 31, 32, 33 and 40 and 21 CFR Subpart D). Company will be provided a "Transfer of Obligations" letter in accordance with 21 CFR 312.52, which sets forth each obligation held by NHLBI or an Institution for Company. Company will have the right to audit Study Institution sites and Study data management centers to ensure that the Study is being conducted in accordance with all applicable regulatory guidelines, including without limitation, 21 CFR 312.56. Company will promptly send NHLBI (or NHLBI's designated agent) a copy of all correspondence to or from the FDA related to the protocol until Company receives the complete data set specified below.

Company will be provided information regarding the Study within the time periods set forth herein or as otherwise agreed between the parties for Company to comply with all relevant regulatory guidelines governing Company's IND. Specifically, without limitation, Company will receive information in accordance with 21 CFR 312.53 for Company to review and

submit to the FDA. Neither Institution nor an investigator may receive Clinical Material until all information requested from that Institution or investigator in accordance with 21 CFR 312.53 has been received and approved by Company. On a monthly basis, Company will receive the number of patients recruited, and for each patient, demographic information (*e.g.*, race, sex, gender, age and disease classification).

No later than one hundred twenty (120) days after the data set is locked, Company will receive a complete data set in a form suitable for use by Company in completing a Clinical Trial Report ("CTR") for use as outlined in Section 6 (b). The parties agree that NHLBI will not provide unblinded Study data to Company during the performance of the Study, unless a safety issue develops.

5. Publications.

(a) Review and Comment. NHLBI will use its best efforts to ensure that Company has a reasonable opportunity to review and comment upon publications, written or oral, dealing with or reporting a material outcome or use of the Clinical Material prepared by NHLBI or any participating investigator or Institution submitted for publication or published within 12 months of providing or making available to Company the locked data set pursuant to paragraph 4 For publications that concern less substantive aspects of the Study, NHLBI may have less involvement, and commensurate best efforts may have less effect with the participating investigators and Institutions. The information is to be made available to Company and to be used only for the purposes herein set forth, as follows:

-- For proposed written publications, NHLBI will use its best efforts to provide Company with a copy of the proposed publication no later than 30 days prior to submission for publication, for written commentary by Company within 25 days after receipt.

-- For proposed abstracts or oral presentations, NHLBI will use its best efforts to provide Company with a copy of the proposed abstract or summary of the major conclusions and data points of the proposed oral presentation, respectively, no later than 10 days prior to submission for publication, for written commentary by Company within 6 days after receipt.

Company recognizes that prepublication manuscripts are made available to Company clinical/scientific/patent staff (who may be consultants or employees) to review and provide written comment for consideration of the writing committee, and to assess the patentability of any invention or discovery that might be disclosed by such publication. Company will treat such manuscripts as Confidential Information and ensure that such Confidential Information is disclosed only to personnel on a "need-to-know" basis, and thus, disclosure will be confined to a limited number of scientific and higher-level employees as discussed in Section 6(b). Promptly following NHLBI's learning of same, NHLBI will notify Company of the acceptance of any such manuscript or abstract for publication (and the accepting journal) and of the publication date.

(b) Use of Publications. Subject to Section 19 of this Agreement, once any such manuscript or abstract has been published, such publication or abstract may be used, copied and disseminated for any purpose as Company deems appropriate, without further obligation or liability to NHLBI.

(c) Recognition. The parties agree to recognize Company, NHLBI, Institutions and respective personnel employed therefor or associated therewith, in any publication. Such recognition shall be consistent with general professional understandings regarding authorship and organization identification and commensurate with the scope and significance of each respective party's contribution.

6. Access and Use of Data.

(a) No intentional efforts will be made by Company to identify individual participants in the Study. Contacts with participating Institutions about patients or patient records may be made for appropriate purposes but only upon reasonable terms agreed to with NHLBI (which consent will not be unreasonably withheld or delayed).

(b) Subject to the provisions of Sections 5 and 19 of this Agreement, Company may use Study data in support of corporate purposes, for use in obtaining regulatory approval for commercial marketing throughout the world for Clinical Material and for use in support of patent applications securing rights in the Clinical Material without further obligation to NHLBI.

7. Inventions.

(a) If Company believes that a publication or presentation would disclose a patentable invention or discovery for which a patent application should be and has not yet been filed, Company will notify NHLBI of same, in which event the parties will meet and confer promptly thereafter to determine inventorship and responsibility for filing and prosecuting any such application and for payment of the costs of same, and will use their best efforts to file an appropriate application in the United States and in foreign countries, if appropriate, prior to the publication or presentation date to avoid loss of any global priority rights in the patentable invention or discovery. If necessary, publication or presentation will be delayed for a period not to exceed 30 days to permit Company to secure priority rights. This delay period may be further extended by the parties' mutual agreement. If any participating Institution(s) and/or investigator(s) would be considered an inventor or co-inventor, NHLBI agrees to use reasonable efforts to secure the cooperation and assistance of such investigator and/or Institution to effect these ends.

(b) If in connection with the Study, a new invention (hereinafter "Invention") results from or in some manner utilizes the Clinical Material and/or its derivatives, Company will be promptly notified. Company, NHLBI, and the Institution employing the inventor(s) will jointly make all necessary determinations as to inventorship, in accordance with applicable laws regarding inventorship. If the Invention is already the subject of one or more

patent applications of Company or a pre-existing trade secret, Company shall so advise NHLBI, and if relevant, the Institution.

(c) Any Invention not previously invented by Company, shall be owned by the respective inventor(s), appropriate assignees, and NHLBI will use commercially reasonable efforts to achieve the result that participating Institutions and investigators grant to Company an exclusive license to use, practice and exploit any such invention or discovery for any purpose on reasonable terms and conditions to be negotiated at such time a patent application is filed.

8. Adverse Events. At Company's request, complete information relating to adverse events associated with the Clinical material will be provided to Company within thirty days of occurrence of an adverse event. However, if an adverse event is determined to be serious and unexpected, Company will be notified of the event within 48 hours of the event occurrence and will be provided a written report within five days of first notification. In addition, if the adverse event is determined to be fatal or life-threatening, Company will be notified of the nature and scope of the event within two business days of the event occurrence and will be provided a written report within 48 hours of first notification. For the purposes of this section, "serious", "unexpected", "associated with the use of the drug", and "life-threatening", are defined in 21 CFR 312.32. Company and NHLBI will collectively agree on the nature and scope of any public announcement prepared in connection with an adverse event; provided that in the event the parties cannot agree on the nature and scope of the public announcement, the parties agree that such non-agreement will not preclude independent announcement by each party.

9. Liability. Each party to this Agreement shall be liable for the acts or omissions of its own employees, agents or contractors. No indemnification is intended or provided hereunder. The NHLBI have no authority to indemnify Company.

Should a Study subject suffer any injury related to the Clinical Material, Company shall provide or arrange to provide, medical care to treat such injury, and shall if necessary and relevant, reimburse NHLBI or any participating investigator or Institution for any medical care and related costs incurred by any of them to treat or care for such subject's injuries, except to the extent such injuries are attributable to negligent acts or omissions of NHLBI or the Institution, its employees, agents or contractors or the investigator. This Agreement is not intended to limit any other available remedies at law.

10. No Implied Rights. Nothing herein shall be construed as granting NHLBI the right or license to use any existing or future patent rights, copyrights, marks or other intellectual property rights of Company, except as needed to conduct the Study. Nothing herein shall be construed as granting Company the right or license to use any existing or future patent rights, copyrights, marks or other intellectual property rights of NHLBI.

11. Confidentiality. Each party shall maintain in confidence, and shall neither disclose to any persons or entities (other than employees, agents or contractors of a party who are obligated to keep same in confidence) or use for its own purposes or that of any third party (except in furtherance of this Agreement), any confidential or proprietary information

or data ("Confidential Information") received from another party in connection with this Agreement and the Study conducted hereunder. Such Confidential Information shall be clearly marked "Confidential." Confidential or proprietary information or data shall not be considered Confidential Information if such information: (a) was known to the receiving party prior to receipt of same from the other party, as shown by competent written evidence; (b) becomes generally available to the public, without fault of the receiving party; (c) is received without restriction as to confidentiality by the receiving party from a third party not affiliated with the receiving party; (d) is independently developed by the receiving party without regard or access to the information or data received by the disclosing party; or (e) is released from confidential status by the disclosing party. A party may also disclose such information to the extent required by law, and in such event, will endeavor to obtain such confidential treatment for same as is permitted by law.

12. Force Majeure. No party shall be liable or considered in default or breach hereunder for any failure or delay in performance under this Agreement which is due in whole or in part, directly or indirectly, to any cause of any nature beyond the reasonable control of such party, including, without limitation, the following: fire, explosion; earthquake; storm; flood; strike; lockout; transportation difficulties; failure to obtain necessary supplies or material; activities of a combination of workmen or other labor difficulties; war; insurrection; riot; act of God or the public enemy; change or adoption after the date hereof of any law, act, regulation, rule, decree or ordinance of any applicable governmental or governmental authority, judgment or decree of a court of competent jurisdiction. In the event of the happening of such a cause, (i) a party will give prompt written notice to the other parties stating the period of time the same is expected to continue, and shall take all reasonable measures to ensure that the effects of such cause of force majeure are kept as minimal as possible; and (ii) any applicable period provided for in this Agreement for the fulfillment of such obligations shall be deemed extended by the period of time during which said cause of delay shall continue.

13. Termination.

(a) This Agreement shall commence upon execution by all parties hereto and shall terminate upon the conclusion of the Study or upon early termination of the Study (or that portion of the Study involving the Clinical Material) by NHLBI. This Agreement may also be sooner terminated, as follows:

(i) as expressly provided herein;

(ii) by mutual written agreement of NHLBI and Company; or

(iii) if either party defaults in the performance of or fails to be in substantial compliance with an obligation hereunder, and such default or noncompliance, if curable, shall not have been remedied to the other party's reasonable satisfaction within sixty (60) days after receipt by the defaulting party of a written notice thereof from the other party, the party not in default may, at its option, terminate this Agreement.

(b) No party shall be liable for termination of this Agreement in accordance with the terms hereof. Upon any termination or expiration of this Agreement, the rights and obligations of the parties hereunder shall cease, except for a party's responsibilities under Paragraphs 1(b), 5, 6, 7, 8, 9, 10, 11, 14, and 19 hereof. However, if NHLBI terminates the Agreement pursuant to a default by Company pursuant to paragraph 13(a)(iii) (and provided that NHLBI is not itself in default under this Agreement), then the continuing rights and responsibilities of all parties are only those under Paragraphs 1(b), 7, 8, 9, 10, 11, 14 and 19 hereof. All causes of action available to a party based upon any acts or omissions of another party occurring prior to termination or expiration shall survive.

14. Miscellaneous.

(a) 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.

(b) This Agreement constitutes the full understanding of the parties and a complete and exclusive statement of the terms of their agreement. No terms, conditions, understanding or agreement purporting to change or supplement the terms of this Agreement will be binding unless hereafter made in writing and signed by all parties.

(c) If any provision (or part thereof) of this Agreement shall be held unenforceable, the remainder of this Agreement (or such provision) shall nevertheless remain in full force and effect to the maximum extent permitted by law.

(d) Each party hereto agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

(e) All notices required by this Agreement shall be in writing. All notices and reports shall be made by personal delivery, telex or certified or registered mail, return receipt requested, or by such other method capable of providing reasonable proof of receipt thereof, and addressed to the parties at the addresses set forth above or to such other addresses as may be designated hereafter in writing by the respective parties and to the attention of the following individuals:

If to Company:

If to NHLBI:

Any notices shall be deemed given when received by the other party.

(f) All parties are independent contractors with the other parties under this Agreement. Nothing contained in this Agreement is intended nor is to be construed so as to constitute the parties as partners or joint venturers with respect to this Agreement. No party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of any other party to any other contract, agreement or undertaking with any third party.

(g) The construction, validity, performance and effect of this Agreement shall be governed by Federal law, as applied by the Federal Courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement.

(h) This Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. If this Agreement is executed in counterparts, no signatory hereto shall be bound until each of the parties named below shall have duly executed or caused to be duly executed a counterpart of this Agreement.

(i) NHLBI will ensure that each participating Institution and investigator in the Study is fully informed of and accepts paragraph 9 of this Agreement and that they inform research subjects of the potential liability. NHLBI will use commercially reasonable efforts to ensure that each participating Institution and investigator in the Study abides by (i) all other terms and conditions of this Agreement and (ii) the terms and conditions of the Study that are pertinent to their responsibilities and activities in the Study.

(j) The captions appearing in this Agreement are for reference purposes only and shall not be considered a part of this Agreement. Such captions shall not modify, amend or affect the provisions hereof. This Agreement shall not be strictly construed against any party hereto.

15. Record Keeping. NHLBI, Institutions and investigators will all retain records associated with Study for a period of two years following the date a marketing application submitted by Company is approved, or if no application is filed or approved, for two years after the investigation is discontinued by Company and the FDA is notified in accordance with 21 CFR 312.62. NHLBI must notify Company before any records are destroyed and Company will authorize the disposition of the records.

16. Regulatory Authority Inspection. NHLBI, Institutions and investigators will permit FDA or other regulatory authorities to inspect its site and records associated with Study. Company will provide notice to NHLBI within 24 hours of notice to Company when prior notice is

supplied by the regulatory authorities. If regulatory authorities inspect NHLBI sites and records associated with Study without prior notice to Company, NHLBI will notify Company immediately of the inspection. NHLBI, Institutions, and investigators will permit Company personnel to be present during any investigation. NHLBI will also permit Company personnel to participate in preparing any site for a scheduled investigation, including interviewing staff with prior notice by the Company.

17. Annual Report. Company is required to submit Annual Reports to the FDA in accordance with 21 CFR 312.33. Subject to the provisions of Section 4, NHLBI will provide information requested by Company for preparation of the Annual Report within fourteen (14) days of Company's request.

18. Assignment. Company may assign this Agreement to Company's assigns, subsidiaries or successors in business.

19. Use of Name or Endorsements. By entering into this Agreement, NHLBI does not directly or indirectly endorse any product or service of the Company. Company shall not in anyway state or imply that this Agreement or actions under it are an endorsement of any such product or service by NHLBI, NIH, HHS or the United States Government.

IN WITNESS WHEREOF, the undersigned parties through their duly authorized representatives have executed this Agreement in multiple counterparts.

[_____]	**NATIONAL HEART, LUNG AND BLOOD INSTITUTE**
_____	_____
Signature	Signature
_____	_____
Printed Name	Printed Name
_____	_____
Title	Title
_____	_____
Date	Date