**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCONTRACT**

This Subcontract is made and entered into as of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ by and between Baylor College of Medicine located in Houston, Texas, hereinafter referred to as Baylor, and The University of Texas Health Science Center at Houston located in Houston, Texas hereinafter referred to as Subcontractor.

**WITNESSETH**

WHEREAS, Baylor has been awarded Grant Number 5 Uo1 AI27551-08 by the U.S. Department of Health and Human Services (DHHS) for the project titled “Pediatric AIDS Clinical Trials Program.”

WHEREAS, this grant provides funds for Subcontractor participation,

WHEREAS, Subcontractor processes the facilities, personnel and/or professional proficiency requisite to the conduct of the work contemplated by this subcontract,

AND WHEREAS, it is in the best interest of Baylor to obtain assistance of Subcontractor in the performance of the work required by the aforesaid grant.

Baylor and Subcontractor mutually agree as follows:

1. **Description of Work**

Subcontractor, as an independent contractor, not as an agent of the Government nor of Baylor, shall furnish all necessary labor (including salary and fringe benefits), facilities and equipment and shall exert its best efforts in carrying out the specific objectives set out in the application for Grant 5 U01 AI27551-08 and summarized in “Exhibit A”.

1. **Period of Performance**

Performance of this Subcontract shall begin on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_and shall not extend beyond the estimated completion date of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ unless the period is extended by amendment of the Subcontract. Subcontractor will undertake to complete the work indicated in “Exhibit A” during the contract period.

1. **Compensation**
	1. Maximum Actual Cost

The actual cost to Baylor, including all direct and indirect costs, for the performance of this work shall not exceed the estimated cost of $\_\_\_\_\_\_\_\_\_\_. Subcontract agrees to use its best efforts to perform all work and all obligations under this Subcontract within the estimated cost and the period of time set forth in paragraph 2.

* 1. Indirect Costs

Indirect cost for this Subcontract shall be reimbursed at the rate of 19.0% MTDC which you hereby represent is the negotiated indirect cost rate for your institution which has been approved by your cognizant audit agency. These are maximum rates.

* 1. Approved Budget

The approved budget is attached as “Exhibit B”.

* 1. Cost Determination

The allowability of costs shall be determined in accordance with the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 94-50,000 (Rev.) April 1, 1994; except that costs for Subcontractor’s independent research and development shall not be allowable.

* 1. Prior Authorization of Certain Direct Costs

Subcontractor can use its Institutional Prior Approval System where applicable provided that a copy of the approval is forwarded to Baylor. If subcontractor does not have an Institutional Prior Approval System, then all requests for any deviations from the approved budget should be sent to Baylor for review and approval.

* 1. Foreign Travel

Requests for foreign travel must be submitted at least six weeks in advance, and shall contain the following: (a) meeting(s) and place(s) to be visited, with costs and dates; (b) name(s) and title(s) of personnel to travel and their functions in the project; (c) purposes to be served by the travel; (d) how travel of personnel will benefit and contribute to accomplishing the project, or will otherwise justify the expenditures of funds; (e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and (f) what additional functions may be performed by the traveler(s) to accomplish other purposes of the project and thus further benefit the project.

1. **Project Director**

All work under this Subcontract shall be performed under the general guidance and technical direction of the Project Director for Baylor, William T. Shearer, M.D. Such guidance and direction shall not, however, effect any change in the cost structure of this Subcontract, increase its estimated cost, or extend the period of performance. Such changes shall be made only by Baylor in writing.

1. **Publicity and Publications**

Subcontractor shall include in any publications resulting from work performed under this Subcontract an acknowledgment substantially as follows: The work upon which this publication is based was performed pursuant to Grant No. 5 U01 AI27551-08 from the U.S. Department of Health and Human Services. All publications will be provided to the Project Director or his assignee at least sixty (60) days but no longer than ninety (90) days prior to submission for publication. All publicity regarding this Subcontract will be coordinated with the Project Director or his assignee.

1. **Billing Instructions**

Subcontractor shall submit monthly invoices, within thirty (30) calendar days following the end of the month, to Baylor for reimbursement of expenses incurred in performance of the project. Invoices should provide actual expenses grouped by category and shall reference Baylor College of Medicine Purchase Order Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Invoices should be submitted to the following contact person:

Peter J. Marabella, Jr.
Director of Grants and Contracts
Office of Grants and Contracts
Baylor College of Medicine
One Baylor Plaza
Houston, Texas 77030-3498

Both parties agree that Baylor may withhold payment of any expenditure that appears questionable, or for which additional information or support is required. Baylor agrees to notify Subcontractor promptly of the item(s) being withheld from payment and the reasons therefore. Subcontractor agrees to furnish Baylor such information as may be required to satisfy reimbursement of the item(s) in questions. Subcontractor agrees to be solely responsible, and holds Baylor harmless, for any expenditures made by it and disallowed by DHHS, and agrees to make restitution to Baylor of funds so disallowed. In the event of disputed items, Baylor shall obtain DHHS’s decision and said decision shall prevail.

1. **Key Personnel**

The key personnel cited below are considered to be essential to the work being performed hereunder. In the event the assigned individuals leave Subcontractor’s employ or are reassigned to other programs, Subcontractor shall notify Baylor reasonably in advance and the contract shall be terminated and all remaining funds will be returned to Baylor within thirty (30) days. A final accounting shall accompany any returned funds. No diversion or replacement shall be made by Subcontractor.

Key Personnel
W. Keith Hoots, M.D.

1. **Assurances**

Subcontractor agrees to exercise its best efforts to insure that all assurances required by Federal and State Law are met. Such assurances and certifications required of Subcontractor shall include but not necessarily be limited to:

* 1. Civil Rights and Equal Employment Opportunity

Subcontractor agrees that all employees, agents or other persons who are or who shall be deigned to perform services or furnish goods or materials under or pursuant to this Subcontract shall be selected without regard to race, color, national origin, religion, sex, age or veteran or handicap status and in accordance with applicable federal and state law governing equal employment and in compliance with the policies of Subcontractor.

* 1. Student Unrest Provision

No part of the funds awarded under this Subcontract shall be used to provide the salary of or any compensation whatever to any individual applying for admission, attending, employed by, teaching at, or doing research at any institution or higher education who has engaged in conduct on or after August 1, 1969, which involves the use of (or the assistance to others in the use of) force or the threat of force of the seizure of property under in the control of an institution of higher education, to require or prevent the availability of certain curriculum, or to prevent the faculty, administrative officials, or students in such institution from engaging in their duties or pursuing their studies at such institution.

* 1. Protection of Human Subjects

The Subcontractor agrees that the rights and welfare of human subjects involved in performance of this subcontract will be protected in accordance with procedures specified in its current Institutional Assurance on file with the Office of Protection from Research Risks, OD, NIH. The subcontractor further agrees to provide certification at least annually that an appropriate institutional committee has reviewed and approved the procedures which involve human subjects in accordance with the applicable Institutional Assurance accepted by the Office for Protection from Research Risks, OD, NIH. The Subcontractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this Subcontract in a proper manner and as safely as is feasible. The parties hereto agree that the subcontractor retains the right to control and direct the performance of all work under this Subcontract. No provision of this Subcontract shall be deemed to constitute the Subcontractor, agent or employee of the Subcontractor or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the U.S. Government. The Subcontractor agrees that it has entered into this subcontract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent subcontractor without imputing liability on the part of the Government for the acts of the Subcontractor or its employees.

* 1. Care Treatment of Laboratory Animals

To the extent warm-blooded animals are involved in the research work, the Subcontractor warrants that it will comply with applicable portions of the Animal Welfare Act (P.L. 89-544 as amended) and with the applicable federal laws, regulations, and policy statements issued by the U.S. Department of Health and Human Services now currently in effect.

* 1. Debarment, Suspension, Repayment of Federal Debt

Subcontractor certifies, by signing this document, that neither it nor its principal(s) is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency. Subcontractor certifies, by signing this document, that neither it nor its principal(s) is delinquent on the repayment of any federal debt.

* 1. Certification Regarding Lobbying

The Subcontractor certifies, to the best of his or her knowledge and belief, that: No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan or cooperative agreement. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, “Disclosure Form to Report Lobbying”, in accordance with its instructions.

* 1. Anti-Kick Back Act of 1986

Subcontractor certifies, by signing this document that to the best of their knowledge they have not received any money, fee, commission, credit, gift, gratuity, things or value, or compensation of any kind, provided directly or indirectly, for the purpose of improperly obtaining or rewarding favorable treatment in connection with the prime contract or in connection with this subcontract relating to a prime contract.

* 1. Standards of Conduct

Subcontractor certifies, by signing this document, that subcontractor’s institution has written policy guidelines on conflict of interest and the avoidance thereof. For the requirement of a code of conduct applicable to procurements under PHS grants and cooperative agreements, see the procurement standards prescribed by 45 CFR Part 74, Subpart P and 45 CFR Part 92.36. Subcontractor must give each officer, employee, board member, and consultant who is working on the subcontract a copy of the written policy guidelines on conflict of interest. These rules of conduct need not be formally submitted to Baylor, however they must be made available for inspection by representatives of Baylor or the Federal Government.

* 1. Other Assurances

Subcontractor agrees to fulfill the requirements of any Assurances(s) as may be required by DHHS for work undertaken during the performance of this Subcontractor.

1. **Patents, Licenses, and Inventions**
	1. Definitions

The term “Know-How” shall mean all patentable and unpatentable technical information, trade secrets, devices, model things, know-how, methods, documents, materials, and all other confidential information related to the performance of work as described in “Exhibit A”. The term “Patent Rights” shall mean any patentable devices, methods or procedures related to the performance of work as described in “Exhibit A”, and all patents, reexaminations, reissues, renewals, extensions, divisionals and continuations issued thereon and all foreign counterparts thereof. The term “Licensed Product(s)” shall mean any product which incorporates or utilizes the Know-How or the Patent Rights.

* 1. Disclosure

Subcontractor shall report to Baylor and the Federal Government any inventions, first actually reduced to practice in the performance of this agreement which shall be administered in accordance with Public Law 98- 620 and 37 CFR Part 401.

* 1. Patents and Know-How

Inventions and patents which result form this agreement shall be administered in accordance with Public Law 98-620 and 37 CRF Part 401. The Subcontractor represents that its policies require appropriate assignments of inventions, know-how and improvements from all persons who perform any part of the work under this agreement. Disposition of title to inventions, the filing of patent applications, disposition of patent rights and licensing covering the manufacture, use and sale of products and processes shall be governed by 37 CFR Part 401.

* 1. Grants of Licenses

Subcontractor hereby grants to Baylor and the Federal Government a non- exclusive, non-transferable, irrevocable license to any licenses product(s), developed under the project research.

1. **Limitation of Costs**

It is recognized that the amount(s) funded for this Subcontract is based on anticipated or estimated costs. However, it is agreed herein that Baylor’s obligation shall not exceed the sum allotted for this Subcontract in paragraph 3. Neither Baylor nor DHHS shall be obligated to reimburse Subcontractor for cost incurred in excess of the amount allotted for the performance of this contract.

1. **Program Income**

Program income will be treated in accordance with PHS Grants Policy Statement, DHHS Publication No. (OASH) 94-50,000 (Rev.) April 1, 1994. Subcontractor will report Program Income to the Sponsor through Baylor at least annually and no later than 60 days after termination of this Subcontract.

1. **Equipment Accountability and Disposition**

For purposes of this subcontract, equipment is defined as those items costing $500 or more and having a useful life of more than two years. Title to all equipment purchased on this subcontract shall vest in subcontractor upon acquisition, subject to the provisions of 45 CFR 74.136. An inventory of all equipment must be maintained by subcontractor.

1. **Reports & Records Inspection**

Subcontractor agrees to furnish in a timely manner and appropriate format, such progress reports, schedules, cost reports, and other information required by the project, for incorporation by Baylor in meeting its reporting requirements to DHHS. Reports should be filed with:

Wiliam T. Shearer, M.D.
Baylor College of Medicine
One Baylor Plaza
Houston, Texas 77030-3498

* 1. Accounting and Records

The accounting for the Subcontract funds will be in accordance with generally accepted accounting principles consistently applied and in accordance with cost principles of the U.S. Department of Health and Human Services. Subcontractor shall maintain records to support identifiable charges to the project. Obligations, commitments, encumbrances or expenditures should be made within the budget period.

* 1. Audit Requirement

If Subcontractor is subject to the audit requirements of OMB Circulars A- 128 or A-133, Subcontractor shall submit a copy of its most recent financial and compliance audit report to the Director of Grants & Contracts, One Baylor Plaza, Rm. MT-601, Houston, Texas 77030, prior to the execution of this subcontract. If the Subcontractor is not subject to A-128 or A-133, the Subcontractor shall have an audit of the program conducted and submitted to Baylor within 90 days of the end of the period of performance as specified in this subcontract. This audit will be conducted by an independent certified public accounting firm and shall be conducted in accordance with generally accepted Governmental Audit Standards as issued by the Comptroller General of the United States. Subcontractor certifies that, in instances of noncompliance with Federal laws and regulations, appropriate corrective action will be taken. Subcontractor agrees to notify Baylor of the management decision issued by the responsible federal agency and of the completion of the corrective action plan within six months of furnishing the audit report to Baylor. The Subcontractor’s facilities, or such part thereof as may be engaged in the performance of this Agreement, and any pertinent books, documents, papers and records shall be subject at all reasonable times to inspection and audit by representatives of Baylor or the Federal Government.

1. **Additional Provisions**

It is agreed that the PHS Grants Policy Statement, policies, etc., in existence at the time of performance of this Subcontract are automatically incorporated and made a part of this Subcontract.

1. **Amendment and Modification**

This agreement, or any portion hereof, may be amended or modified in writing at any time as mutually agreed upon, or as required by DHHS.

1. **Limitation of Liability**

Subcontractor is and will at all times be acting as an independent contractor in the performance of this work and not as an agent or joint venturer of Baylor. In so far as is authorized under the constitution and laws of the State of Texas, Subcontractor shall indemnify and hold Baylor harmless from liability resulting from Subcontractor acts or omissions within the terms of this agreement; provided, however, Subcontractor shall not hold Baylor harmless from any claims, demands, or causes of action arising in favor of any person or entity, growing out of, incident to, or resulting directly or indirectly from negligence (whether sole, join, concurrent or otherwise), or Baylor, its officers, agents or representatives, or employees not subject to supervision or control. Baylor shall hold Subcontractor harmless from liability resulting from Baylor’s acts or omissions within the terms of this agreement; provided, however, Baylor shall not hold Subcontractor harmless from any claims, demands, or causes of action arising in favor of any person or entity, growing out, incident to, or resulting directly or indirectly from any negligence (whether sole, joint, concurrent or otherwise), of the Subcontractor, its officers, agents or representatives, or employees not subject to supervision or control.

1. **Termination of Agreement**

Either Baylor or Subcontractor may terminate this subcontract upon thirty (30) days written notification to the other party. In the event of termination, Subcontractor will be reimbursed for any non-cancelable obligations properly incurred prior to the date of notice of termination.

1. **Law**

This subcontract shall be construed according to the laws of the State of Texas and any and all disputes arising hereunder shall be resolved in the courts of the State of Texas; provided, however, that any patent question or controversy shall be resolved in the courts having jurisdiction over the patent or patents in question and in accordance with the laws applicable to such patent or patents.

1. **Federal Demonstration Project**

Where subcontractor is a participant in the Federal Demonstration Project, this subcontract is subject to the Federal Demonstration Project General Terms and Conditions and any agency specific requirements. Baylor retains approval authority for extension of time and the carryover of unobligated funds and foreign travel.

By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Baylor College of Medicine
R.R. Rich, M.D.
Vice President and Dean for Research

By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The University of Texas Health Science Center at Houston
Jim Darcy
Director of Accounting
Financial Resources

Read and understood:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Dr. Keith Hoots
Principal Investigator

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_



**EXHIBIT A WORKSCOPE
5 U01 AI27551-08**

Dr. Hoots will be responsible for all activities of this subcontract including coordination of all research activities at the various study sites to be used by the University of Texas. Dr. Hoots will coordinate research and clinical care for all hemophilic and pediatric AIDS patients enrolled at the University of Texas and will coordinate all clinical and research activities. Dr. Marilyn Doyle will serve as clinical coordinator for the pediatric patients enrolled at the University of Texas. She will oversee the day by day activities of patient enrollment and management and will be the clinical coordinator for all hemophilic patients enrolled and will oversee the day by day activities of patient management.

The protocol nurse will assist with enrollment of patients, coordination and supervision of outpatient and inpatient care and close follow-up after the patients return home. Additional responsibilities will include referral to appropriate consultants, patient and family education, facilitating school attendance, promotion of other activities of daily living and scheduling examination, laboratory tests and radiographs. The pediatric nurse practitioner will assist with implementation of chemotherapy protocols, medications, and growth development assessment. The social worker will assist families of all patients enrolled by identifying community resources to meet their social and financial needs. She also will provide supportive counseling in the areas of adjustment to diagnosis, treatment regimen and long term prognosis. The development neuropsychologist will evaluate each patient for growth and development and obtain complete psychosocial assessments on each patient.

**EXHIBIT B**

**BUDGET**
5 U01 AI27551-08

The University of Texas Health Science Center at Houston

Personnel $60,909
Supplies $1,466
Travel $1,955
Other Expenses $4,888



**Total Direct Costs $69,218**



Indirect Costs $13,152



**Total Costs $82,370**

