

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended June 30, 1998, or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission file number 000-21615

BOSTON BIOMEDICA, INC.
(Exact name of Registrant as Specified in its Charter)

Massachusetts 04-2652826

(State or other (I.R.S. Employer
Jurisdiction of Identification No.)
Incorporation or
Organization)

375 West Street,
West Bridgewater,
Massachusetts 02379-1040

(Address of Principal (Zip Code)
Executive Offices)

Registrant's telephone number, including area code (508) 580-1900

Indicate by check whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

The number of shares outstanding of the Registrant's only class of common stock as of July 31, 1998 was 4,665,426.

Part I. Financial Information
Item 1. Financial Statements

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
(Unaudited)

<TABLE>
<CAPTION>

For the Three Months Ended		For the Six Months Ended	
June 30,		June 30,	
-----		-----	
1998	1997	1998	1997

REVENUE:

<S>	<C>	<C>	<C>	<C>
Products	\$3,316,804	\$2,416,956	\$ 6,380,163	\$4,543,912
Services	3,066,328	2,231,998	6,275,764	4,314,091
Total revenue	6,383,132	4,648,954	12,655,927	8,858,003

COSTS AND EXPENSES:

Cost of product sales	1,674,837	1,271,662	3,446,588	2,327,084
Cost of services	1,999,019	1,456,194	4,322,230	2,931,726
Research and development	583,592	256,995	1,015,981	493,745
Acquired research and development	-	-	850,000	-
Selling and marketing	926,015	775,594	1,854,627	1,388,954
General and administrative	983,075	694,875	2,013,011	1,374,082
Total operating costs and expenses	6,166,538	4,455,320	13,502,437	8,515,591
Income (loss) from operations	216,594	193,634	(846,510)	342,412
Interest (expense) income, net	(660)	99,184	22,899	196,670
Income (loss) before income taxes	215,934	292,818	(823,611)	539,082
(Provision for) benefit from income taxes	(82,055)	(117,128)	312,972	(215,634)
Net income (loss)	\$ 133,879	\$ 175,690	\$ (510,639)	\$ 323,448

Net income (loss) per share, basic	\$ 0.03	\$ 0.04	\$ (0.11)	\$ 0.07
Net income (loss) per share, diluted	\$ 0.03	\$ 0.04	\$ (0.11)	\$ 0.07

Number of shares used to calculate net income per share

Basic	4,652,519	4,403,277	4,642,343	4,391,715
Diluted	4,865,593	4,839,407	4,642,343	4,824,731

</TABLE>

See Notes to Consolidated Financial Statement
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BOSTON BIOMEDICA, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30,	December 31,
	1998	1997

ASSETS

CURRENT ASSETS:

Cash and cash equivalents	\$ 123,527	\$ 2,772,360
Accounts receivable, less allowances of \$579,142 in 1998 and \$446,517 in 1997	5,563,699	5,558,710
Inventories	6,603,413	5,902,821
Prepaid expense and other	640,555	288,481
Deferred income taxes	378,458	328,562
Total current assets	13,309,652	14,850,934

Property and equipment, net	5,783,730	4,980,164
-----------------------------	-----------	-----------

OTHER ASSETS:

Long term investment	1,482,500	1,482,500
Goodwill and other intangibles, net	2,126,745	2,212,220
Notes receivable and other	108,365	124,178

	-----	-----
	3,717,610	3,818,898
	-----	-----
TOTAL ASSETS	\$22,810,992	\$23,649,996
	=====	=====

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES:

Current maturities of long term debt	\$ 14,831	\$ 14,878
Accounts payable	1,650,345	2,218,685
Accrued compensation	1,046,658	1,103,837
Accrued income taxes	-	132,802
Other accrued expenses	585,486	498,247
Deferred revenue	884,317	1,249,024
	-----	-----
Total current liabilities	4,181,637	5,217,473
	-----	-----

LONG-TERM LIABILITIES:

Long term debt, less current liabilities	535,726	26,820
Deferred rent and other liabilities	321,503	189,117
Deferred income taxes	142,887	149,333

COMMITMENTS AND CONTINGENCIES

STOCKHOLDERS' EQUITY:

Common stock, \$.01 par value; authorized 20,000,000 shares in 1998 and 1997; issued and outstanding 4,660,426 in 1998 and 4,622,566 in 1997	46,604	46,226
Additional paid-in capital	16,101,296	16,029,049
Retained earnings	1,481,339	1,991,978
	-----	-----
Total stockholders' equity	17,629,239	18,067,253
	-----	-----

TOTAL LIABILITIES & STOCKHOLDERS' EQUITY	\$22,810,992	\$23,649,996
	=====	=====

See Notes to Consolidated Financial Statements

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BOSTON BIOMEDICA, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

For the Six Months Ended
June 30,

-----	-----
1998	1997
-----	-----

CASH FLOWS FROM OPERATING ACTIVITIES:

Net (loss) income	\$ (510,639)	\$ 323,448
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation and amortization	607,252	353,843
Provision for doubtful accounts	103,036	77,781
Deferred rent and other liabilities	132,386	(53,916)
Deferred income taxes	(56,342)	(31,655)
Acquired research and development	850,000	-
Changes in operating assets and liabilities:		
Accounts receivable	(108,025)	(51,366)
Other assets	-	(27,083)
Inventories	(700,592)	(380,593)
Prepaid expenses	(352,074)	(76,392)
Accounts payable	(568,340)	83,043
Accrued compensation and other expenses	(102,742)	(402,705)
Deferred revenue	(364,707)	274,938
	-----	-----
Net cash (used in) provided by operating activities	(1,070,787)	89,343
	-----	-----

CASH FLOWS FROM INVESTING ACTIVITIES:

Acquired research and development	(850,000)	-
Payments for additions to property and equipment	(1,325,097)	(839,364)
Purchase of intangible assets	(246)	-
Advances under notes receivable and other assets	15,813	(893,005)
Purchase of long term investment	-	(750,000)
	-----	-----
Net cash used in investing activities	(2,159,530)	(2,482,369)
	-----	-----

CASH FLOWS FROM FINANCING ACTIVITIES:

Proceeds from long term debt	508,906	-
Repayments of long-term debt	(47)	(6,255)
Proceeds of common stock issued	72,625	93,687
	-----	-----
Net cash provided by financing activities	581,484	87,432
	-----	-----

DECREASE IN CASH AND CASH EQUIVALENTS: (2,648,833) (2,305,594)

Cash and cash equivalents, beginning of period 2,772,360 8,082,642

Cash and cash equivalents, end of period \$ 123,527 \$ 5,777,048

See Notes to Consolidated Financial Statements

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BOSTON BIOMEDICA, INC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles for the interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the six months ended June 30, 1998 are not necessarily indicative of the results that may be expected for the year ending December 31, 1998. For further information, refer to the consolidated financial statements and footnotes thereto included in the annual report of Form 10-K filing for the fiscal year ended December 31, 1997 for Boston Biomedica, Inc. and Subsidiaries ("the Company" or "Boston Biomedica"). Certain prior years' amounts in the consolidated financial statements may have been reclassified to conform to the current year's presentation.

(2) Use of Estimates

In conformity with generally accepted accounting principles, management is required to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses for the periods presented. Such estimates include reserves for uncollectable accounts receivable as well as the net realizable value of its inventory. Actual results could differ from the estimates and assumptions used by management.

(3) Inventories

Inventories consisted of the following:

	June 30, 1998	December 31, 1997
	-----	-----
Raw materials.....	\$2,170,155	\$2,033,040
Work-in-process.....	1,629,171	1,190,567
Finished goods.....	2,804,087	2,679,214

 \$6,603,413 \$5,902,821
 =====

(4) Comprehensive Income

Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" (SFAS 130) is effective for fiscal years beginning after December 15, 1997. SFAS 130 requires that changes in comprehensive income be shown in a financial statement that is displayed with the same prominence as other financial statements. The Company adopted SFAS 130 in the first quarter of fiscal year ended December 31, 1998. Adoption of this statement has had no impact on the Company's consolidated financial position and results of operations as comprehensive income (loss) is the same as net income (loss).

(5) Acquired Research and Development

In March 1998, the Company acquired from BioSeq, Inc. ("BioSeq"), the sole and exclusive worldwide right to development stage technology, including the use of BioSeq technical information, licensed processes and improvements to develop, manufacture, market and sell or sublicense products or services in the field of human in vitro immunodiagnostics. Under this agreement, the Company will pay BioSeq an annual royalty based on net sales to customers and sublicensees. The agreement is effective March 20, 1998 and ends on the date the last patent expires, which is approximately 16 years. In accordance with accounting standards for development stage technology, the purchase price, minimum royalty payments and acquisition costs totaling \$850,000, were expensed in the first quarter.

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(6) Computation of Net Income per Share

In February 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 128, "Earnings per Share". SFAS 128 establishes a different method of computing net income per share than was required under the provisions of the previous standard-Accounting Principles Board opinion No. 15. The following illustrates the computation of basic and diluted net income per share.

	Three Months Ended June 30,		Six Months Ended June 30,	
	1998	1997	1998	1997
Average common stock outstanding	4,652,519	4,403,277	4,642,343	4,391,715
Net effect of dilutive common stock equivalents- based on treasury stock method using average market price *	213,074	436,130	-	433,016
	4,865,593 4,839,407 4,642,343 4,824,731			
Net income (loss)	133,879	175,690	(510,639)	323,448
Net income (loss) per share	0.03	0.04	(0.11)	0.07

* Potentially dilutive securities of 228,875 were not included in the computation of diluted earnings per share because to do so would have been antidilutive for the six months ended June 30, 1998.

(7) Extension of Line of Credit

Effective June 30, 1998, the maturity date of the revolving line of credit agreement was extended from June 30, 1999 to June 30, 2000. Accordingly, the balance borrowed against the line as of June 30, 1998 is classified as long term debt.

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Item 2. Management's Discussion and Analysis of Results of Operations and Financial Condition.

Three Months Ended June 30, 1998 and 1997

Total revenue increased 37.3%, or \$1,734,000, to \$6,383,000 for the three months ended June 30, 1998 from \$4,649,000 in the prior year period. This increase was the result of an increase in product sales of 37.2%, or \$900,000, to \$3,317,000 from \$2,417,000 and an increase in specialty laboratory services of 37.4%, or \$834,000, to \$3,066,000 from \$2,232,000. The inclusion of BBI Source Scientific ("Source") in the second quarter results added to product and service revenue in the amounts of \$614,000 and \$392,000, respectively. The remaining increase in product revenue was the result of significant increases in Accurun(r) controls and OEM panel sales. The remaining increase in service revenue was the result of a significant increase in billed labor on government contracts for R&D services at the Company's new facility in Gaithersburg, MD. The Company also realized increased revenue from immunology testing including Hepatitis C and tickborne diseases.

Gross profit increased 41.0%, or \$788,000, to \$2,709,000 for the current three months from \$1,921,000 in the prior year period. Overall gross margin increased to 42.4% from 41.3%. All of the increase was attributable to product sales. The gross margin on products increased to 49.5% from 47.4%, as the sales growth was in Accurun(r) and OEM panel products, which carry higher margins.

Research and development expenses increased 127.1%, or \$327,000, to \$584,000 for the current three months from \$257,000 in the prior year period. The increase is primarily the result of the inclusion of Source and its development efforts in the laboratory instrumentation product line, including the PlateMate(and reflectance reader projects. Also contributing to the increase was additional spending on molecular tests and Quality Control Products.

Selling and marketing expenses increased 19.4%, or \$150,000, to \$926,000 for the current three months from \$776,000 in the prior year period. This increase was primarily the result of the first time inclusion of Source.

General and administrative expenses increased 41.5%, or \$288,000, to \$983,000 for the current three months from \$695,000 in the prior year period. The inclusion of Source accounted for \$173,000 of this increase. The remaining increase relates to the addition of human resource, collection, and administrative support personnel.

Net interest expense was \$660 for the current quarter compared to net interest income of \$99,000 in the prior year period. The Company has productively employed the proceeds from its initial public offering and, at the end of the quarter, began to borrow funds under its line of credit to continue its infrastructure investments.

Based on current tax planning, the Company provided taxes at the combined federal and state statutory rate of 38% in the current quarter versus 40% in the prior year period.

Six Months Ended June 30, 1998 and 1997

Total revenue increased 42.9%, or \$3,798,000, to \$12,656,000 for the six months ended June 30, 1998 from \$8,858,000 in the prior year period. This increase was the result of an increase in product sales of 40.4%, or \$1,836,000, to \$6,380,000 from \$4,544,000 and an increase in specialty laboratory services of 45.5%, or \$1,962,000, to \$6,276,000 from \$4,314,000. The inclusion of Source added to product and service revenue in the amounts of \$1,081,000 and \$1,124,000, respectively. The remaining increase in product revenue is due to a doubling of Accurun(r) sales and a significant increase in OEM panel sales. The remaining increase in specialty laboratory services is attributable to an increase in clinical testing and contract research revenue.

Gross profit increased 35.8%, or \$1,288,000, to \$4,887,000 for the current six months from \$3,599,000 in the prior year period. The gross profit margin decreased to 38.6% for the current six months versus 40.6% in the prior year period. This is due primarily to lower margins on Source instruments and the impact of higher fixed overhead at BBI Biotech as a result of its move to its new facility in Gaithersburg, MD, both adversely affecting the first quarter.

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Research and development expenses increased 105.8%, or \$522,000, to \$1,016,000 for the current six months from \$494,000 in the prior year period. The increase is primarily the result of the inclusion of Source's development efforts for new laboratory instruments as well as additional spending on molecular tests and Quality Control Products.

There was an accounting charge of \$850,000, in the first quarter, related to the acquisition of the worldwide exclusive rights to BioSeq Inc's immunodiagnostic research and development technology as noted in footnote 5.

Selling and marketing expenses increased 33.5%, or \$466,000, to \$1,855,000 for the current six months from \$1,389,000 in the prior year period. The inclusion of Source added \$130,000. The remaining increase was attributable to increased personnel costs associated with the expansion of the TQS sales, marketing and technical support staff as well as additions to the clinical laboratory sales staff.

General and administrative expenses increased 46.5%, or \$639,000, to \$2,013,000 for the current six months from \$1,374,000 in the prior year period. This increase was a result of the first time inclusion of Source as well as additional human resource, MIS, collection, and administrative support personnel.

Net interest income decreased 88.3%, or \$174,000 to \$23,000 for the current six months from \$197,000 in the prior year period. The Company has productively employed its proceeds from its initial public offering and, at the end of the six month period, began to borrow funds from its revolving line of credit to continue its infrastructure investments.

Based on current tax planning, the Company provided taxes at the combined federal and state statutory rate of 38% in the current quarter versus 40% in the prior year period.

Liquidity and Financial Condition

At June 30, 1998, the Company had cash and cash equivalents of approximately \$124,000 and working capital of \$9,128,000. Both of these items have decreased significantly from year end as the Company continued its planned capital expenditures.

The Company has financed its operations to date through cash flow from operations, borrowings from banks and issuance of common stock. The Company expects its cash flow, current cash position and its \$7.5 million uncollateralized revolving line of credit to meet its working capital needs.

Net cash used for operations for the six months ended June 30, 1998 was (\$1,071,000) as compared to cash provided by operations of \$89,000 in the prior year period. This decrease in cash flow was primarily attributable to the net loss for the period, increased purchases of strategic inventory for its Quality Control Products, a reduction in current liabilities, and the delay, until July, in settlement of a large receivable..

Cash used in investing activities for the six months ended June 30, 1998 was \$2,160,000 as compared to \$2,482,000 in the prior year period. The cash used relates to the acquired BioSeq research and development as described above, as well as continued improvements at its Massachusetts and Maryland facilities.

Cash provided by financing activities for the six months ended June 30, 1998 was \$581,000 as compared to \$87,000 in the prior year period. The cash received was from borrowing against the revolving line of credit and the exercise of stock options during the period.

The Company anticipates capital expenditures for the expansion of the West Bridgewater facility and additional improvements in its Maryland facility as a result of recently awarded contracts to be completed by the end of 1998. The Company also expects to replace its business information software over the next twelve months at a cost of approximately \$750,000. The Company believes that existing cash balances, the borrowing capacity available under its revolving line of credit and cash generated from operations are sufficient to fund operations and

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anticipated capital expenditures for the foreseeable future. Except for purchase orders and contracts in connection with the expansion and the business information software, there were no material financial commitments for capital expenditures as of June 30, 1998.

Recent Accounting Pronouncements

Statement of Financial Accounting Standards No. 132, "Employers' Disclosure about Pensions and Other Postretirement Benefits" (SFAS 132) is effective for fiscal years beginning after December 15, 1997. SFAS 132 revises employers' disclosures about pension and other postretirement benefit plans. It does not change the measurement or recognition of those plans. The Company will adopt SFAS 132 in the fiscal year ended December 31, 1998, although no impact on operating results of financial position is expected.

Year 2000 Computer Systems Compliance

Concerns have been widely expressed regarding the inability of certain computer programs to process date information beyond year 1999. These concerns focus on the impact of the Year 2000 problem on business operations and the potential costs associated with identifying and addressing the problem. The Company is in the process of evaluating and taking steps to deal with the potential impact of this problem in areas under its control, including its products and sources of supply, as well as its operations management, administration and financial systems.

Based on its review to date, the Company believes that its products are "Year 2000 compliant." The Company has confirmed with existing software vendors that year 2000 compliant versions either exist or will be available to upgrade or replace its operations management, administrative and financial systems. The Company plans to begin a program to survey major suppliers to determine the status and schedule for their Year 2000 compliance. Where it believes that a particular supplier's situation poses unacceptable risks, the Company plans to identify an alternative source.

Based upon its review, the Company does not believe that the Year 2000 problem will have a material adverse effect on the Company. However, there can be no assurances that failure to comply with Year 2000 by parties outside its control will not have a material adverse affect on the Company.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements concerning the Company's financial performance and business operations. The Company wishes to caution readers of this Quarterly Report on Form 10-Q that actual results might differ materially from those projected in any forward-looking statements.

Factors which might cause actual results to differ materially from those projected in the forward-looking statements contained herein include the

following: inability of the Company to develop the end user market for quality control products; inability of the Company to integrate the business of Source Scientific, Inc. into the Company's business; inability of the Company to grow the sales of Source Scientific, Inc. to the extent anticipated; the renewal and full funding of contracts with National Institutes of Health (NIH), National Heart, Lung and Blood Institute (NHLBI) and other government agencies; a material adverse change in the business, financial condition or prospects of BioSeq, Inc., an early stage biotechnology company in which the Company has made a significant investment, including inability to develop its technology to the level of commercial utilization; inability of the Company to obtain an adequate supply of the unique and rare specimens of plasma and serum necessary for certain of its products; significant reductions in purchases by any of the Company's major customers; and the potential insufficiency of Company resources, including human resources, plant and equipment and management systems, to accommodate any future growth. Certain of these and other factors which might cause actual results to differ materially from those projected are more fully set forth under the caption "Risk Factors" in the Company's Registration Statement on Form S-1 (SEC File No. 333-10759).

BOSTON BIOMEDICA, INC.

Part II. Other Information

Item 4. Submission of Matters to a Vote of Security Holders.

The Company held its Annual Meeting of Stockholders of May 21, 1998 (the "Meeting"). A total of 3,749,521 shares, or 81%, of the Common Stock issued and outstanding as of the record date, were represented at the meeting in person or by proxy. At the Meeting, the only matter to be acted upon was the election of directors. The results of the election were as follows:

Henry Malkasian was elected as a Class II Director of the Company, to serve as such until the Year 2001 Annual Meeting of Stockholders and until his successor has been duly elected and qualified; with 3,732,115 shares voting in favor, 17,406 votes withheld.

The terms of office of Richard T. Schumacher, Kevin W. Quinlan, Calvin A. Saravis, and Francis E. Capitanio, continued after the Meeting.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit No. -----	Reference -----	
3.1	Amended and Restated Articles of Organization of the Company	A**
3.2	Amended and Restated Bylaws of the Company	A**
4.1	Specimen Certificate for Shares of the Company's Common Stock	A**
4.2	Description of Capital Stock (contained in the Restated Articles of Organization of the Company filed as Exhibit 3.1)	A**
10.1	Contract, dated July 1, 1998, between the National Institutes of Health and the Company (NO1-AI-85341)	Filed herewith
10.2	Contract, dated June 15, 1998, between the National Heart Lung and Blood Institute and the Company (NO1-HB-87144)	Filed herewith
21.1	Subsidiaries of the Company	B**
27	Financial Data Schedule	Filed herewith

A Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration No. 333-10759)(the "Registration Statement"). The number set forth herein is the number of the Exhibit in said registration statement.

B Incorporated by reference to the Company's Annual Report on Form 10K for the fiscal year ended December 31, 1997.

** In accordance with Rule 12b-32 under the Securities Exchange Act of 1934, as amended, reference is made to the documents previously filed with the Securities and Exchange Commission, which documents are hereby

incorporated by reference.

(b) Reports on Form 8-K

None

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

BOSTON BIOMEDICA, INC.

Date: August 14, 1998 By /s/ KEVIN W. QUINLAN

Kevin W. Quinlan, Chief Financial Officer
(Principal Financial Officer)

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SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objectives of this project are to maintain a repository of blood specimens from NHLBI-sponsored studies and to make appropriate specimens available to the scientific community for use in research related to transfusion-transmitted diseased and a variety of other disorders of blood or the cardiovascular system.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

- a. The estimated cost of this contract is \$_____.
- b. The fixed fee for this contract is \$_____. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.
- c. The Government's obligation, represented by the sum of the estimated cost plus fixed fee, is \$2,901,590.
- d. Total funds currently available for payment and allotted to this contract are \$377,835, of which \$356,448 represents the estimated costs, and of which \$21,387 represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.
- e. It is estimated that the amount currently allotted will cover performance of the contract through June 14, 1999.
- f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.
- g. Future increments to be allotted to this contract are estimated as follows:

Period	Amount
--------	--------

June 15, 1999 through June 14, 2000	\$ 461,262
June 15, 2000 through June 14, 2001	481,974
June 15, 2001 through June 14, 2002	503,693
June 15, 2002 through June 14, 2003	526,469
June 15, 2003 through June 14, 2004	550,357

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses, ALLOWABLE COST AND PAYMENT and FIXED FEE, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

- (1) Acquisition, by purchase or lease, of any interest in real property;
- (2) Special rearrangement or alteration of facilities;
- (3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

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- (4) Travel to attend general scientific meetings;
- (5) Foreign travel;
- (6) Patient care costs;
- (7) Accountable Government property (defined as both real and personal property with an acquisition cost of \$1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide for

Control of Government Property), 1990, regardless of acquisition value.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. Consultants

Consultant fees to be paid to the following individuals:

b. Repository Relocation

A transition phase (June 15, 1998 through December 15, 1998) is provided for relocation of the NHLBI biological specimen repository

from McKesson BioServices, 685 Loftstrand Lane, Rockville, Maryland 20850 to the repository facility operated by BBI-Biotech Research Laboratories, Inc., 217 Perry Parkway, Gaithersburg, Maryland. The Contractor shall complete interior fit out of the NHLBI repository space, located at 217 Perry Parkway, Gaithersburg, Maryland, so as to allow for a safe and orderly transition of the NHLBI biological specimen repository from McKesson BioServices to the new location. The Contractor shall transfer all Government-owned NHLBI freezers, biological specimens, files, and inventory records, on or before December 15, 1998. Repository relocation costs shall not exceed \$23,932.

c. Confidential Treatment of Sensitive Information

The Contractor shall guarantee strict confidentiality of the information/data that it is provided by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature and cannot be disclosed in any manner.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

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ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below:

PHASE I - Transition

The contractor shall coordinate an orderly and safe transition from the current incumbent contractor site to the new location, including the transport of stored specimens, data, and all Government-furnished property. Contractor shall adhere to the moving plan previously approved by the Department of Transportation (DOT). This approval allows for the exemption from the requirements of 46 CFR Part 64 regarding Federal hazardous material transportation law so that specimens shall be moved in the freezers in which they are stored.

Relocation of the NHLBI repository from McKesson BioServices, 685 Lofstrand Lane, Rockville, MD 20850 to the Contractor's facility at 217 Perry Parkway, Gaithersburg, Maryland 20877 shall be completed before December 15, 1998. At the time of repository relocation, it is estimated that 2.8 million specimens will be stored in 98 freezers and 5 liquid nitrogen tanks.

PHASE II Repository Maintenance

Task 1 - Maintain Serum, Plasma, and Cell Repository

The contractor shall provide facilities and equipment to receive, store, aliquot, and distribute potentially hazardous biologics such as serum, plasma, and cells from individuals infected with AIDS virus and hepatitis viruses. The facilities must provide aseptic and/or sterile conditions as appropriate

(Biosafety Level 2 Containment). The specimens shall be maintained by the contractor in freezers at temperatures between -70 degrees and -80 degrees centigrade. Freezers shall be located in an air-conditioned facility with temperatures maintained between 20 degrees and 25 degrees centigrade (60 degrees to 77 degrees F) when freezers are in operation. The contractor shall supply uninterruptible power to accommodate the refrigerators/freezers and other equipment. Freezers shall be connected to a central alarm system monitored twenty-four hours per day. The contractor shall provide an automated temperature monitoring system composed of individual temperature probes monitored 24 hours a day and controlled by a master computer, and a plan to ensure that necessary personnel are notified in the event of freezer malfunction. Emergency standby freezers shall be available in case of mechanical failure of any portion of storage space. In addition, alternative emergency freezer cooling systems such as a liquid nitrogen system or dry ice must be available. The contractor must have backup electric generators capable of operating all storage equipment for at least 48 hours in the event of utility company power failure. Backup generators must be tested monthly. Cell specimens (or tissues) shall be maintained at liquid nitrogen gas phase, in special liquid nitrogen chests.

In order to accommodate the estimated increase of the number of specimens/vials contained in the repository and the replacement of obsolete freezers, the contractor shall purchase approximately six freezers per year, using contract funds. The estimated increase in vials will result from the splitting of specimens and arrival of new specimens.

Task 2 - Preparing Aliquots from Selected Specimens *

The contractor shall provide laboratory facilities and personnel for dividing the serum or plasma samples into aliquots. All requests for samples are reviewed by the NHLBI. Once an original specimen is identified for distribution, it is thawed

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and divided into aliquots, one of which is sent to the investigator, and the remaining aliquots refrozen for later use. It is estimated that approximately 1,000 specimens shall be divided into 10,000 aliquots annually.

Thus, the size of the repository increases regularly as original specimens are divided and distributed and new specimens are added to the repository. The handling of all biological specimens and Government-owned property under this contract shall be in accordance with all applicable local, state, and federal regulations. In addition, in order to provide safety controls for protection to the life and health of employees and other persons, the contractor shall consult, comply with, and include in all applicable subcontracts, the following standards, as appropriate:

- 1) Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and the NIH, DHHS Pub. No. (CDC) 93-8395.
- 2) Occupational Safety and Health Administration (OSHA), Publication 29 CFR Part 1910.1030, Occupational Exposure to Blood Borne Pathogens, Final Rule.

Task 3 -Prepare and Ship Panels of Aliquots or Specimens *

The Project Officer receives and reviews requests from investigators for specimens or panels of aliquots. When a request is approved, the NHLBI Project Officer will design panels of aliquots or specimens on the basis of the investigator's experimental needs. On the basis of that design, the Project Officer will provide to the contractor the information needed to prepare and ship each panel. It is estimated that preparation and shipment of approximately 50 panels, containing 100 vials each, will be required annually. A list identifying the specimens to be included in a panel will be provided to the contractor.

The contractor shall prepare the panels as required by the Project Officer.

Shipments will require preparation of the panel, packing the panel in dry ice, packaging the panel in insulated boxes, and express shipment (usually by air) to the final destination (specifically, the approved investigator). The contractor shall ship all vials C.O.D.; transportation and postage costs are to be paid by the recipients from point of carrier receipt. The contractor shall verify receipt of the panel by the investigator both in writing and by phone. Packaging and shipment shall meet standards for biologically hazardous materials (see publication prepared by the International Air Transport Association (IATA), Dangerous Goods Regulations, current edition).

Task 4 - Add Specimens to the Repository *

The contractor shall inventory, prepare for storage, package, and label, as necessary, specimens to be added to the repository. The project officer will specify the dates of arrival of such specimens, the number of specimens, and the means of packaging, labeling and storing these samples as well as the type, number and location of freezers to be relocated to the contractor's site. It is essential that shipments be coordinated by the contractor so that personnel will be available to receive the arriving packages and transport shipment to the NHLBI repository for storage at the required temperature.

Task 5 - Performance of Virologic and Serologic Assays *

The contractor shall provide the capability to perform (in-house or through a subcontractor) serologic and virologic assays for the evaluation and validation of candidate blood screening tests for the detection of transfusion-associated agents. For this purpose, laboratory biosafety level 2 shall be required, as well as laboratory personnel with specific training in handling pathogenic agents.

Laboratory personnel, safety practices, and techniques shall be supplemented by appropriate facility design and engineering features, safety equipment, and management practices. The contractor shall ensure that persons working with these infectious agents are aware of potential hazards and strictly adhere to standard microbiological practices and techniques. Costs for these assays will be negotiated and the contract amount increased as the need arises.

The human pathogens for which blood screening tests are being developed or improved and, therefore, are likely to be involved in future assay evaluation and validation procedures, include hepatitis viruses, human retroviruses, and agents of

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transmissible spongiform encephalopathies. Among the serologic and virologic test formats that the contractor is expected to perform are enzyme immunoassays, polymerase chain reactions, immunoblotting, and in situ hybridization. It is expected that 500 - 1,000 assays will be required per year.

Task 6 - Inventory Control

The contractor shall update and maintain a computerized inventory control data base using a desktop personal computer system to track and assist in the coordination of the activities under this contract. At the time of contract award, the FoxPro data base will contain information on approximately 2.1 million specimens. This will provide inventory and management information to reflect activities of the repository, i.e., location of specimens, aliquoting of specimens, preparation of panels, and addition of new specimens. In addition, the SAS/Repository Management System (RMS) inventory and management data base shall reflect activities on approximately 700,000 specimens including location of specimens, aliquoting of specimens, preparation of panels, addition of new specimens, and results of assays performed by outside investigators using NHLBI specimens. The SAS software and license shall be provided to the contractor by the Government.

Task 7 - Ensure an Orderly Transition of the NHLBI Biological Specimen

Repository to a Successor Contractor

In the event there is a recompetition of the subject contract and an organization other than the incumbent is selected for contract award, incumbent shall assist in ensuring an orderly and safe transition of the repository from the current location at (address of repository at time of relocation) to any successor of this contract. This shall include providing repository access to the new contractor at mutually agreed upon times.

* SPECIAL TRAINING REQUIREMENTS:

Repository personnel involved in tasks 2, 3, 4, and 5 shall have specific training in handling pathogenic agents and dealing with potential hazards of the pathogens likely to be involved in the operation of the repository.

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract:

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following format:

1. Quarterly Progress Report: This report shall include descriptive information on activities in the repository during the reporting period. The reporting period consists of the first full three months of performance plus any fractional part of the initial month. The first report shall be due September 30, 1998. Thereafter, the reporting period shall consist of three full calendar months. This report shall include the following:

- a. the number of vials stored on the first and last days of the reporting period;
- b. the number of vials prepared during the reporting period;
- c. a list of panels prepared and shipped during the reporting period including, for each panel:
 - 1) number of specimens (vials),
 - 2) date of shipment,
 - 3) date of receipt of shipment, and
 - 4) problems with any shipment;

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- d. maintenance problems encountered and corrective actions taken;
- e. needs for replacement or repair of government-furnished equipment; and

2. Final Report: Cumulative information for period of performance of all information included in quarterly progress reports.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked, and shipped in accordance with Government specifications. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this ARTICLE the Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

Division of Blood Diseases & Resources
National Heart, Lung, & Blood Institute
6701 Rockledge Drive, MSC 7950, Room 10146
Bethesda, MD 20892-7950

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause No. 52.246-5, INSPECTION OF SERVICES-COST REIMBURSEMENT (APRIL 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

- a. Satisfactory performance of this contract shall be deemed to occur upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.
- b. The items specified below as described in SECTION C, ARTICLE C.1 and ARTICLE C.2. shall be made f.o.b. destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984) and in accordance with and by the dates specified below:

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Item	Description	Quantity	Delivery Schedule
1.	Quarterly Progress Report Officer (CO)	2 copies to the Project Officer (PO), 1 copy to the Contracting Officer (CO)	Quarterly during period of performance
2.	Final Report Officer (CO)	2 copies to the Project Officer (PO) 1 copy to the Contracting Officer (CO)	On or before expiration of contract
3.	All stored biological specimens, data files, computerized listings of accurate and updated information on inventory,	To be determined	On or before expiration of contract

data bases, original data, and any necessary information related thereto

Copies of reports shall be sent to the following addresses:

<TABLE>
<CAPTION>

Project Officer - 2 copies	AND	Contracting Officer - 1 copy
-----		-----
<S>	<C>	
Blood Resources Program		BDR Contracts Section
Division of Blood Diseases & Resources		Contracts Operations Branch
National Heart, Lung, & Blood Institute		National Heart, Lung, & Blood Institute
6701 Rockledge Drive, MSC 7950, Room 10146		6701 Rockledge Drive, MSC 7902, Room 6140
Bethesda, MD 20892-7950		Bethesda, MD 20892-7902
Federal Express and Couriers:		Federal Express and Couriers:
 6701 Rockledge Drive		 6701 Rockledge Drive
Rockledge 2, 10th Floor, Room 10146		Rockledge Two, 6th Floor, Room 6140
Bethesda, MD 20817		Bethesda, MD 20817

</TABLE>

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address:
<http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).

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SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer will represent the Government for the purpose of this contract:

Luiz H. Barbosa, D.V.M.

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in this contract, the following individual is considered to be essential to the work being performed hereunder:

NAME	TITLE
Mark Cosentino, Ph.D.	Principal Investigator

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

(1) Invoices/financing requests shall be submitted as follows:

An original and two copies to the following designated billing office:

Contracting Officer
BDR Contracts Section, Contracts Operations Branch
National Heart, Lung, and Blood Institute, NIH
RKL2, Room 6140
6701 ROCKLEDGE DRIVE, MSC 7902
BETHESDA MD 20892-7902

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 435-0359.

b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal

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Year funds subject to the salary rate limitation provisions as specified in ARTICLE H.5. of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. [cite the applicable Public Law Number for the applicable Fiscal Year as stated in ARTICLE H.5.] and ARTICLE H.5. of the above referenced contract."

ARTICLE G.4 . CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

- b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled "PREPARATION INSTRUCTIONS," all columns A through J, shall be completed for each report submitted.
- c. The first financial report shall cover the period consisting of the FIRST FULL THREE CALENDAR MONTHS following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.
- d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.
- e. The listing of expenditure categories to be reported is incorporated within the Financial Report of Individual Project/Contract, NIH 2706, SECTION J, ATTACHMENT 2, attached hereto and made a part of this contract.
- f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

ARTICLE G.5. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Division of Financial Advisory Services
 Office of Contract Management
 National Institutes of Health
 6100 EXECUTIVE BLVD ROOM 6B05
 BETHESDA MD 20892

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.6 . GOVERNMENT PROPERTY

- a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in Section I of this contract, the Contractor shall comply with the provisions of DHHS Publication, Contractor's Guide for Control of Government Property, (1990), which is incorporated into this contract by reference. Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract. A copy of this publication is available upon request to the Contract Property

Administrator.

This contract's Contract Property Administrator is:

Marea Petrelles
 Contracts Property Administrator
 Research Contracts Property Administration, NIH
 6011 Executive Blvd., Room 641E
 ROCKVILLE MD 20852-7670
 (301) 496-6466

- b. Contractor-Acquired Government Property - Schedule I-B

Pursuant to the Clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor shall be authorized to acquire the property listed in Schedule I-B for use in direct performance of the contract, following receipt of the Contracting Officer's written approval, based on contractor-furnished prices and evidence of competition.

c. Property Acquired Under Predecessor Contract - Schedule II-A

Pursuant to the clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor shall be authorized, at the time of relocation of the NHLBI Biological Specimen Repository, to obtain custody of all Government Property listed in the attached Schedule II-A for use in direct performance of this contract. Accountability for the items listed in Schedule II-A shall be transferred, at the time of relocation of the NHLBI Biological Specimen Repository, to this contract from the predecessor Contract No. N01-HB017087, under which these items were provided by the Government. Title to this property shall remain in the Government.

ARTICLE G.7. POST AWARD EVALUATION OF PAST PERFORMANCE

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. Any disagreement between the parties regarding an evaluation will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT

PROJECTS

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research

by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they consider worthy of support by submitting those

projects to the appropriate Public Health Service grant office for review. Since these projects may be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

ARTICLE H.2 . HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.3. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

Section 513 of the Fiscal Year 1998 Appropriations Act (P.L. 105-78) prohibits NIH from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C . 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the Act, that are derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

ARTICLE H.4. NEEDLE EXCHANGE

Pursuant to Section 505 of Public Law 105-78, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. Section 505, however, is subject to the condition stated in Section 506. Specifically, Section 506 states that after March 31, 1998, a program for exchanging needles and syringes for used hypodermic needles and syringes may be carried out in a community if: (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by the Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.

ARTICLE H.5. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds for the applicable fiscal year(s) and periods cited in paragraph b., below may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year and period covered. Direct salary is exclusive of overhead, fringe benefits and general and administrative expenses. The per year salary rate limit also applies to individuals proposed under subcontracts. If this is a multi-year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts.

Public Law No.	Fiscal Year	Period Covered	Dollar Amount of Salary Limitation
105-78	1998	10/01/1997-09/30/1998	\$125,000

ARTICLE H.6. PUBLICATION AND PUBLICITY

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The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Heart, Lung, and Blood Institute, National Institutes of Health, under Contract No. N01-HB-87144."

ARTICLE H.7. PRESS RELEASES

Pursuant to Section 508 of Public Law 105-78, the contractor shall clearly state, when issuing statements, press released, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal Money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernment sources.

ARTICLE H.8. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on (<http://www1.od.nih.gov/oma/oma.htm>).

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PART II

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT

CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	TITLE AND DATE
52.202-1	Definitions (OCTOBER 1995)

- 52.203-3 Gratuities (Over \$100,000) (APRIL 1984)
- 52.203-5 Covenant Against Contingent Fees (Over \$100,000) (APRIL 1984)
- 52.203-6 Restrictions on Subcontractor Sales to the Government (Over \$100,000) (JULY 1995)
- 52.203-7 Anti-Kickback Procedures (Over \$100,000) (JULY 1995)
- 52.203-8 Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000) (JANUARY 1997)
- 52.203-10 Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000) (JANUARY 1997)
- 52.203-12 Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000) (JUNE 1997)
- 52.204-4 Printing/Copying Double-Sided on Recycled Paper (Over \$100,000) (JUNE 1996)
- 52.209-6 Protecting the Government's Interests when Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000) (JULY 1995)
- 52.215-2 Audit and Records - Negotiation (Over \$100,000) (AUGUST 1996)
- 52.215-8 Order of Precedence-Uniform Contract Format (OCTOBER 1997)
- 52.215-10 Price Reduction for Defective Cost or Pricing Data (Over \$500,000) (OCTOBER 1997)
- 52.215-12 Subcontractor Cost or Pricing Data (Over \$500,000) (OCTOBER 1997)
- 52.215-14 Integrity of Unit Prices (Over \$100,000) (OCTOBER 1997)
- 52.215-15 Termination of Defined Benefit Pension Plans (OCTOBER 1997)
- 52.215-18 Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions (OCTOBER 1997)

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- 52.215-19 Notification of Ownership Changes (OCTOBER 1997)
- 52.215-21 Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data--Modifications (OCTOBER 1997)
- 52.216-7 Allowable Cost and Payment (APRIL 1998)
- 52.216-8 Fixed Fee (MARCH 1997)
- 52.219-8 Utilization of Small, Small Disadvantaged, and Women-Owned Small Business Concerns (Over \$100,000) (JUNE 1997)
- 52.219-9 Small, Small Disadvantaged, and Women-Owned Small Business Subcontracting Plan (Over \$500,000) (AUGUST 1996)
- 52.219-16 Liquidated Damages - Subcontracting Plan (Over \$500,000) (OCTOBER 1995)

- 52.222-2 Payment for Overtime Premium (Over \$100,000) (JULY 1990) (NOTE: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
- 52.222-3 Convict Labor (AUGUST 1996)
- 52.222-26 Equal Opportunity (APRIL 1984)
- 52.222-28 Equal Opportunity Preaward Clearance of Subcontracts (Over \$1,000,000) (APRIL 1984)
- 52.222-35 Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (APRIL 1998)
- 52.222-36 Affirmative Action for Handicapped Workers (APRIL 1984)
- 52.222-37 Employment Reports on Disabled Veterans and Veterans of the Vietnam Era (APRIL 1998)
- 52.223-2 Clean Air and Water (Over \$100,000) (APRIL 1984)
- 52.223-6 Drug-Free Workplace (JANUARY 1997)
- 52.223-14 Toxic Chemical Release Reporting (OCTOBER 1996)
- 52.225-3 Buy American Act--Supplies (JANUARY 1994)
- 52.225-11 Restrictions on Certain Foreign Purchases (OCTOBER 1996)
- 52.227-1 Authorization and Consent (Over \$50,000) (JULY 1995)--Alternate I (APRIL 1984)
- 52.227-2 Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000) (AUGUST 1996)
- 52.227-11 Patent Rights - Retention by the Contractor (Short Form) (JUNE 1997) NOTE: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2) (i) through (iv). The frequency of reporting in (i) is annual.

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- 52.227-14 Rights in Data - General (JUNE 1987)
- 52.232-9 Limitation on Withholding of Payments (APRIL 1984)
- 52.232-17 Interest (Over \$100,000) (JUNE 1996)
- 52.232-20 Limitation of Cost (APRIL 1984)
- 52.232-23 Assignment of Claims (JANUARY 1986)
- 52.232-25 Prompt Payment (JUNE 1997)
- 52.232-33 Mandatory Information for Electronic Funds Transfer Payment (AUGUST 1996)
- 52.233-1 Disputes (OCTOBER 1995)
- 52.233-3 Protest After Award (AUGUST 1996) With Alternate I (JUNE 1985)
- 52.242-1 Notice of Intent to Disallow Costs (APRIL 1984)
- 52.242-3 Penalties for Unallowable Costs (Over \$500,000) (OCTOBER 1995)

- 52.242-4 Certification of Final Indirect Costs (JANUARY 1997)
- 52.242-13 Bankruptcy (Over \$100,000) (JULY 1995)
- 52.243-2 Changes - Cost Reimbursement (AUGUST 1987) Alternate V (APRIL 1984)
- 52.244-2 Subcontracts (Cost-Reimbursement and Letter Contracts) (FEBRUARY 1997) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
- 52.244-5 Competition in Subcontracting (Over \$100,000) (DECEMBER 1996)
- 52.245-5 Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract) (JANUARY 1986)
- 52.246-23 Limitation of Liability (Over \$100,000) (FEBRUARY 1997)
- 52.249-6 Termination (Cost-Reimbursement) (SEPTEMBER 1996)
- 52.249-14 Excusable Delays (APRIL 1984)
- 52.253-1 Computer Generated Forms (JANUARY 1991)

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b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR
 CLAUSE NO. TITLE AND DATE

- 352.202-1 Definitions (APRIL 1984) Alternate I (APRIL 1984)
- 352.228-7 Insurance - Liability to Third Persons (DECEMBER 1991)
- 352.232-9 Withholding of Contract Payments (APRIL 1984)
- 352.233-70 Litigation and Claims (APRIL 1984)
- 352.242-71 Final Decisions on Audit Findings (APRIL 1984)
- 352.270-5 Key Personnel (APRIL 1984)
- 352.270-6 Publication and Publicity (JULY 1991)
- 352.270-7 Paperwork Reduction Act (APRIL 1984)

End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT]

ARTICLE I.2 AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the contracting officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

- (1) FAR 52.223-3, Hazardous Material Identification and Material Safety Data (JANUARY 1997), ALTERNATE I (JULY 1995).
- (2) FAR 52.223-12, Refrigeration Equipment and Air Conditioners (MAY 1995).
- (3) FAR 52.232-18, Availability of Funds (APRIL 1984).
- (4) FAR 52.237-3, Continuity of Services (JANUARY 1991).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

- (1) PHS 352.223-70, Safety and Health (Deviation) (AUGUST 1997).

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c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clause is attached and made a part of this contract:

- (1) NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

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PART III

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1 (5/97), 4 pages.
2. Financial Report of Individual Project/Contract, NIH 2706, (5/97), 1 page.
3. Instructions for Completing form NIH 2706, Financial Report of Individual Project/Contract, (5/97), 3 pages.
4. Safety and Health (Deviation) , PHSAR Clause 352.223-70, (8/97), 1 page.
5. Procurement of Certain Equipment, NIH(RC)-7, 4/1/84, 1 page.
6. Contractor-Acquired Government Property - Schedule I-B, dated June 1998, 1 page.
7. Property Acquired Under Predecessor Contract, Schedule II-A, dated June 1998, 1 page.

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PART IV

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. Representations and Certifications, dated October 17, 1997. .

END of the CONTRACT

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Property Acquired Under Predecessor Contract

Schedule II-A

June 1998

See attached DHHS Report of Accountable Property (HHS-565), dated 3/16/98 and 10/29/97.

Attachment 6

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Contractor-Acquired Government Property

Schedule I-B

June 1998

Estimated Description -----	Quantity -----	Unit Price -----	Total -----
So-Low freezer cabinet Model C80-27, temperature range -40 degrees C to -80 degrees C, 27 cu. ft. capacity	36	\$ 6,650	\$239,400

Attachment 6

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SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objectives of this project are to maintain a repository of blood specimens from NHLBI-sponsored studies and to make appropriate specimens available to the scientific community for use in research related to transfusion-transmitted diseased and a variety of other disorders of blood or the cardiovascular system.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

- a. The estimated cost of this contract is \$_____.
- b. The fixed fee for this contract is \$_____. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.
- c. The Government's obligation, represented by the sum of the estimated cost plus fixed fee, is \$2,901,590.
- d. Total funds currently available for payment and allotted to this contract are \$377,835, of which \$356,448 represents the estimated costs, and of which \$21,387 represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.
- e. It is estimated that the amount currently allotted will cover performance of the contract through June 14, 1999.
- f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.
- g. Future increments to be allotted to this contract are estimated as follows:

Period	Amount
--------	--------

June 15, 1999 through June 14, 2000	\$ 461,262
June 15, 2000 through June 14, 2001	481,974
June 15, 2001 through June 14, 2002	503,693
June 15, 2002 through June 14, 2003	526,469
June 15, 2003 through June 14, 2004	550,357

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses, ALLOWABLE COST AND PAYMENT and FIXED FEE, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

- (1) Acquisition, by purchase or lease, of any interest in real property;
- (2) Special rearrangement or alteration of facilities;
- (3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

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- (4) Travel to attend general scientific meetings;
- (5) Foreign travel;
- (6) Patient care costs;
- (7) Accountable Government property (defined as both real and personal property with an acquisition cost of \$1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide for

Control of Government Property), 1990, regardless of acquisition value.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. Consultants

Consultant fees to be paid to the following individuals:

b. Repository Relocation

A transition phase (June 15, 1998 through December 15, 1998) is provided for relocation of the NHLBI biological specimen repository

from McKesson BioServices, 685 Loftstrand Lane, Rockville, Maryland 20850 to the repository facility operated by BBI-Biotech Research Laboratories, Inc., 217 Perry Parkway, Gaithersburg, Maryland. The Contractor shall complete interior fit out of the NHLBI repository space, located at 217 Perry Parkway, Gaithersburg, Maryland, so as to allow for a safe and orderly transition of the NHLBI biological specimen repository from McKesson BioServices to the new location. The Contractor shall transfer all Government-owned NHLBI freezers, biological specimens, files, and inventory records, on or before December 15, 1998. Repository relocation costs shall not exceed \$23,932.

c. Confidential Treatment of Sensitive Information

The Contractor shall guarantee strict confidentiality of the information/data that it is provided by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature and cannot be disclosed in any manner.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

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ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below:

PHASE I - Transition

The contractor shall coordinate an orderly and safe transition from the current incumbent contractor site to the new location, including the transport of stored specimens, data, and all Government-furnished property. Contractor shall adhere to the moving plan previously approved by the Department of Transportation (DOT). This approval allows for the exemption from the requirements of 46 CFR Part 64 regarding Federal hazardous material transportation law so that specimens shall be moved in the freezers in which they are stored.

Relocation of the NHLBI repository from McKesson BioServices, 685 Lofstrand Lane, Rockville, MD 20850 to the Contractor's facility at 217 Perry Parkway, Gaithersburg, Maryland 20877 shall be completed before December 15, 1998. At the time of repository relocation, it is estimated that 2.8 million specimens will be stored in 98 freezers and 5 liquid nitrogen tanks.

PHASE II Repository Maintenance

Task 1 - Maintain Serum, Plasma, and Cell Repository

The contractor shall provide facilities and equipment to receive, store, aliquot, and distribute potentially hazardous biologics such as serum, plasma, and cells from individuals infected with AIDS virus and hepatitis viruses. The facilities must provide aseptic and/or sterile conditions as appropriate

(Biosafety Level 2 Containment). The specimens shall be maintained by the contractor in freezers at temperatures between -70 degrees and -80 degrees centigrade. Freezers shall be located in an air-conditioned facility with temperatures maintained between 20 degrees and 25 degrees centigrade (60 degrees to 77 degrees F) when freezers are in operation. The contractor shall supply uninterruptible power to accommodate the refrigerators/freezers and other equipment. Freezers shall be connected to a central alarm system monitored twenty-four hours per day. The contractor shall provide an automated temperature monitoring system composed of individual temperature probes monitored 24 hours a day and controlled by a master computer, and a plan to ensure that necessary personnel are notified in the event of freezer malfunction. Emergency standby freezers shall be available in case of mechanical failure of any portion of storage space. In addition, alternative emergency freezer cooling systems such as a liquid nitrogen system or dry ice must be available. The contractor must have backup electric generators capable of operating all storage equipment for at least 48 hours in the event of utility company power failure. Backup generators must be tested monthly. Cell specimens (or tissues) shall be maintained at liquid nitrogen gas phase, in special liquid nitrogen chests.

In order to accommodate the estimated increase of the number of specimens/vials contained in the repository and the replacement of obsolete freezers, the contractor shall purchase approximately six freezers per year, using contract funds. The estimated increase in vials will result from the splitting of specimens and arrival of new specimens.

Task 2 - Preparing Aliquots from Selected Specimens *

The contractor shall provide laboratory facilities and personnel for dividing the serum or plasma samples into aliquots. All requests for samples are reviewed by the NHLBI. Once an original specimen is identified for distribution, it is thawed

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and divided into aliquots, one of which is sent to the investigator, and the remaining aliquots refrozen for later use. It is estimated that approximately 1,000 specimens shall be divided into 10,000 aliquots annually.

Thus, the size of the repository increases regularly as original specimens are divided and distributed and new specimens are added to the repository. The handling of all biological specimens and Government-owned property under this contract shall be in accordance with all applicable local, state, and federal regulations. In addition, in order to provide safety controls for protection to the life and health of employees and other persons, the contractor shall consult, comply with, and include in all applicable subcontracts, the following standards, as appropriate:

- 1) Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and the NIH, DHHS Pub. No. (CDC) 93-8395.
- 2) Occupational Safety and Health Administration (OSHA), Publication 29 CFR Part 1910.1030, Occupational Exposure to Blood Borne Pathogens, Final Rule.

Task 3 -Prepare and Ship Panels of Aliquots or Specimens *

The Project Officer receives and reviews requests from investigators for specimens or panels of aliquots. When a request is approved, the NHLBI Project Officer will design panels of aliquots or specimens on the basis of the investigator's experimental needs. On the basis of that design, the Project Officer will provide to the contractor the information needed to prepare and ship each panel. It is estimated that preparation and shipment of approximately 50 panels, containing 100 vials each, will be required annually. A list identifying the specimens to be included in a panel will be provided to the contractor.

The contractor shall prepare the panels as required by the Project Officer.

Shipments will require preparation of the panel, packing the panel in dry ice, packaging the panel in insulated boxes, and express shipment (usually by air) to the final destination (specifically, the approved investigator). The contractor shall ship all vials C.O.D.; transportation and postage costs are to be paid by the recipients from point of carrier receipt. The contractor shall verify receipt of the panel by the investigator both in writing and by phone. Packaging and shipment shall meet standards for biologically hazardous materials (see publication prepared by the International Air Transport Association (IATA), Dangerous Goods Regulations, current edition).

Task 4 - Add Specimens to the Repository *

The contractor shall inventory, prepare for storage, package, and label, as necessary, specimens to be added to the repository. The project officer will specify the dates of arrival of such specimens, the number of specimens, and the means of packaging, labeling and storing these samples as well as the type, number and location of freezers to be relocated to the contractor's site. It is essential that shipments be coordinated by the contractor so that personnel will be available to receive the arriving packages and transport shipment to the NHLBI repository for storage at the required temperature.

Task 5 - Performance of Virologic and Serologic Assays *

The contractor shall provide the capability to perform (in-house or through a subcontractor) serologic and virologic assays for the evaluation and validation of candidate blood screening tests for the detection of transfusion-associated agents. For this purpose, laboratory biosafety level 2 shall be required, as well as laboratory personnel with specific training in handling pathogenic agents.

Laboratory personnel, safety practices, and techniques shall be supplemented by appropriate facility design and engineering features, safety equipment, and management practices. The contractor shall ensure that persons working with these infectious agents are aware of potential hazards and strictly adhere to standard microbiological practices and techniques. Costs for these assays will be negotiated and the contract amount increased as the need arises.

The human pathogens for which blood screening tests are being developed or improved and, therefore, are likely to be involved in future assay evaluation and validation procedures, include hepatitis viruses, human retroviruses, and agents of

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transmissible spongiform encephalopathies. Among the serologic and virologic test formats that the contractor is expected to perform are enzyme immunoassays, polymerase chain reactions, immunoblotting, and in situ hybridization. It is expected that 500 - 1,000 assays will be required per year.

Task 6 - Inventory Control

The contractor shall update and maintain a computerized inventory control data base using a desktop personal computer system to track and assist in the coordination of the activities under this contract. At the time of contract award, the FoxPro data base will contain information on approximately 2.1 million specimens. This will provide inventory and management information to reflect activities of the repository, i.e., location of specimens, aliquoting of specimens, preparation of panels, and addition of new specimens. In addition, the SAS/Repository Management System (RMS) inventory and management data base shall reflect activities on approximately 700,000 specimens including location of specimens, aliquoting of specimens, preparation of panels, addition of new specimens, and results of assays performed by outside investigators using NHLBI specimens. The SAS software and license shall be provided to the contractor by the Government.

Task 7 - Ensure an Orderly Transition of the NHLBI Biological Specimen

Repository to a Successor Contractor

In the event there is a recompetition of the subject contract and an organization other than the incumbent is selected for contract award, incumbent shall assist in ensuring an orderly and safe transition of the repository from the current location at (address of repository at time of relocation) to any successor of this contract. This shall include providing repository access to the new contractor at mutually agreed upon times.

* SPECIAL TRAINING REQUIREMENTS:

Repository personnel involved in tasks 2, 3, 4, and 5 shall have specific training in handling pathogenic agents and dealing with potential hazards of the pathogens likely to be involved in the operation of the repository.

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract:

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following format:

1. Quarterly Progress Report: This report shall include descriptive information on activities in the repository during the reporting period. The reporting period consists of the first full three months of performance plus any fractional part of the initial month. The first report shall be due September 30, 1998. Thereafter, the reporting period shall consist of three full calendar months. This report shall include the following:

- a. the number of vials stored on the first and last days of the reporting period;
- b. the number of vials prepared during the reporting period;
- c. a list of panels prepared and shipped during the reporting period including, for each panel:
 - 1) number of specimens (vials),
 - 2) date of shipment,
 - 3) date of receipt of shipment, and
 - 4) problems with any shipment;

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- d. maintenance problems encountered and corrective actions taken;
- e. needs for replacement or repair of government-furnished equipment; and

2. Final Report: Cumulative information for period of performance of all information included in quarterly progress reports.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked, and shipped in accordance with Government specifications. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this ARTICLE the Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

Division of Blood Diseases & Resources
National Heart, Lung, & Blood Institute
6701 Rockledge Drive, MSC 7950, Room 10146
Bethesda, MD 20892-7950

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause No. 52.246-5, INSPECTION OF SERVICES-COST REIMBURSEMENT (APRIL 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

- a. Satisfactory performance of this contract shall be deemed to occur upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.
- b. The items specified below as described in SECTION C, ARTICLE C.1 and ARTICLE C.2. shall be made f.o.b. destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984) and in accordance with and by the dates specified below:

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Item	Description	Quantity	Delivery Schedule
1.	Quarterly Progress Report Officer (CO)	2 copies to the Project Officer (PO), 1 copy to the Contracting Officer (CO)	Quarterly during period of performance
2.	Final Report Officer (CO)	2 copies to the Project Officer (PO) 1 copy to the Contracting Officer (CO)	On or before expiration of contract
3.	All stored biological specimens, data files, computerized listings of accurate and updated information on inventory,	To be determined	On or before expiration of contract

data bases, original data, and any necessary information related thereto

Copies of reports shall be sent to the following addresses:

<TABLE>
<CAPTION>

Project Officer - 2 copies	AND	Contracting Officer - 1 copy
-----		-----
<S>	<C>	
Blood Resources Program		BDR Contracts Section
Division of Blood Diseases & Resources		Contracts Operations Branch
National Heart, Lung, & Blood Institute		National Heart, Lung, & Blood Institute
6701 Rockledge Drive, MSC 7950, Room 10146		6701 Rockledge Drive, MSC 7902, Room 6140
Bethesda, MD 20892-7950		Bethesda, MD 20892-7902
Federal Express and Couriers:		Federal Express and Couriers:
 6701 Rockledge Drive		 6701 Rockledge Drive
Rockledge 2, 10th Floor, Room 10146		Rockledge Two, 6th Floor, Room 6140
Bethesda, MD 20817		Bethesda, MD 20817

</TABLE>

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address:
<http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).

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SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer will represent the Government for the purpose of this contract:

Luiz H. Barbosa, D.V.M.

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in this contract, the following individual is considered to be essential to the work being performed hereunder:

NAME	TITLE
Mark Cosentino, Ph.D.	Principal Investigator

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

(1) Invoices/financing requests shall be submitted as follows:

An original and two copies to the following designated billing office:

Contracting Officer
BDR Contracts Section, Contracts Operations Branch
National Heart, Lung, and Blood Institute, NIH
RKL2, Room 6140
6701 ROCKLEDGE DRIVE, MSC 7902
BETHESDA MD 20892-7902

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 435-0359.

b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal

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Year funds subject to the salary rate limitation provisions as specified in ARTICLE H.5. of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. [cite the applicable Public Law Number for the applicable Fiscal Year as stated in ARTICLE H.5.] and ARTICLE H.5. of the above referenced contract."

ARTICLE G.4 . CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

- b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled "PREPARATION INSTRUCTIONS," all columns A through J, shall be completed for each report submitted.
- c. The first financial report shall cover the period consisting of the FIRST FULL THREE CALENDAR MONTHS following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.
- d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.
- e. The listing of expenditure categories to be reported is incorporated within the Financial Report of Individual Project/Contract, NIH 2706, SECTION J, ATTACHMENT 2, attached hereto and made a part of this contract.
- f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

ARTICLE G.5. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Division of Financial Advisory Services
Office of Contract Management
National Institutes of Health
6100 EXECUTIVE BLVD ROOM 6B05
BETHESDA MD 20892

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.6 . GOVERNMENT PROPERTY

- a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in Section I of this contract, the Contractor shall comply with the provisions of DHHS Publication, Contractor's Guide for Control of Government Property, (1990), which is incorporated into this contract by reference. Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract. A copy of this publication is available upon request to the Contract Property

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Administrator.

This contract's Contract Property Administrator is:

Marea Petrelles
Contracts Property Administrator
Research Contracts Property Administration, NIH
6011 Executive Blvd., Room 641E
ROCKVILLE MD 20852-7670
(301) 496-6466

- b. Contractor-Acquired Government Property - Schedule I-B

Pursuant to the Clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor shall be authorized to acquire the property listed in Schedule I-B for use in direct performance of the contract, following receipt of the Contracting Officer's written approval, based on contractor-furnished prices and evidence of competition.

c. Property Acquired Under Predecessor Contract - Schedule II-A

Pursuant to the clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor shall be authorized, at the time of relocation of the NHLBI Biological Specimen Repository, to obtain custody of all Government Property listed in the attached Schedule II-A for use in direct performance of this contract. Accountability for the items listed in Schedule II-A shall be transferred, at the time of relocation of the NHLBI Biological Specimen Repository, to this contract from the predecessor Contract No. N01-HB017087, under which these items were provided by the Government. Title to this property shall remain in the Government.

ARTICLE G.7. POST AWARD EVALUATION OF PAST PERFORMANCE

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. Any disagreement between the parties regarding an evaluation will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT

PROJECTS

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research

by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they consider worthy of support by submitting those

projects to the appropriate Public Health Service grant office for review. Since these projects may be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

ARTICLE H.2 . HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.3. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

Section 513 of the Fiscal Year 1998 Appropriations Act (P.L. 105-78) prohibits NIH from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C . 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the Act, that are derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

ARTICLE H.4. NEEDLE EXCHANGE

Pursuant to Section 505 of Public Law 105-78, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. Section 505, however, is subject to the condition stated in Section 506. Specifically, Section 506 states that after March 31, 1998, a program for exchanging needles and syringes for used hypodermic needles and syringes may be carried out in a community if: (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by the Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.

ARTICLE H.5. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds for the applicable fiscal year(s) and periods cited in paragraph b., below may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year and period covered. Direct salary is exclusive of overhead, fringe benefits and general and administrative expenses. The per year salary rate limit also applies to individuals proposed under subcontracts. If this is a multi-year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts.

Public Law No.	Fiscal Year	Period Covered	Dollar Amount of Salary Limitation
105-78	1998	10/01/1997-09/30/1998	\$125,000

ARTICLE H.6. PUBLICATION AND PUBLICITY

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The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Heart, Lung, and Blood Institute, National Institutes of Health, under Contract No. N01-HB-87144."

ARTICLE H.7. PRESS RELEASES

Pursuant to Section 508 of Public Law 105-78, the contractor shall clearly state, when issuing statements, press released, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal Money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernment sources.

ARTICLE H.8. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on (<http://www1.od.nih.gov/oma/oma.htm>).

Contract No. N01-HB-87144

PART II

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT

CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	TITLE AND DATE
52.202-1	Definitions (OCTOBER 1995)

- 52.203-3 Gratuities (Over \$100,000) (APRIL 1984)
- 52.203-5 Covenant Against Contingent Fees (Over \$100,000) (APRIL 1984)
- 52.203-6 Restrictions on Subcontractor Sales to the Government (Over \$100,000) (JULY 1995)
- 52.203-7 Anti-Kickback Procedures (Over \$100,000) (JULY 1995)
- 52.203-8 Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000) (JANUARY 1997)
- 52.203-10 Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000) (JANUARY 1997)
- 52.203-12 Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000) (JUNE 1997)
- 52.204-4 Printing/Copying Double-Sided on Recycled Paper (Over \$100,000) (JUNE 1996)
- 52.209-6 Protecting the Government's Interests when Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000) (JULY 1995)
- 52.215-2 Audit and Records - Negotiation (Over \$100,000) (AUGUST 1996)
- 52.215-8 Order of Precedence-Uniform Contract Format (OCTOBER 1997)
- 52.215-10 Price Reduction for Defective Cost or Pricing Data (Over \$500,000) (OCTOBER 1997)
- 52.215-12 Subcontractor Cost or Pricing Data (Over \$500,000) (OCTOBER 1997)
- 52.215-14 Integrity of Unit Prices (Over \$100,000) (OCTOBER 1997)
- 52.215-15 Termination of Defined Benefit Pension Plans (OCTOBER 1997)
- 52.215-18 Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions (OCTOBER 1997)

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- 52.215-19 Notification of Ownership Changes (OCTOBER 1997)
- 52.215-21 Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data--Modifications (OCTOBER 1997)
- 52.216-7 Allowable Cost and Payment (APRIL 1998)
- 52.216-8 Fixed Fee (MARCH 1997)
- 52.219-8 Utilization of Small, Small Disadvantaged, and Women-Owned Small Business Concerns (Over \$100,000) (JUNE 1997)
- 52.219-9 Small, Small Disadvantaged, and Women-Owned Small Business Subcontracting Plan (Over \$500,000) (AUGUST 1996)
- 52.219-16 Liquidated Damages - Subcontracting Plan (Over \$500,000) (OCTOBER 1995)

- 52.222-2 Payment for Overtime Premium (Over \$100,000) (JULY 1990) (NOTE: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
- 52.222-3 Convict Labor (AUGUST 1996)
- 52.222-26 Equal Opportunity (APRIL 1984)
- 52.222-28 Equal Opportunity Preaward Clearance of Subcontracts (Over \$1,000,000) (APRIL 1984)
- 52.222-35 Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (APRIL 1998)
- 52.222-36 Affirmative Action for Handicapped Workers (APRIL 1984)
- 52.222-37 Employment Reports on Disabled Veterans and Veterans of the Vietnam Era (APRIL 1998)
- 52.223-2 Clean Air and Water (Over \$100,000) (APRIL 1984)
- 52.223-6 Drug-Free Workplace (JANUARY 1997)
- 52.223-14 Toxic Chemical Release Reporting (OCTOBER 1996)
- 52.225-3 Buy American Act--Supplies (JANUARY 1994)
- 52.225-11 Restrictions on Certain Foreign Purchases (OCTOBER 1996)
- 52.227-1 Authorization and Consent (Over \$50,000) (JULY 1995)--Alternate I (APRIL 1984)
- 52.227-2 Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000) (AUGUST 1996)
- 52.227-11 Patent Rights - Retention by the Contractor (Short Form) (JUNE 1997) NOTE: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2) (i) through (iv). The frequency of reporting in (i) is annual.

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- 52.227-14 Rights in Data - General (JUNE 1987)
- 52.232-9 Limitation on Withholding of Payments (APRIL 1984)
- 52.232-17 Interest (Over \$100,000) (JUNE 1996)
- 52.232-20 Limitation of Cost (APRIL 1984)
- 52.232-23 Assignment of Claims (JANUARY 1986)
- 52.232-25 Prompt Payment (JUNE 1997)
- 52.232-33 Mandatory Information for Electronic Funds Transfer Payment (AUGUST 1996)
- 52.233-1 Disputes (OCTOBER 1995)
- 52.233-3 Protest After Award (AUGUST 1996) With Alternate I (JUNE 1985)
- 52.242-1 Notice of Intent to Disallow Costs (APRIL 1984)
- 52.242-3 Penalties for Unallowable Costs (Over \$500,000) (OCTOBER 1995)

- 52.242-4 Certification of Final Indirect Costs (JANUARY 1997)
- 52.242-13 Bankruptcy (Over \$100,000) (JULY 1995)
- 52.243-2 Changes - Cost Reimbursement (AUGUST 1987) Alternate V (APRIL 1984)
- 52.244-2 Subcontracts (Cost-Reimbursement and Letter Contracts) (FEBRUARY 1997) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
- 52.244-5 Competition in Subcontracting (Over \$100,000) (DECEMBER 1996)
- 52.245-5 Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract) (JANUARY 1986)
- 52.246-23 Limitation of Liability (Over \$100,000) (FEBRUARY 1997)
- 52.249-6 Termination (Cost-Reimbursement) (SEPTEMBER 1996)
- 52.249-14 Excusable Delays (APRIL 1984)
- 52.253-1 Computer Generated Forms (JANUARY 1991)

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b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR
 CLAUSE NO. TITLE AND DATE

- 352.202-1 Definitions (APRIL 1984) Alternate I (APRIL 1984)
- 352.228-7 Insurance - Liability to Third Persons (DECEMBER 1991)
- 352.232-9 Withholding of Contract Payments (APRIL 1984)
- 352.233-70 Litigation and Claims (APRIL 1984)
- 352.242-71 Final Decisions on Audit Findings (APRIL 1984)
- 352.270-5 Key Personnel (APRIL 1984)
- 352.270-6 Publication and Publicity (JULY 1991)
- 352.270-7 Paperwork Reduction Act (APRIL 1984)

End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT]

ARTICLE I.2 AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the contracting officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

- (1) FAR 52.223-3, Hazardous Material Identification and Material Safety Data (JANUARY 1997), ALTERNATE I (JULY 1995).
- (2) FAR 52.223-12, Refrigeration Equipment and Air Conditioners (MAY 1995).
- (3) FAR 52.232-18, Availability of Funds (APRIL 1984).
- (4) FAR 52.237-3, Continuity of Services (JANUARY 1991).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

- (1) PHS 352.223-70, Safety and Health (Deviation) (AUGUST 1997).

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c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clause is attached and made a part of this contract:

- (1) NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

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PART III

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1 (5/97), 4 pages.
2. Financial Report of Individual Project/Contract, NIH 2706, (5/97), 1 page.
3. Instructions for Completing form NIH 2706, Financial Report of Individual Project/Contract, (5/97), 3 pages.
4. Safety and Health (Deviation) , PHSAR Clause 352.223-70, (8/97), 1 page.
5. Procurement of Certain Equipment, NIH(RC)-7, 4/1/84, 1 page.
6. Contractor-Acquired Government Property - Schedule I-B, dated June 1998, 1 page.
7. Property Acquired Under Predecessor Contract, Schedule II-A, dated June 1998, 1 page.

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PART IV

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. Representations and Certifications, dated October 17, 1997. .

END of the CONTRACT

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Property Acquired Under Predecessor Contract

Schedule II-A

June 1998

See attached DHHS Report of Accountable Property (HHS-565), dated 3/16/98 and 10/29/97.

Attachment 6

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Contractor-Acquired Government Property

Schedule I-B

June 1998

Estimated Description -----	Quantity -----	Unit Price -----	Total -----
So-Low freezer cabinet Model C80-27, temperature range -40 degrees C to -80 degrees C, 27 cu. ft. capacity	36	\$ 6,650	\$239,400

Attachment 6