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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 1997, 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 0-21615

BOSTON BIOMEDICA, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

| MASSACHUSETTS | 04-2652826 |
|---|---|
| (State or other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |

| 375 WEST STREET, WEST BRIDGEWATER, MASSACHUSETTS | 02379 |
|---|---|
| (Address of Principal Executive Offices) | (Zip Code) |

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.

[X] Yes [ ] No

The number of shares outstanding of the Registrant's only class of common stock as of April 30, 1997 was 4,391,403.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

<TABLE>
<CAPTION>

For the Three Months Ended

| | March 31, | |
|---|---|---|
| | 1997 | 1996 |
| REVENUE: | | |
| <S> | <C> | <C> |
| Product sales | $ 2,126,956 | $ 1,815,481 |
| Services | 2,082,093 | 1,268,528 |
| Total revenue | 4,209,049 | 3,084,009 |
| COSTS AND EXPENSES: | | |
| Cost of product sales | 1,055,422 | 899,826 |
| Cost of services | 1,475,532 | 1,133,439 |
| Research and development | 236,750 | 166,565 |
| Selling and marketing | 613,360 | 415,012 |
| General and administrative | 679,207 | 536,503 |
| Total operating costs and expenses | 4,060,271 | 3,151,345 |
| Income (loss) from operations | 148,778 | (67,336) |
| Interest income (expense), net | 97,486 | (93,560) |
| Income (loss) before income taxes | 246,264 | (160,896) |
| (Provision for) benefit from income taxes | (98,506) | 64,358 |
| Net income (loss) | $ 147,758 | $ (96,538) |
| Net income (loss) per share | $ .03 | $ (0.04) |
| Weighted average common and common equivalent shares outstanding | 4,825,582 | 2,564,774 |

</TABLE>

See Notes to Consolidated Financial Statements.



BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

<TABLE>
<CAPTION>

| | March 31, | December 31, |
|---|---|---|
| | 1997 | 1996 |
| ASSETS | | |
| CURRENT ASSETS: | | |
| <S> | <C> | <C> |
| Cash and cash equivalents | $ 7,019,559 | $ 8,082,642 |
| Accounts receivable, less allowances of $362,612 in 1997 and $352,058 in 1996 | 3,144,197 | 3,415,994 |
| Inventories | 4,461,582 | 4,180,334 |
| Prepaid expense and other | 316,634 | 239,950 |
| Deferred income taxes | 283,200 | 283,200 |
| Total current assets | 15,225,172 | 16,202,120 |
| Property and equipment, net | 2,937,354 | 2,699,158 |
| OTHER ASSETS: | | |
| Long term investment | 732,500 | 732,500 |

| | | |
|---|---|---|
| Goodwill and other intangibles, net | 90,694 | 95,302 |
| Notes receivable and other | 795,409 | 69,234 |
| | 1,618,603 | 897,036 |
| TOTAL ASSETS | $ 19,781,129 | $ 19,798,314 |

LIABILITIES AND STOCKHOLDERS' EQUITY

| | | |
|---|---|---|
| CURRENT LIABILITIES: | | |
| Current maturities of long term debt | $ 13,136 | $ 12,820 |
| Accounts payable | 1,146,988 | 991,839 |
| Accrued compensation | 521,023 | 840,666 |
| Accrued income taxes | 122,260 | 427,140 |
| Other accrued expenses | 331,228 | 264,262 |
| Deferred revenue | 1,056,531 | 829,477 |
| Total current liabilities | 3,191,166 | 3,366,204 |
| LONG-TERM LIABILITIES: | | |
| Long-term debt, less current maturities | 37,543 | 40,948 |
| Deferred income taxes | 101,580 | 101,580 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY | | |
| Common stock, $.01 par value; authorized 20,000,000 shares in 1997 and 1996; issued and outstanding 4,381,157 in 1997 and 4,378,157 in 1996 | 43,812 | 43,782 |
| Additional paid-in capital | 15,272,126 | 15,258,656 |
| Retained earnings | 1,134,902 | 987,144 |
| Total stockholders' equity | 16,450,840 | 16,289,582 |
| TOTAL LIABILITIES & STOCKHOLDERS' EQUITY | $ 19,781,129 | $ 19,798,314 |

</TABLE>

See Notes to Consolidated Financial Statements.



BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

<TABLE>
<CAPTION>

| | For the Three Months Ended March 31, | |
|---|---|---|
| | 1997 | 1996 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| <S> | <C> | <C> |
| Net income (loss) | $ 147,758 | $ (96,538) |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 166,774 | 120,632 |
| Provision for doubtful accounts | 10,554 | 7,338 |
| Deferred rent | (26,958) | (16,618) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 261,243 | 661,915 |
| Other assets | - | 1,421 |

| | | |
|---|---|---|
| Inventories | (281,248) | (154,374) |
| Prepaid expenses | (76,684) | (35,300) |
| Accounts payable | 155,149 | 222,167 |
| Accrued compensation and other expenses | (530,599) | (150,575) |
| Deferred revenue | 227,054 | 229,185 |
| Net cash provided by operating activities | 53,043 | 789,253 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Payments for additions to property and equipment | (400,362) | (116,257) |
| Advances under notes receivable and other assets | (726,175) | - |
| Net cash used in investing activities | (1,126,537) | (116,257) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Repayments of long-term debt | (3,089) | (675,285) |
| Proceeds of common stock issued | 13,500 | - |
| Net cash provided by (used in) financing activities | 10,411 | (675,285) |
| DECREASE IN CASH: | (1,063,083) | (2,289) |
| Cash, beginning of period | 8,082,642 | 11,463 |
| Cash, end of period | $ 7,019,559 | $ 9,174 |
| SUPPLEMENTAL INFORMATION: | | |
| Income taxes paid | $ 403,842 | $ 130,962 |
| Interest paid | $ 110 | 96,917 |

</TABLE>

See 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 three months ended March 31, 1997 are not necessarily indicative of the results that may be expected for the year ending December 31, 1997. For further information, refer to the consolidated financial statements and footnotes thereto included in the Form 10-K filing for the fiscal year ended December 31, 1996 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) Inventories

Inventories consisted of the following:

| | March 31, 1997 | December 31, 1996 |
|---|---|---|
| Raw materials ..... | $ 1,392,297 | $ 1,359,569 |
| Work-in-process ..... | 883,249 | 697,749 |
| Finished goods ..... | 2,186,036 | 2,123,016 |

| | |
|---|---|
| $ 4,461,582 | $ 4,180,334 |

(3) Computation of Income (Loss) Per Share

Net income per common share is computed based upon the weighted average number of common shares and as appropriate, common equivalent shares (using the treasury stock method) outstanding after certain adjustments described below. Common equivalent shares consist of common stock options and warrants outstanding. In accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 83, all common, redeemable common, and common equivalent shares issued during the twelve month period prior to the proposed date of the initial filing of the Registration Statement have been included in the calculation as if they were outstanding for all periods prior to the initial public offering using the treasury stock method and an offering price of $8.50 per share. Fully diluted net income (loss) per common share is not presented as it does not materially differ from primary earnings 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 is currently required under the provisions of Accounting Principles Board Opinion No. 15. Under SFAS No. 128, the Company will be required to present both basic net income per share and diluted net income per share. Basic net income (loss) per share for the quarters ended March 31, 1997 and 1996 would have been the same as the reported primary net income (loss) per share. The impact of SFAS 128 on the calculation of diluted net income per share for these quarters does not materially differ from basic net income (loss) per share. The Company plans to adopt SFAS 128 for periods after December 15, 1997 and at that time all historical net income per share data presented will be restated to conform to the provisions of SFAS No. 128.

Subsequent Event

In April 1997, the Company exercised its option to purchase an additional 165,000 shares of BioSeq, Inc. stock at an aggregate cost of $750,750, thereby increasing its ownership of BioSeq to 19%.



ITEM2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

THREE MONTHS ENDED MARCH 31, 1997 AND 1996

Total revenue increased 36.5%, or $1,125,000, to $4,209,000 for the quarter ended March 31, 1997 from $3,084,000 in the prior year period. This increase was the result of an increase in product sales of 17.2%, or $312,000, to $2,127,000 from $1,815,000 and an increase in specialty laboratory services of 64.1%, or $813,000, to $2,082,000 from $1,269,000. Product revenue increased primarily as a result of an overall sales increase of 40.2% in Quality Control Products, due to continued strong sales of new and existing of Accurun( and panel products. This was partially offset by a decline of 36% in sales of Diagnostic Components as certain custom orders were delayed. The increase in service revenue was primarily attributable to a 74.3% increase in Specialty Clinical Laboratory Testing revenue, particularly from Lyme Disease and the new HIV molecular tests.

Gross profit increased 59.7%, or $627,000, to $1,678,000 for the current quarter from $1,051,000 in the prior year period. The gross profit margin increased to 39.9% for the current quarter versus 34.1% in the prior year period. The gross margin improvement was entirely driven by improved margins in services (10.6% in 1996 to 29.1% in 1997) as the Company continued to benefit from both the addition of several new tests and higher volume in Specialty Clinical Laboratory Testing.

Research and development expenses increased 42.1%, or $70,000, to $237,000

for the current quarter from $167,000 in the prior year period. This increase was primarily the result of additional research project expenditures for new Quality Control Products, including panels and Accurun(, as well as continued work on additional molecular tests for our Specialty Clinical Laboratory.

Selling and marketing expenses increased 47.8%, or $198,000, to $613,000 for the current quarter from $415,000 in the prior year period. This increase was primarily attributable to increased personnel costs associated with the addition of both tele-sales and field staff, as well as technical support staff for Quality Control Products, particularly Accurun(, increased advertising and trade show costs for all the Company's products and services, and increased travel costs.

General and administrative expenses increased 26.6%, or $143,000, to $679,000 for the current quarter from $536,000 in the prior year period. This increase was primarily a result of increased MIS and other support personnel, as well as the increased costs incurred as a public company.

Net interest income of $97,000 was earned for the first quarter of 1997 versus a ($94,000) expense in the prior year period as the Company repaid most of its debt in the fourth quarter of 1996 and invested its available cash in short term, investment grade securities.

For both first quarters, the Company provided taxes at the combined federal and state statutory rate of 40%.

LIQUIDITY AND FINANCIAL CONDITION

On October 31, 1996 the Company commenced trading as a result of its initial public offering of its common stock ("IPO"), selling 1,600,000 shares at $8.50 per share. Net proceeds raised after underwriting discounts and commissions (but before offering costs) was $12,648,000. On November 5, 1996, the Company repaid substantially all of its outstanding bank debt which totaled approximately $3.9 million.

The Company has financed its operations to date through cash flow from operations, borrowings from banks and sales of equity. With the repayment of debt from the IPO proceeds, the Company expects its cash flow and cash position to meet existing operational needs. In addition, the Company has available to it a $7.5 million uncollateralized revolving line of credit with its bank should additional needs arise.

Net cash provided by operations for the three months ended March 31, 1997 was $53,000 as compared to $789,000 in the prior year period. This decrease in cash flow was primarily attributable to increased working capital requirements and net payments of $531,000 during the first quarter of 1997 of expenses accrued as of December 31, 1996 related to income taxes and commissions.



Cash used in investing activities for the three months ended March 31, 1997 was $1,127,000 as compared to $116,000 in the prior year period. This increase in investing activities was the result of increased capital expenditures as the Company began construction of improvements at its manufacturing facility, and financed certain working capital needs in connection with its announced acquisition of the assets of Source Scientific, Inc., scheduled for closing in the second quarter of 1997 at an agreed upon cost of $2.1 million dollars, subject to shareholder approval. In April 1997, the Company exercised its option to purchase an additional 165,000 shares of BioSeq, Inc. stock at an aggregate cost of $750,750, thereby increasing its ownership of BioSeq to 19%.

Cash provided by financing activities for the three months ended March 31, 1997 was $10,000 as compared to $675,000 used to repay debt in the prior comparable year period. The net cash provided in 1997 resulted from $14,000 received for stock options exercises.

The Company anticipates capital expenditures to increase over the near term as it expects to use approximately $750,000 from the proceeds of its IPO to expand its manufacturing capacity in West Bridgewater over the next nine months.

The Company believes that existing cash balances, the borrowing capacity available under its new revolving line of credit and cash generated from operations are sufficient to fund operations and anticipated capital expenditures for the foreseeable future. There were no material financial commitments for capital expenditures as of March 31, 1997, and currently there are no material commitments for capital or investment expenditures other than the April BioSeq investment, the Source Scientific, Inc. asset acquisition, and the manufacturing expansion, all as previously discussed above.

RECENT ACCOUNTING PRONOUNCEMENTS

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 is currently required under the provisions of Accounting Principles Board Opinion No. 15. Under SFAS No. 128, the Company will be required to present both basic net income per share and diluted net income per share. Basic net income (loss) per share for the quarters ended March 31, 1997 and 1996 would have been the same as the reported primary net income (loss) per share. The impact of SFAS 128 on the calculation of diluted net income per share for these quarters does not materially differ from basic net income (loss) per share. The Company plans to adopt SFAS 128 for periods after December 15, 1997 and at that time all historical net income per share data presented will be restated to conform to the provisions of SFAS No. 128.

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; inability of Source Scientific, Inc. to repay the $750,000 loan made by the Company; 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; 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).





PART II. OTHER INFORMATION

<TABLE>
<CAPTION>

ITEM 6. EXHIBITS AND REPORTS ON FORM 8K

(A) EXHIBITS

| Exhibit No. | |
|---|---|
| <S> | <C> |
| 3.1 | Amended and Restated Articles of Organization of the Company** |
| 3.2 | Amended and Restated Bylaws of the Company** |

4.1 Specimen Certificate for Shares of the Company's Common Stock**

4.2 Description of Capital Stock (contained in the Restated Articles of Organization of the Company filed as Exhibit 3.1) **

10.1 Agreement, dated January 17, 1994, between Roche Molecular Systems, Inc. and the Company**

10.2 Exclusive License Agreement, dated December 6, 1994, between the University of North Carolina at Chapel Hill and the Company**

10.3 Contract, dated September 30, 1995, between the National Institutes of Health and the Company (No. 1-AI55273) **

10.4 Contract, dated September 30, 1995, between the National Institutes of Health and the Company (No. 1-AI-55277) **

10.6 Agreement, dated October 1, 1995, between Ajinomoto Co., Inc. and the Company**

10.7 Lease Agreement, dated June 30, 1992, for Rockville, Maryland Facility between Cambridge Biotech Corporation and the Company**

10.8 Lease Agreement, dated July 28, 1995, for New Britain, Connecticut Facility between MB Associates and the Company**

10.9 Worcester County Institution for Savings Warrant dated December 1, 1995 (No. 1) **

10.10 Worcester County Institution for Savings Warrant dated July 26, 1993 (No. 2) **

10.11 Stock Purchase Agreement, dated June 5, 1990, between G&G Diagnostics Limited Partnership I and the Company, as amended**

10.12 Purchase and Sale Agreement, dated December 11, 1995, for 375 West Street Property between James Leonard, Trustee, C.W.B. Trust and the Company**

10.13 Purchase and Sale Agreement, dated December 20, 1995, for 80 Manley Street Property between the Company and Donald M. Leonard, Trustee, Live Oak Realty Trust**

10.14 Stock Purchase Agreement, dated April 26, 1996, between Kyowa Medex Co., Ltd. and the Company**

10.15 1987 Non-Qualified Stock Option Plan**++

10.16 Employee Stock Option Plan**++

10.17 Underwriters Warrants, each dated November 4, 1996, between the Company and each of Oscar Grus & Son Incorporated and Kaufman Bros., L.P. **

10.20 Purchase Agreement, dated October 7, 1996, between BioSeq, Inc. and the Company**

10.21 Warrant Agreement, dated October 7, 1996, between BioSeq, Inc. and the Company**



10.22 Stockholders' Agreement, dated October 7, 1996, between BioSeq, Inc. and the Company**

10.23 License Agreement, dated October 7, 1996, between BioSeq, Inc. and the Company**

10.24.1 Commercial Loan Agreement, dated as of March 28, 1997, between The First National Bank of Boston and the Company**

10.25 Asset Purchase Agreement, dated March 26, 1997 between Source Scientific, Inc. and the Company**

10.26 Contract, dated March 1, 1997, between National Cancer Institute and the Company

11 Statement re: Computation of Per Share Earnings

21.1 Subsidiaries of the Company **

27 Financial Data Schedule

</TABLE>

- ----------

++ Management contract or compensatory plan or arrangement.

** 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 8K

None



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: May 14, 1997 By /s/ KEVIN W. QUINLAN

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



BOSTON BIOMEDICA, INC.

EXHIBIT INDEX

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<TABLE>
<CAPTION>

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|---|---|---|
| <S> | <C> | |
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| | | |
|---|---|---|
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| 10.15 | 1987 Non-Qualified Stock Option Plan* | A** |
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|---|---|---|
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| 10.25 | Asset Purchase Agreement, dated March 26, 1997 between Source Scientific, Inc. and the Company | C** |
| 10.26 | Contract, dated March 1, 1997, between National Cancer Institute and the Company | Filed herewith |
| 11 | Statement re: Computation of Per Share Earnings | Filed herewith |
| 21.1 | Subsidiaries of the Company | C** |
| 27 | Financial Data Schedule | Filed herewith |

</TABLE>

- ----------

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 Registration Statement, where the Exhibit was filed as Exhibit No. 10.17 and contained in Exhibit 1.1.

C Incorporated by reference to the Company's Form 10K filed March 31, 1997

* Management contract or compensatory plan or arrangement.

** 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.

EXHIBIT 10.26

<TABLE>
<CAPTION>

FILE COPY OMB NO. 0990-0115

| AWARD/CONTRACT | 1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350) | RATING | PAGE OF PAGES |
|---|---|---|---|
| | | 1 | 25 |

| 2. CONTRACT (Proc. Inst Ident.)NO. | 3. EFFECTIVE DATE | 4. REQUISITION PURCHASE REQUEST/PROJECT NO. |
|---|---|---|
| N02-CP-71001 | 03/01/97 | |

| 5.1SSUED BY CODE 26191001 | 6.ADMINISTERED BY(If other than item 5) CODE |
|---|---|
| NATIONAL CANCER INSTITUTE<br>RESEARCH CONTRACTS BRANCH, CECS<br>EXECUTIVE PLAZA SOUTH, ROOM 620<br>9000 ROCKVILLE PIKE MSC 7224<br>BETHESDA MARYLAND 20892-7224 | GENETIC EPIDEMIOLOGY BRANCH<br>EPIDEMIOLOGY AND BIOSTATISTICS PROGRAM<br>DIVISION OF EPIDEMIOLOGY AND GENETICS<br>(RFP NO. NCICP61001-09) |

| 7.NAME AND ADDRESS OF THE CONTRACTOR (No., street, city, county, State and ZIP Code) | 8. DELIVERY |
|---|---|
| BTRL CONTRACTS & SER., INC.<br>DBA/BIOTECH RES. LAB.<br>3 TAFT COURT<br>ROCKVILLE, MARYLAND 20850 | [ ]FOB OTHER [X]FOB DESTINATION<br>9. DISCOUNT FOR PROMPT PAYMENT |
| PLACE OF PERFORMANCE:<br>ROCKVILLE, MARYLAND | 10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN<br>ITEM<br>SEE SECTION G<br>ARTICLE G 3. |

| CODE | FACILITY CODE |
|---|---|
| | |

| 11.SHIP TO/MARK FOR CODE: | 12.PAYMENT WILL BE MADE BY CODE |
|---|---|
| SEE SECTION C, ARTICLE C.2. | SEE SECTION G, ARTICLE G3. |

| 13.AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION | 14.ACCOUNTING AND APPROPRIATION DATA |
|---|---|
| [ ]10 U.S.C. 2304(c) ( ) | CAN1 78428001 TIN 1043152484A1 |
| [ ]41 U.S.C. 253(c) ( ) | CAN2 DOC NO. N2CP71001A |
| | OC CODE 25.2E LOC |

| <S> | <C> | <C> | <C> | <C> | <C> |
|---|---|---|---|---|---|
| 15A.ITEM NO. | 15B.SUPPLIES/SERVICES | 15C.QUANTITY | 15D.UNIT | 15E.UNIT PRICE | 15F.AMOUNT |
| | TITLE: LABORATORY SUPPORT FOR PROCESSING AND STORAGE OF BIOLOGICAL SPECIMENS FROM PERSONS AT HIGH RISK FROM CANCER | | | | CAN1: $ 915,803<br>CAN2: |
| | CURRENT OBLIGATION: | | | | $ 915,803 |
| | CONTRACT PERIOD: 03/01/97 THROUGH 02/28/98 | | | | |
| | CONTRACT TYPE: COST-PLUS FIXED FEE, TERM | | | | |

15G. TOTAL AMOUNT OF CONTRACT $ 915,803

16. TABLE OF CONTENTS

| (X) SEC. | DESCRIPTION | PAGE(S) | (X) SEC. | DESCRIPTION | PAGE(S) |
|---|---|---|---|---|---|
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| X | B SUPPLIES OF SERVICES AND PRICES/COSTS | 4 | PART III- LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH | | |
| X | C DESCRIPTION/SPECS-/WORK STATEMENT | 6 | X | J LIST OF ATTACH | 24 |
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X H SPECIAL CONTRACT REQUIREMENTS 14 [] M EVALUATION FACTORS FOR AWARD

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. [X] CONTRACTORS NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of tbe parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representation certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18 [ ] AWARD(Contract is not required to sign this document.) Your offer on Solicitation Number_____ including the additions or changes made by you which addititons or changes are set forth in full above, is herein accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer and (b) this award/contract. No further contractual document is necessary.

| 19A. NAME AND TITLE OF SIGNER (Type or print) | 20A. NAME OF CONTRACTING OFFICER |
|---|---|
| Mark Manak, Ph.D., Senior Vice President | MARY E. LANDI O'LEARY |
| 19B. NAME OF CONTRACTOR | 19C. DATE SIGNED | 20B. UNITED STATES OF AMERICA | 20C. DATE SIGNED |
| /s/ Mark Manak | Feb 4, 1997 | /s/ Mary E. Landi O'Leary | 2/12/97 |
| (Signature of person authorized to sign) | | (Signature of Contracting Officer) | |

</TABLE>

Contract No. N02-CP-71001

DETAILED TABLE OF CONTRACT CONTENTS

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Contractor shall maintain a repository of biologic specimens for the Epidemiology and Biostatistics Program (EBP). This shall include frozen serum, plasma, urine, tumor tissue, tumor tissue extracts, whole blood cells, separated and frozen white blood cells, or fractions of white blood cell populations, bone marrow cells, body fluids, lymphoblastoid cell lines, DNA, stool specimens or smears on slides and other types of specimens as specifies by the project Officer. These materials shall be maintained at optimum temperatures for long-term storage, including liquid nitrogen, if appropriate.

ARTICLE B.2. ESTIMATED COST AMD FIXED FEE

a. The estimated cost of this contract is $868,060.

b. If the Government exercises its option pursuant to ARTICLE H.5. of this contract the estimated cost of this contract will be increased as follows:

ESTIMATED COST

Option I, Year 2 - $ 900,000
Option II, year 3 - $ 908,670
Option III, Year 4 - $ 968,730
Option IV, Year 5 - $ 978,507

c. The fixed fee for this contract is $47,743. The fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended. Payment shall be 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.

d. If the Government exercises it's options pursuant to ARTICLE H.5. of this contract, the fixed fee of this contract will be increased as follows:

FIXED FEE

Option I, Year 2 - $49,500
Option II, Year 3 - $49,977
Option III, Year 4 - $53,280
Option IV, Year 5 - $53,818

e. The Government's obligation, represented by the sum of the estimated cost plus the fixed fee, is $915,803.

f. If the Government exercises it's options pursuant to Article H.5. of this contract, the Government's obligation represented by the sum of the estimated cost plus the fixed fee will be as follows:

| | COST | FEE | TOTAL CPFF |
|---|---|---|---|
| Option I, Year 2 | $900,000 | $49,500 | $ 949,500 |
| Optioh II, Year 3 | $908,670 | $49,977 | $ 958,647 |
| Option III, year 4 | $968,730 | $53,280 | $1,022,010 |
| Option IV, year 5 | $978,507 | $53,818 | $1,032,325 |



g. Total funds currency available for payment and allotted to this contract are

$915,803, of which $868,060 represents the estimated costs, and of which $47,743 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.

h. It is estimated that the amount currently allotted will cover performance of the contract through February 28, 1998.

i. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

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) Specia1 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.);

(4) Travel to attend general scientific meetings;

(5) Foreign travel - See paragraph b.2., below;

(6) Paient 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.

b. Travel Costs

(1) Domestic Travel

(a) No expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) are to be incurred in direct performance of this contract without the prior written approval of the Contracting Officer. In the event travel costs may be required as a direct cost to this contract, these costs must be approved in writing, in advance, by the Contracting Officer, and must be certified that the cost will not be included in the indirect costs.

(b) This contract is subject to the provisions of Section 24 of Public Law 99-234 which amends the Office of Federal Procurement Policy Act to provide that contractor costs for travel, including lodging, other subsistence, and incidental expenses, shall be allowable only to the extent that they do not exceed the amount allowed for Federal employees.

(2) Foreion Travel

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

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. Indirect Costs

In no event shall the billing rate or the final amount reimbursable for Overhead expenses exceed a ceiling of 115% of total direct labor. The Contractor shall complete all work in accordance with the Statement of Work, terms and conditions of this contract. Any costs over and above this cost ceiling shall not be reimbursed under this contract or by any other Government contract, grant, or cooperative agreement.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

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, SECTION J, ATTACHMENT #1, dated 2/97, attached hereto and made a part of this contract.

ARTICLE C.2. REPORTING REQUIREMENTS

In addidon to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports during the period of performance of this contract:

a. TECHNICAL REPORTS

1. Quarterly Computerized and Written Reports

The Contractor shall submit Ouarterly Computerized and Written Reports summarizing the status of all newly received specimens and outlining all dispersals by the laboratory. A summary of all correspondence consisting of requests for shipment, cover letters and inquiries from outside collaborators shall be submitted quarterly to the NCI Project Officer and made available upon request. Emphasis shall be on conciseness as well as comprehensiveness.

The first quarterly report shall cover the period consisting of the first full calendar month following the effective date of the contract and shall be due on or before the 15th day after the end of the reporting period. Thereafter, quarterly reports shall be due on before the 15th day of the month following each reporting period. The submission of quarterly reports shall continue through the exercise of each option period. A Ouarterly Computerized and Written Report shall not be required when submitting the Annual Reports or Final Report.

2. Final Technical Progress Report

The Contractor shall submit a final technical progress report on or before the expiration date of the contract. The Final Report shall include information in sufficient detail to describe comprehensively the results achieved and shall include a summation (not to exceed 200 words) of the work performed for the entire contract period of performance.

IF OPTIONS EXERCISED

3. Annua1 Technica1 Progress Reports

The Contractor shall prepare Annual Technical Progress Reports which explain the progress of work performed under this contract. Each report shall describe the progress of the project to date, noting all technical areas in which effort is being directed and indicating the status of work in each area. This report shall include:

a) a quantitative summary of the number of specimens processed by the Contractor, their type and investigator source;

b) shipments and logistics;

c) an indication of current problems that may impede performance under the contract and proposed corrective actdon; and

d) a discussion of work to be performed during the next reporting period.

The annual report shall, in addition, include an up-to date inventory of the Repository and its contents. Additional interim reports may be requested as necessary.

The first annual report shall cover the period consisting of the first full 12 calendar months of performance and any fractional part of the initial month and shall be due on or before the 15th day after the end of the reporting period. Thereafter, reports shall be due on or before the 15th day following each reporting period. An annual report shall not be required when a final report is due.

B. REPORT SUBMISSION

1. Copies of the reports shall be submitted in the following manner:

| Reports | Period Covered | Due Date | Ouantities |
|---|---|---|---|
| | 03/01/97 - 05/31/97 | 06/15/97 | |
| Quarterly | 06/01/97 - 08/31/97 | 09/15/97 | Original + |
| | 09/01/97 - 11/30/97 | 12/15/97 | 3 copies |

NOTE: IF THE GOVERNMENT EXERCISES ITS OPTIONS PURSUANT TO ARTICLE H., OPTION PROVISION, THE QUARTERLY PROGRESS REPORT WILL CONTINUE TO BE DELIVERED IN THE FOLLOWING MANNER:





| Reports | Period Covered | Due Date | Quantities |
|---|---|---|---|
| | 03/01/98 - 05/31/98 | 06/15/98 | |

| | | | |
|---|---|---|---|
| | 06/01/98 - 08/31/98 | 09/15/98 | |
| | 09/01/98 - 11/30/98 | 12/15/98 | |
| | 03/01/99 - 05/31i99 | 06/15/99 | Original + |
| Quarterly | 06/01/99 - 08/31/99 | 09/15/99 | 3 copies |
| | 09/01/99 - 11/30/99 | 12/15/99 | |
| | 03/01/00 - 05/31/00 | 06/15/00 | |
| | 06/01/00 - 08/31/00 | 09/15/00 | |
| | 09/01/00 - 11/30/00 | 12/15/00 | |
| | 03/01/01 - 05/31/01 | 06/15/01 | |
| | 06/01/01 - 08/31/01 | 09/15/01 | |
| | 09/01/01 - 11/30/01 | 12/15/01 | |
| | 03/01/02 - 05/31/02 | 06/15/02 | |
| | 06/01/02 - 08/31/02 | 09/15/02 | |
| | 09/01/02 - 11/30/02 | 12/15/02 | |

NOTE: IF THE GOVERNMENT EXERCISES ITS OPTIONS PURSUANT TO ARTICLE H., OPTION PROVISION, THE ANNUAL PROGRESS REPORT WILL BE DELIVERED IN THE FOLLOWING MANNER:

| | | | |
|---|---|---|---|
| | 03/01/97 - 02/28/98 | 03/15/98 | |
| | 03/01/98 - 02/28/99 | 03/15/99 | Original + |
| Annual | 03/01/99 - 02/28/00 | 03/15/00 | 3 Copies |
| | 03/01/00 - 02/28/01 | 03/15/01 | |

| | | | |
|---|---|---|---|
| Final | Life of contract | Expiration date | Original + |
| | | Of Contract | 3 copies |

2. THE ABOVE ITEMS SHALL BE ADDRESSES AND DELIVERED TO:

| Addressee | No. Of copies |
|---|---|
| Mary E. Landi O'Leary<br>Contracting Officer<br>Research Contracts Branch<br>National Cancer Institute, EPS/620<br>6120 EXECUTIVE BLVD MSC 7224<br>Bethesda, MD 20892-7224 | Original +<br>1 copy |
| Dr. Niel Caporaso, Project Officer<br>Genetic Epidemiology branch<br>Epidemiology & Biostatistics program<br>Division of Cancer Etiology<br>Executive Plaza North, Room 439<br>6130 EXECUTIVE BLVD 7372<br>BETHESDA MD 20892-7372 | 2 Copies |





SECTION D - PACKAGING, MARKETING AND SHIPPING

ARTICLE D. 1. PACKAGING

Specimens shall be protected from temperature extremes by use of insulated containers or other acceptable means as needed. A portable liquid nitrogen container for transport of frozen cells shall also be required.

ARTICLE D.2. MARKING

All deliverables under this contract shall be clearly identified with the subject contract number. All specimens shall be submitted to the Contractor, accompanied by written identification of the specimen source, using forms supplied by the Project Officer. All specimens from members of the NCI-associated families will be submitted with a unique alpha-numeric code number which will be the only identification of the specimen in future laboratory processing, dispersal, etc. The name of the donor shall not be used

in the labeling of specimens by laboratory personnel. NO NAMES OF PERSONS ENROLLED IN AIDS ASSOCIATED STUDIES SHALL BE WRITTEN ON VIALS.

ARTICLE D.3. SHIPPING

The Contractor shall prepare specimens for shipment, supply shipping containers appropriate to maintain specimens in the proper state (cool, frozen, deep frozen, etc.) and make arrangements through commercia1 air freight companies and other carriers to send biologic specimens to collaborating investigators in an expeditious (e.g., overnight or same day) fashion. For immunologic or genetic typing studies, the Contractor shall prepare specimens for delivery to the local Human Leutocyte Antigen (HLA) typing laboratory or immune function laboratory in a suitable form. The local in-house delivery service shall be used for these particular specimens to ensure expeditious delivery under optimum conditions. In some cases, commercial freight companies shall be used for overnight shipments to investigators in other cities. The Contractor shall be responsible for notifying the receiving laboratory of the specimens shipment and anticipated arrival time to insure that the receiving laboratory is prepared to receive the specimens.

SECTION E - lNSPECTION AND ACCEPTANCE

ARTICLE E. 1 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: The National Cancer Institute, Division of Cancer Epidemiology and Genetics, Genetic Epidemiology Branch, Epidemiology & Biostatistics Program, 6130 Execubve Boulevard, Executive Plaza North, Room 439, Rockville, MD 20852. 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 52.246-5, INSPECTION OF SERVICES COST REIMBURSEMENT(APRIL 1984).





SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from March 1, 1997 through February 28, 1998. If the Government exercises its options pursuant to ARTICLE H.5., of this contract the period of performance of this contract will be:

| Option | | Period of Performance |
|---|---|---|
| Option I - Year 2 | - | March 1, 1998 through February 28, 1999 |
| Option II - Year 3 | - | March 1, 1999 through February 28, 2000 |
| Option III - Year 4 | - | March 1, 2200 through February 28, 2001 |
| Option IV - Year 5 | - | March 1, 2001 through February 28, 2002 |

ARTICLE F.2. LEVEL OF EFFORT

a. During the period of performance of this contract, the Contractor shall provide 18,620 direct labor hours each year totaling 93,100 if all options are exercised. The labor hours exclude vacation, sick leave, and holiday. It is estimated that the labor hours are constituted as specified below and

will be expended approximately as follows:

| | Labor Hours | | | | |
|---|---|---|---|---|---|
| | Base | Option I | Option II | Option III | Option IV |
| Labor Category | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| Principal Investigator | 1,120 | 1,120 | 1,120 | 1,120 | 1,120 |
| Professional | 7,488 | 7,488 | 7,488 | 7,488 | 7,488 |
| Lab Technicians | 3,744 | 3,744 | 3,744 | 3,744 | 3,744 |
| AdminlData Entry | 4,864 | 4,864 | 4,864 | 4,864 | 4,864 |
| Driver | 1,404 | 1,404 | 1,404 | 1,404 | 1,404 |
| Totals | 18,620 | 18,620 | 18,620 | 18,620 | 18,620 |

b. The Contractor shall have satisfied the reguirement herein if not less than 95% nor more than 105% of the total direct labor hours, specified herein are furnished.

c. In the event fewer hours than the minimum specified number of direct labor hours in the total categories are used by the Contractor in accomplishing the prescribed work and the Government has not invoked its rights under the FAR Clause 52.249, TERMINATION (Cost-Reimbursement), incorporated in this contract, these parties agree that the fee will be adjusted based solely upon the guantity of hours by which the number of direct labor hours furnished is less than the number of direct labor hours specified in this ARTICLE. The resulting adjustment shall be evidenced by a contract modification.

ARTICLE F.3. STOP WORK ORDER

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.

FEDERAL ACQUISITION REGULATION (48 CFR CHAFTER 1) CLAUSE: 52.242-15, STOP WORK ORDER (AUGUST 1989) with ALTERNATE I (APRIL 1984).



- ----------



SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

Dr. Neil Caporaso

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 individuals are considered to be essential to the work being performed hereunder:

| NAME | TITLE |
|---|---|
| Mark Cosentino | Principal Investigator |
| Kathi Shea | Lab Manager |

ARTICLE G.3. INVOICE SUBMISSION

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.

Invoices/financing requests shall be submitted concurrently as follows:

(1) An original and two copies to the following designated payment office:

National Institutes of Health
Office of Financial Management
Contracts Section, FAAB
Building 31, Room BlB05
31 CENTER DR MSC 2050
BETHESDA MD 20892-2050





(2) FOUR copies to the following approving officer:

Mary E. Landi O'LEARY
Contracting Officer
Research Contracts Branch
National Cancer Institute, NIH
EPS, Room 620
6120 EXECUTIVE BLVD MSC 7224
BETHESDA MD 20892-7224

Inquiries regarding payment of invoices should be directed to the designated payment office, attention of Chief, Contract Accounting Section, DEFS (301) 496-6452.

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 45th day after the close of the reporting period. The line entries for subdivisions of work end elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraphe; 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 following is a listing of expenditure categories to be reported:

| Expenditure Category |
| --- |
| A |
| --- |
| (1) Direct Labor |
| (a) Principal Investigator |
| (b) Key Personnel |
| (2) Other Personnel |
| (3) Overhead |
| (4) Materials/Supplies |
| (5) ODC's (ODC's must be itemized) |
| (6) Equipment (Equipment must be itemized) |
| (7) G&A Expense |
| (8) Total Cost |
| (9) Fixed Fee |
| (10) Total Cost Plus Fixed Fee |





f. Copies of the above report shall be submitted in the following manner:

| REPORTS | PERIOD COVERED | DUE DATE | QUANTITIES |
| --- | --- | --- | --- |
| Contract Financial Reports | 03/01/97 - 05/31/97 | 07/15/97 | |
| | 06/01/97 - 08/31/97 | 10/15/97 | Original + |
| | 09/01/97 - 11/30/97 | 01/15/98 | 2 copies |

NOTE: IF THE GOVERNMENT EXERCISES ITS OPTIONS PURSUANT TO ARTICLE H., OPTION PROVISION, THE CONTRACT FINANCIAL REPORTS (NIH-2706) WILL CONTINUE TO BE DELIVERED IN THE FOLLOWING MANNER:

| | | | |
| --- | --- | --- | --- |
| | 12/01/97 - 02/28/98 | 04/15/98 | |
| | 03/01/98 - 05/31/98 | 07/15/98 | |
| | 06/01/98 - 08/31/98 | 10/15/98 | |
| | 09/01/98 - 11/30/98 | 01/15/99 | |
| | 12/01/98 - 02/28/99 | 04/15/99 | |
| | 03/01/99 - 05/31/99 | 07/15/99 | Original + |
| Contract Financial Report | 06/01/99 - 08/31/99 | 10/15/99 | 2 copies |
| | 09/01/99 - 11/30/99 | 01/15/00 | |
| | 12/01/99 - 02/28/00 | 04/15/00 | |

| | |
|---|---|
| 03/01/00 - 05/31/00 | 07/15/00 |
| 06/01/00 - 08/31/00 | 10/15/00 |
| 09/01/00 - 11/30/00 | 01/15/01 |
| 12/01/00 - 02/28/01 | 04/15/01 |
| 03/01/01 - 05/31/01 | 07/15/01 |
| 06/01/01 - 08/31/01 | 10/15/01 |
| 09/01/01 - 11/30/01 | 01/15/02 |
| 12/01/01 - 02/28/02 | 02/28/02 |

g. The above item shall be addresses and delivered to:

Contracting Officer
N02-CP-71001
Cancer Epidemiology Contracts Section
Research Contracts Branch
Nadonal Cancer Institute, NIH
6120 EXECUTIVE BLVD MSC 7224
BETHESDA MD 20892-7224

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 1, the cognizant Contracting Officer responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Chief, Financial Advisory Services Branch
Division of Contracts and Grants
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:

David A. Hubbard, II
Contracts Property Administrator
Research Contracts Property Administration, NIH
Building 13, Room 2E-65
13 SOUTH DR MSC 5748
BETHESDA MD 20892-5748
(301) 496-6467

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

Pursuant to the clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor will be authorized to acquire the property listed in Schedule I-B, Attachment #5, 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. Government Furnished Property - Schedule II-A

Pursuant to the clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor is hereby authorized to retain custody of the property listed in Schedule II-A, Attachment #6 for use in direct performance of this contract. Accountability for the items listed in Schedule II-A is hereby transferred to this contract from predecessor Contract No. N01-CP-33060, under which these items were provided by the Government. Title to this property shall remain in the Government.

## 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 devdopment 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. HUMAN MATERIALS

It is understood that the acquisition and supply of all human specimen material (including fetal material) used under this contract will be obtained by the Contract or in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.4. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0130. This document is incorporated into this contract as Attachment #6.

ARTICLE H.5. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the entire Statement of Work for 12 months only as defined in Sections C and F of the contract. Pursuant to clause 52.217-9 set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform the Statement of Work for an additional 48 months (12 months per each option) as also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in ARTICLE B.2.





ARTICLE H.6. CONFIDENTIALITY OF INFORMATTON

The following information is covered by HHSAR Chase 352.224-70, Confidendality of Information (APRIL 1984):

a. Identification of Specimen source or donor name;
b. All records of manipulations on all specimens;
c. Information concerning the identification of the patient, the diagnosis, demographic information or other such information;
d. Written, hard-copy records of inventory sheets.

ARTICLE H.7. PUBLICATION AND PUBLICITY

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 acknowledgement substantially as follows:

"This project has been funded in whole or in part with federal funds from the National Cancer Institute, National Institutes of Health, under Contract No.N02-CP-71001."





PART II - CONTRACT CLAUSES

PART II

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT - CLAUSES INCORPORATED BY REFERENCE (APRIL 1984)

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 [FAR 52.252-2 (JUNE 1988)].

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

| FAR CLAUSE NO. | TITLE AND DATE |
|---|---|
| 52.202-1 | Definitions (OCTOBER l995) |
| 52.203-3 | Gratuides (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) |
| 52.203-10 | Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000) (SEPTEMBER l990) |
| 52.203-12 | Limitation on Payments to Influence Certain Federal Transactions (Over $100,000) (JANUARY 1990) |
| 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 (JULY 1995) |
| 52.215-2 | Audit and Records - Negotiation (Over $100,000) (AUGUST 1996) |
| 52.215-22 | Price Reduction for Defective Cost or Pricing Data (OCTOBER 1995) |
| 52.215-24 | Subcontractor Cost or Pricing Data (Over $500,000) (OCTOBER 1995) |
| 52.215-26 | Integrity of Unit Prices (Over $100,000) (OCTOBER 1995) |
| 52.215-27 | Termination of Defined Benefit Pension Plans (MARCH 1996) |
| 52.215-33 | Order of Precedence (JANUARY 1986) |



FAR CLAUSE NO. TITLE AND DATE

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52.215-39 Reversion or Adjustment of Plans for Post-Retirement Benefits other than Pensions (PRB) (MARCH 1996)

52.215-40 Notification of Ownership Changes (Over $500,000) (FEBRUARY 1995)

52.215-42 Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data-- Modifications (OCTOBER 1995)

52.216-7 Allowable Cost and Payment (AUGUST 1996)

52.216-8 Fixed Fee (APRIL 1984)

52.219-8 Utilization of Small, Small Disadvantaged, and Women-Owned Small Business Concerns (Over $100,000) (OCTOBER 1995)

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 EEO Preaward Clearance of Subcontracts (Over $1,000,000) (APRIL 1984)

52.222-35 Affirmative Action for Special Disabled and Vietnam Era Veterans (APRIL 1984)

52.222-36 Affirmative Action for Handicapped Workers (APRIL 1984)

52.222-37 Employment Reports on Special Disabled Veterans and Veterans of the Vietnam Era JANUARY 1988)

52.223-2 Clean Air and Water (Over $100,000) (APRIL 1984)

52.223-6 Drug Free Workplace(JULY 1990)

52.223-14 Toxic Chemical Release Reporting (OCTOBER 1996)

52.225-11 Restrictions on Certain Foreign Purchases (OCTOBER 1996)

52.227-1 Authorization and Consent (Over $50,000) (JULY 1995)

52.227-2 Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000) (AUGUST 1996)

| CLAUSE NO. | TITLE AND DATE |
|---|---|
| 52.227-3 | Patent Indemnity (APRIL 1984) |
| 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 (MARCH l994) |
| 52.232-33 | Mandatory Information for Electronic Funds Transfer Payment (AUGUST 1996) |
| 52.233-1 | Disputes (OCTOBER l995) |
| 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 l995) |
| 52.242-4 | Certification of Indirect Costs (OCTOBER 1995) |
| 52.242-13 | Bankruptcy (Over $100,000) (JULY 1995) |
| 52.243-2 | Changes - Cost Reimbursement (AUGUST 1987) Alternate I (APRIL 1984) |
| 52.244-2 | Subcontracts (Cost-Reimbursement and Letter Contracts) (MARCH l996) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings of the contract. |
| 52.244-5 | Competition in Subcontracting (Over $100,00)(JANUARY l996) |
| 52.245-5 | Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract) (JANUARY 1986) |
| 52.246-25 | Limitation of Liability - Services (Over $100,000) (APRIL 1984) |
| 52.249-6 | Termination (Cost-Reimbursement) (SEPTEMBER l996) |
| 52.249-14 | Excusable Delays (APRIL 1984) |
| 52.253-1 | Computer Generated Forms (JANUARY 199l) |



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

| | |
|---|---|
| 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 l99l) |
| 352.270-7 | Paperwork Reduction Act (APRIL 1984) |

[End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT]



Contract No. NO2-CP-71001

ARTICLE 1.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

ARTICLE 1.1. of this SECTION is hereby modified as follows:

(1) FAR Clause 52.219-9, SMALL, SMALL DISADVANTAGED, AND WOMEN-OWNED SMALL BUSINESS SUBCONTRACTING PLAN (OCTOBER 1995), and FAR Clause 52.219-16, LIQUIDATED DAMAGES-- SUBCONTRACTING PLAN (OCTOBER 1995) are deleted in their entirety.

(2) FAR Clause 52.232-20, LIMITATION OF COST (APRIL 1984), 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.
Where necessary, the Government has indicated required clause information specific to this contract.

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

(1) FAR Clause 52.215-31, Waiver of Facilities Capital Cost of Money (SEPTEMBER 1987) is added.

(2) FAR 52.217-9, Option to Extend the Term of the Contract (MARCH 1989).

"(a) The Government may extend the term of this contract by written notice to the Contractor within 60....

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 60 MONTHS.

(3) FAR 52.219-6, Notice of Small Business Set-Aside JULY 1996).

(4) FAR 52.219-14, Limitations on Subcontracting JANUARY 1991).

(5) FAR 52.224-1, Privacy Act Notification (APRIL 1984).

(6) FAR 52.224-2, Privacy Act (APRIL 1984).

(7) Alternate I (JUNE 1987), FAR 52.227-14, Rights in Data--General JUNE 1987).

(8) FAR 52.251-1, Government Supply Sources (APRIL 1984).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATIONS/PUBLIC HEALTH SERVICE ACQUISITION ON REGULATIONS (HHSAR)(PHSAR)(48 CFR CHAPTER 3) CLAUSES: This contract incorporates the following clauses by reference,

(unless otherwise noted) 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.

(1) PHS 352.223-70, Safety and Health (APRIL 1984), is hereby incorporated in full text. See Part III, Section J of this contract.

(2) HHSAR 352.224-70, Confidendality of Information (APRIL 1984).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES: The following clause(s) are attached and made a part of this contract:

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





ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

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

a. FAR Clause 52.203-9 REQUIREMENT FOR CERTIFICATE OF PROCUREMENT INTEGRITY--MODIFICATION (OVER $100.000) (SEPTEMBER 1995)

(a) DEFINITIONS. The definitions set forth in FAR 3.1044 are hereby incorporated in this clause.

(b) The Contractor agrees that it will execute the certification set forth in paragraph (c) of this clause when requested by the Contracting Officer in connection with the execution of any modification of this contract.

(c) CERTIFICATION. As required in paragraph (b) of this clause, the officer or employee responsible for the modification proposal shall execute the following certification. The certification in paragraph (c)(2) of this clause is not required for a modification which procures commercial items.

CERTIFICATE OF PROCUREMENT INTEGRITY-MODIFICATION (NOVEMBER 1990)

(1) I, _____ [NAME OF CERTIFIER] am the officer or employee responsible for the preparation of this modification proposal and hereby certify that, to the best of my knowledge and belief, with the exception of any information described in this certification, I have no information concerning a violation or possible violation of subsection 27(a), (b), (d), or (f) of the Office of Federal Procurement Policy Act, as amended* (41 U.S.C. 423), (hereinafter referred to as "the Act"), as implemented in the FAR, occurring during the conduct of this procurement [contract and modifcation number].

(2) As required by subsection 27(e)(1)(B) of the Act, I further certify that to the best of my knowledge and belief, each officer, employee, agent, representative, and consultant of _____(Name of Offerer) who has participated personally and substantially in the preparation or submission of this proposal has certified that he or she is familiar with, and will comply with, the requirements of subsection 27(a) of the Act, as implemented in the PAR, and will report immediately to me any information concerning a violation or possible violation of subsections 27(a), (b), (d), or (f) of the Act, as implemented in

the FAR, pertaining to this procurement.

(3) VIOLATIONS OR POSSIBLE VIOLATIONS: [CONTINUE ON PLAIN BOND PAPER IF NECESSARY AND LABEL CERTIFICATE OF PROCUREMENT INTEGRITY-MODIFICATION (CONTINUATION SHEET), ENTER "NONE" IF NONE EXISTS]

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[SIGNATURE OF THE OFFICER OR EMPLOYEE RESPONSIBLE FOR THE MODIFICATION PROPOSAL AND DATE]

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[TYPED NAME OF THE OFFICER OR EMPLOYEE RESPONSIBLE FOR THE MODIFICATION PROPOSAL]

*Subsections 27(a), (b), and (d) are effective on December 1, 1990. Subsection (f) is effective on June 1, 1991.





THIS CERTIFICATION CONCERNS A MATTER W1THIN THE JURISDICTION OF AN AGENCY OF THE UNITED STATES AND THE MAKING OF A FALSE, FICTITIOUS, OR FRAUDULENT CERTIFICATION MAY RENDER THE MAKER SUBJECT TO PROSECUTION UNDER TITLE 18, UNITED STATES CODE, SECTION 1001.

[End of certification]

(d) In making the certification in paragraph (2) of the certificate, the officer or employee of the competing Contractor responsible for the offer or bid, may rely upon a one-time certification from each individual required to submit a certification to the competing Contractor, supplemented by periodic training. These certifications shall be obtained at the earliest possible date after an individual required to certify begins employment or association with the Contractor. If a contractor decides to rely on a certification executed prior to the suspension of secdon 27 (i.e., prior to December 1, 1989), the Contractor shall ensure that an individual who has so certified is notified that section 27 has been reinstated. These certifications shall be maintained by the Contractor for a period of 6 years from the date a certifying employee's employment with the company ends or, for an agent, representative, or consultant, 6 years from the date such individual ceases to act on behalf of the Contractor.

(e) The certification required by paragraph (c) of this clause is a material representation of fact upon which reliance will be placed in executing this modification.

[End of clause]

PART III

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, (02/97), 6 pages.

2. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1 (6/18/92), 4 pages.

3. Financial Report of Individual Project/Contract, NIH 2706, (5/92), 1 page.

4. Instructions for Completing form NIH 2706, Financial Report of Individual Project/Contract, (5/92), 3 pages.

5. Contractor-Acquired Government Property - Schedule I-B, (2/97), 1 page.

6. Government Furnished Property - Schedule II-A, (2/97), 2, pages.

7. Privacy Act System of Records, Number 09-25-0130, as cited in the Federal Register Notice issued in Volume 56, Number 8, 2 pages, dated 1/91

8. Safety and Health, PHSAR Clause 352.223-70,(4/84), 2 pages.

9. Procurement of Certain Equipment, NIH(RC)-7, 4/1/84, 1 page.





PART IV
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SECTION K - REPRESENTATIONS AND CERTIFICATIONS
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The following documents are incorporated by reference in this contract:

1. Representations and Certifications, dated November 27, 1996.

END of the SCHEDULE
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(CONTRACT)





Statement of work
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a. Independently and not as an agent of the Government, the Contractor shall be required to 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:

1) The Contractor shall provide the services described below in accordance with Contractor-developed, Government-approved protocols:

a) separation and viable cryopreservation of blood mononuclear Lymphocytes;

b) separation, aliquotting and storage of serum, plasma and/or urine as needed;

c) cryopreservation of bone marrow samples;

d) storage of tumor extracts;

e) cryopreservation of whole tumor tissue;

f) cryopreservation of intact red blood cells;

g) viable cryopreservation of previously established lymphoblastoid cell lines;

h) storage of DNA and other biological materials as specified by the Project Officer (e.g., pathology slides and tissue block);

i) extraction of DNA from biologic materials;

j) specimen processing as required by NCI to preserve special biologic materials;

k) logging in, labeling and tracking of each vial of each sample employing an NCI developed computerized specimen tracking system, including all laboratory safeguards to insure the fidelity and purity of each sample; and

1) maintenance of the previously-established repository currently containing more than 1.4 million biological specimens and allowance for an estimated increase of up to 25% of freezer storage space.





2) Processing services shall be available routinely between the hours of 9:00 a.m. and 2:00 p.m., Monday through Friday, and at any other time (including nights, weekends and holidays) by special arrangement, usually with advance notice. A laboratory staff member shall be available during nonbusiness hours for emergency specimen processing (as might occur when a patient dies). A biobazard area adequate for processing specimens with Acquired Immunodeficiency Syndrome (AIDS) shall be available for the processing of all biologic samples.

3) The Contractor shall supply messenger service to pick up specimens or inter-laboratory communication from medical care facilities in the Washington, D C., area or at area transportation centers (i.e., Dulles International, D.C. National and Baltimore/Washington International Airports). This messenger service shall be supplied by the Contractor and not subcontracted to commercial carriers. All specimens submitted to the laboratory for processing shall be scheduled in advance, except in emergencies as detailed below. Specimens shall be delivered to

the Contractor's laboratory within four hours of notification for pick-up. Specimens shall be protected from temperature extremes by use of insulated containers or other acceptable means as needed. A portable liquid nitrogen container for transport of frozen cells or tumor specimens shall also be required. Only specimens provided by or approved by the Project Officer shall be accepted for processing and storage by the Contractor.

4) The Contractor shall be responsible for recording and monitoring the location of all specimens that are being sent or received through use of a log book of all requests and specimens. The Contractor shall be responsible for monitoring, shipping and receipt of specimens to minimize delay or loss. If a specimen is not received within four hours of expected delivery, the Contractor shall inform the Project Officer by telephone. An after-hours telephone number of the Contractor's staff member shall be available to assist in this follow-up and the staff member shall be available at that number. The Contractor shall be responsible for immediately tracing the location of delinquent specimens not received when expected. All specimens that are of questionable research value shall be noted and the Project Officer immediately notified by telephone, as well as in writing, providing identifying names or numbers, quantity, place of origin, a concise narrative description of the event, etc., so that appropriate action can be initiated. The Contractor shall designate a specific individual to be responsible for after-hours specimen processing and name an alternate to act when the primary person is not available.

5) The Contractor shall maintain a repository of biologic specimens for the Epidemiology and Biostatistics Program (EBP). This shall include frozen serum, plasma, urine, tumor tissue, tumor tissue extracts, whole red blood cells, separated and frozen white blood cells, or fractions of white blood cell populations, bone marrow cells, body fluids, lymphoblastoid cell lines, DNA, stool specimens or smears or slides, pathology paraffin blocks, and other types of specimens as specified by the Project Officer. These materials shall be maintained at optimum temperatures for long-term storage, including liquid nitrogen, if appropriate.





6) All specimens will be submitted to the Contractor, accompanied by written identification of the specimen source, using forms supplied by the Project Officer. Specimens from members of NCI-associated families will be submitted with a unique Family Studies identification number to insure compatibility with NCI laboratory computer data bases. Specimens shall be assigned a unique code number which shall be the only identification of the specimen in future laboratory processing, dispersal, etc. This code number shall comply with the format and convention established by the NCI Project Officer. The name of the donor shall not be used in labeling of specimens or in correspondence concerning the specimen by laboratory personnel. Such labeling shall uniquely identify each vial of each specimen and the quality of that individual vial will be recorded and updated as needed in the NCI-developed computer system.

7) The Contractor shall provide and train primary and backup staff in the operation of a computerized record system for specimens which has been developed and furnished by the Project Officer. Using this system, the laboratory shall keep records of all

manipulation on all specimens and accurately enter data on each specimen. The data shall include but not be limited to vial identification number, study ID, material type and material description, volume, weight or cell concentration, freezer location, subject ID, crisis events, data received, specimen vial quality, etc. Data shall be entered into the system, with attention to extreme accuracy, within 48 hours of receipt or as specified by the NCI Project Officer. The Contractor shall be responsible for extracting this information from either data forms or floppy disks which will be transmitted with the samples. The Contractor shall also use this system to monitor and track all activities related to specimens. The Project Officer will supply computer support for generating management reports for the Contractor on a regular basis.

8) The Contractor shall prepare a variety of specimens for storage. Specifically, white blood cell separation, fractionation and viable cryopreservation, red blood cell cryopreservation, serum separation and storage of aliquots of 0.5 ml, plasma separation and storage, tumor tissue freezing, tumor tissue extracts, urine, serum, or blood fluid lyophilization, freezing and/or extraction of stool specimens and other techniques as required. Specimens shall be stored in containers impervious to entry of CO2 so that they can be shipped on dry ice. In order to ensure the viability of valuable specimens, the Contractor shall be prepared to have appropriate personnel travel to a contract site, foreign or domestic, to train local staff on optimal techniques for freezing viable material.





9) Freezers shall be equipped with a stylus recording system indicating consistency of temperature which shall be reviewed an a scheduled basis each day at specified times. Freezer malfunctions must give warning by means of an alarm system. The Contractor must provide a central alarm system monitored 24-hours a day, 365 days a year. A switch-operated electric generator of appropriate wattage for these particular freezers shall be hooked up and be maintained on standby in the event of a major power outage. Liquid nitrogen freezers must have automatic filling mechanisms drawing on a constant central source of liquid nitrogen with emergency back-up. All unplanned defrostings must be logged, giving date and times during which defrostings were in effect and temperature reached, and reported by telephone as soon as possible to the Project Officer. The circumstances of the defrosting shall be reported immediately to the Project Officer in writing, giving full particulars.

10) The laboratory shall keep clear records of all manipulations on all specimens and carefully document specimen type, volume, cell concentration, source, "crisis events", etc. for each sample. The exact freezer location shall be known for each specimen and shall be kept in a master log which is easy to understand. Information shall be supplied routinely to the NCI Project Officer on forms designed and supplied by NCI in conjunction with laboratory personnel. Ihese records shall include number of vials, exact location of vials and specimen type. The Contractor shall conduct a complete inventory of all stored specimens on an annual basis. Thorough quality control protocols must be designed, documented and approved by the NCI Project Officer. These protocols must be rigorously implemented in the conduct of the inventories. The

results of each inventory shall be documented in the Annual Technical Progress Report.

11) The Contractor shall respond only to written requests for biological specimens from collaborating investigators, which have been approved by the NCI Project Officer or his/her designee(s). Specimens shall not be sent to any investigator without a written request from the NCI Project Officer or his/her designee(s). A copy of this written request and Contractor-generated correspondence shall be sent to the NCI Project Officer. All written requests for specimen distribution shall be acted upon within four working days of receipt, unless permission to delay such action is obtained from the Project Officer.

The Contractor shall not supply the outside collaborator with any information concerning the biological specimens other than code number, specimen type or other infomrmation essential to specimen processing. Requests for identificatian of the patient, the diagnosis, demographic data or other such information shall be referred to the NCI Project Officer.

The Contractor shall never send out the last vial from a particular specimen without explicit authorization from the Project Officer.





The Contractor shall prepare specimens for shipment, supply shipping containers appropriate to maintain specimens in the proper state (cool, frozen, deep frozen, etc.) and make arrangements through commercial air freight companies and other carriers to send biologic specimens to collaborating investigators in an expeditious (e.g., overnight or same day) fashion. For immunologic or genetic typing studies, the Contractor shall prepare specimens for delivery to the local HLA typing laboratory or immune function laboratory in a suitable form. The local in-house delivery service shall be used for these particular specimens to ensure expeditious delivery under optimum conditions. In some cases, commercial freight companies shall be used in overnight shipments to investigators in other cities. The Contractor shall be responsible for notifying the receiving laboratory of the specimens' shipment and anticipated arrival time to insure that the receiving laboratory is prepared to receive the specimens. All specimens for both immunologic testing and HLA typing and serum or other type storage shall be processed by the Contractor. Peripheral blood cells shall be aliquotted for storage in suitable quantities for subsequent testing. Other specimens, such as red blood cells, plasma, serum, urine, stool, tumor tissue, and body fluids shall be processed for storage in appropriate aliquots.

12) The Contractor shall be prepared to process the following quantities of materials:

| Material | Max Daily /person | Typical Total Vials /person | Monthly Volume (Individual Samples) |
|---|---|---|---|
| WBC Cryopreservation | 1,500 cc (60) | 5 | 15,000 cc (250) |
| Plasma/serum aliquotting | 2,500 cc (60) | 6-12 | 25,000 cc (250) |

| | | | |
|---|---|---|---|
| RBC cryopreservation | 250 cc (25) | 5 | 750 cc (75) |
| Pelleted lymphocytes | 150 cc (15) | 4 | 600 cc (60) |
| Buffy coat preps | 200 cc (20) | 2 | 300 cc (30) |
| Receipt frozen vials | 10,000 vials | any | 120,000 vials |
| Thawing/ aliquotting | N/A | any | 500 vials |
| Dispersal specimens | N/A | any | 4,000 vials |

Although these are ESTIMATES of the amount of work, the Contractor must be able to accommodate highly variable amounts of processing and possible changes in specimen types and volumes depending on the new studies evolving during the contract (e.g. increased processing of buccal swabs and rinses; gastric juice; feces; urine, etc.). All prioritization of the specimen processing is determined by the NCI Project Officer. Not all maximal quantities of each material will arrive on a given day.

For this aspect of the contract, it is anticipated that technicians shall be available at least one day per weekend through the entire period of this contract (the weekend blood samples will be less than 200 ml and from less than five donors).





13) The Contractor shall handle international shipments of biological specimens (blood components, urine, gastric juice, and biopsy specimens) and clearance of these shipments through U.S. and foreign customs. The Contractor must provide a separate shipping/customs agent to coordinate shipping clear specimens through customs at U.S. entry port, transfer to appropriate courier/express delivery service for shipment within the U.S., and notify Contractor of all arrangements so that specimens can be easily tracked. Close coordination is vital because these samples may need to be kept frozen with dry ice, and freezer-to-freezer shipping time must be less than 72 hours. Delays of just one or two days will seriously jeopardize months of scientific and medical work. Large quantities of samples are shipped from Europe, the East Indies, Africa, China and other geographic locales. In each instance, the repository Contractor shall have responsibility for coordinating logistics to insure their timely arrival, including contracting with appropriate customs brokers and agents to expedite shipment and customs clearances.





INVOICE/FINANCING REQUEST INSTRUCTIONS

FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS, NIH(RC)-1

General: The Contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing

request.

Format: Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal; and Standard Form 1035, Public Voucher for Purchases and Services Other Than Personal-Continuation Sheet, or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on Form NIH 2706, Financial Report of Individual Project/Contract, or on the payee's letterhead or self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the payment clause shall be submitted monthly unless otherwise authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Bi11ing of Costs Incurred: If billed costs include: (1) Costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the Contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. Where expenditures are made in a currency other than United States dollars, billings on the contract shall be expressed, and reimbursement by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approva1: Costs requiring the Contracting Officer's approval which are not set forth in an advance understanding in the contract sball be so identified and reference the Contracting Officer's Authorization (COA) number.

Invoice/Financing Request Identification: Each invoice/financing request shall be identified as either:

(a) Interim Invoice/Contract Financing Request: These are interim payment requests submitted during the contract performance period.

(b) Completion Invoice: The completion invoice is a final invoice which is submitted promptly upon completion of the work, but no later than one year from the contract completion date. The completion invoice should be submitted when all costs (except for finalization of indirect cost rates) have been assigned to the contract and all performance provisions have been completed.

(c) Fina1 Invoice: A revised final invoice may be required after the amounts owed have been settled between the Govermnent and the Contractor (e.g., final indirect cost rates and resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries of the sample invoice/financing request.

(a) Payor's Name and Address: The paying office and address, identifier in the Invoice Submission clause of the contract, shall be entered on all copies of the invoice/financing request.

(b) Invoice/Financing Request Number: Insert the appropriate serial number of the invoice/financing request.

(c) Date Invoice/Financing Request Prepared: Insert the date the invoice/financing request is prepared.

(d) Contract Number and Date: Insert the contract number and the date of the contract.

(e) Payee's Name and Address: Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible offficial to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the Contractor.

(f) Total Estimated Cost of Contract: Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) Total Fixed-Fee: Insert the total fixed-fee (where applicable).

(h) Billing Period: Insert the beginning and ending dates (day, month, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) Amount Billed for Current Period: Insert the amount billed for the major cost elements, adjustment and adjusted amounts for the period.

(j) cumulative Amount from Inception to Date of this Billing: Insert the cumulative amount billed for the major cost elements and adjusted amounts claimed during this contract.

(k) Direct Costs: Insert the major cost elements. For each element, consider the application of the paragraph entitled Costs Requiring Prior Approval on page 1 of these instructions.

(1) Direct Labor: This consists of salaries and wages paid (or accrued) for direct performance of the contract.

(2) Fringe Benefit: This represents fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) Accountable Personal Property: This category of cost includes permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (See the DHHS Contractor's Guide for Control of Government Property.) Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS 565, Report of Accountable Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

(A) The item number for the specific piece of equipment listed in the Property Schedule;

(B) The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule, or;

(C) Be preceded by an asterisk (*) if the equipment is below the approval level.

Further itemization of invoices/financing requests shall only be required for items having specific limitations set forth in the contract.



Contract No. NO2-CP-71001

(4) Materials & Supplies: This category includes equipment with unit costs of less than $500 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) Premium Pay: This is remuneration in excess of the basic hourly rate.

(6) Consultant Fee: Fees paid to consultants. Identify consultant by name or category as set forth in the contract's advance understanding or in the COA letter, as wel1 as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) Travel Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and posessions, foreign travel means travel outside that country. Foreign travel should be billed separately from domestic travel.

(8) Subcontract Costs: List subcontractor(s) by name and amount billed.

(9) Other: List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amount separately. If the contract contains restrictions on any cost element, that cost element should be listed separately.

(l) Cost of Money (COM): Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) Indirect Costs Overhead: Cite the formula (rate and base) in effect during the time the cost was incurred and for which reimbursement is claimed. If special rate is being used; e.g., off-site, then so specify.

(n) Fixed-Fee: If the contract provides for a fixed-fee, it must be claimed as provided for by the contract. Cite the formula or method of computation.

(o) Total Amounts Claimed: Insert the total amounts claimed for the current and cumulative periods.

(p) Adjustments: This includes amounts conceded by the Contractor, outstanding suspensions and disapprovals subject to appeal.

(q) Grand Totals: The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.



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SAMPLE INVOICE/FINANCING REQUEST

- ---

(a) Payor's Name and Address (b) Invoice/financing Requed No.
NATIONAL INSTITUTES OF HEALTH
Division of Financial Management
Contract Accounting Branch, DBS (c) Date Voucher Prepared
Building 31, Room B1B05A
31 CENTER DR MSC 2050
BETHESDA MD 20892-2050 (d) MAO No. and Date

- ---

(e) Payee's Name and Address (f) Total Estimated Cod of MAO
ABC CORPORATION
100 Main Street
Anywhere, U.S.A. Zip Code
(g) Total Fixed Fee
---

Attention: Name, Title and Phone Number of
Official to Whom Payment is Sent

- ---

(h) This invoice/financing request represents reimbursable costs from August 1, 1992 through August 31, 1992.

- ---

<TABLE>
<CAPTION>

| <S> | <C> (i) Amount Billed for Current Period | <C> (j) Cumulative Amount From Inception to Date of this Billing |
|---|---|---|
| (k) Direct Costs | | |
| (l) Direct labor | $ 3,400 | $ 6,800 |
| (2) Fringe Benefits | 600 | 1,200 |
| (3) Accountable Personal Property (Attach HHS 565) | | |
| Permanent Research | 3,000 | 8,000 |
| General Purpose | 2,000 | 2,000 |
| (4) Materials and Supplies | 2,000 | 4,000 |
| (5) Premium Pay | 100 | 150 |
| (6) Consultant Fee | 100 | 100 |
| Dr. Jones/1 day @, 100-COA #3 | | |
| (7) Travel - Domestic | 200 | 200 |
| Foreign | 200 | 200 |
| (8) Subcontract Cost | 0 | 0 |
| (9) Other | $ 0 | $ 0 |
| Total Direct Costs | $11,600 | $20,650 |
| (l) Cost of Money (Factor) or (Appropriate Base) | 2,400 | 3,6OO |
| | 4,000 | 6,000 |
| (m) Indirect Costs - Overhead % of Direct Labor or Other Base (Formula) | | |
| | 700 | 1,400 |
| (n) Fixed-Fee Earned (Formula) | $18,700 | $31,650 |
| (o) Total Amount Claimed | | |
| (p) Adjustments Outstanding Suspensions | $18,700 | $29,950 |
| (q) Grand Totals | | |

</TABLE>

"I certify that all payments requested are for appropriate purposes and in accordance with the contract."

_____ _____
(Name of Official) (Title)

- ---

<TABLE>
<CAPTION>

Contract No. NO2-CP-71001

| <S> | <C> | <C> | <C> | <C> | <C> | <C> | <C> |
|---|---|---|---|---|---|---|---|
| National Institutes of Health | Project Task: | | Contract No.: | | Date of Report: | | |
| FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT, NIH FORM 2706 | | | N02-CP-71001 | | 0990-0131 | | |
| Note: Complete this Form in Accordance with Accompanying Instructions. | Reporting Period: | | Contractor Name and Address: BTRL Contracts & Services, Inc. dba/Biotech Research Laboratories. 3 Taft Court Rockville, MD 20850 | | | | |

| Expenditure Category | Percentage of Effort/Hours Funded | Actual | Cumulative Incurred Cost at End of Prior Period | Incurred Cost Current | Cumulative Cost (D + E) | Estimated Cost to Complete | Estimated Cost at Completion (F & G) | Funded Contract Amount | Variance (Over or Under) (I - H) |
|---|---|---|---|---|---|---|---|---|---|
| | A | B | C | D | E | F | G | H | I | J |
| Professional Staff | 4,864 | | | | | | | | $104,245 | |
| Laboratory Staff | 7,488 | | | | | | | | $ 96,963 | |
| Administrative/Other | 6,268 | | | | | | | | $ 70,146 | |
| Total Direct Labor | 18,620 | | | | | | | | $271,354 | |
| Overhead | | | | | | | | | $312,057 | |
| Materials | | | | | | | | | $101,738 | |
| ODC's | | | | | | | | | $ 30,143 | |
| Equipment | | | | | | | | | $ 66,745 | |
| G&A | | | | | | | | | $ 86,024 | |
| TOTAL COST | | | | | | | | | $868,060 | |
| Fee | | | | | | | | | $ 47,743 | |
| TOTAL CPFF | | | | | | | | | $915,803 | |

</TABLE>

NIH 2706 (5/92) (Formerly HHS-646) ATTACHMENT #3

Contract No. NO2-CP-71001

INSTRUCTIONS FOR COMPLETING FORM NIH 2706
"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

PURPOSE. Form NIH 2706 is designed to: (1) provide a management tool for use by NIH in monitoring the application of financial and personnel resources to NIH

contracts, (2) provide contractors with financial and personnel management data which is usable in their management processes, (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actua1 performance and projections with prior estimates on individual elements of cost and personnel and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimated of financial and personnel performance.

REPORTING REQUIREMENTS

(a) SCOPE. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may reqiure the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

(b) NUMBER OF COPIES AND MAILING ADDRESS. An original and two (2) copies of the report(s) shall be sent to the Contracting Officer at the address shown on the face page of the contract, no later than the 30th working day after the end of the period reported.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not reqiure reporting on a separate Form NIH 2706, except where it is determined by the Contracting Officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

DEFINITIONS AND INSTRUCTIONS FOR COMPLETING FORM NIH 2706. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) PERSONNEL-PROFESSIONAL. Included are the senior level and all other personnel whose total annual salary rates are $50,000 or more. It should include key personnel regardless of annnn1 salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) PERSONNEL--OTHER. This will be listed as one amount unless otherwise required by the contract.

(3) FRINGE BENEFITS. Include allowances and services provided by the Contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) ACCOUNTABLE PERSONAL PROPERTY. Nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property, must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."



(5) SUPPLIES. Includes the cost of supplies and material and equipment charged

directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) INPATIENT CARE. Costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) OUTPATIENT CARE. Costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) TRAVEL. Includes all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and constants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) CONSULTANT FEE. Fees paid to consultant. Identify each consultant with effort expended, billing rate, and amount billed.

(10) PREMIUM PAY. Includes the amount of salaries and wages over and above the basic rate of pay.

(11) SUBCONTRACTS. List each subcontract by name and amount billed.

(12) OTHER COSTS. Includes a number of separate expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) OVERHEAD/INDIRECT COSTS. Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) GENERAL AND ADMINISTRATIVE EXPENSE. Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) FEE. If any, cite the fee earned.

(16) TOTAL COSTS TO THE GOVERNMENT.

PREPARATION INSTRUCTIONS

These instructions are keyed to the columns on Form NIH 2706.

COLUMN A--EXPENDITURE CATEGORY. Enter in column A the expenditure categories required by the contract.

COLUMN B--PERCENTAGE OF EFFORT/HOURS FUNDED. Enter in column B the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in column A.

COLUMN C--PERCENTAGE OF EFFORT/HOURS-ACTUAL. The Contractor will enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

COLUMN D--CUMULATIVE INCURRED COST AT END OF PRIOR PERIOD. This column should show the cumulative incurred, costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

COLUMN E--INCURRED COST-CURRENT PERIOD. The Contractor should enter the costs which were incurred during the current period.

COLUMN F-CUMULATIVE INCURRED COST TO DATE. The Contractor should enter the combined tota1 of Columns D and E.

COLUMN G-ESTIMATED COST TO COMPLETE. Entries need only be made when the Contractor estimates that a particular expenditure category will vary from the amount funded. Realistic estimates are essential.

COLUMN H-ESTIMATED COSTS AT COMPLETION. No entry is required in this column unless an entry is made in Column G.

COLUMN I-FUNDED CONTRACT AMOUNT. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

COLUMN J-VARIANCE (OVER OR UNDER). This column need not be filled in when Column H is blank. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and funded costs (Column 1). When a line item varies by plus or minus 10%, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) clause of the contract.

MODIFICATIONS. Any modification in the amount funded for an item since the preceding report should be listed in the appropriate cost category.

EXPENDITURES NOT FUNDED. An expenditure for an item for which no amount was funded (e.g., at the discretion of the Contractor in performance of its contract) should be listed in the appropriate cost category and all columns filled in except for I. Column J will of course show a 100% variance and will be explained along with those identified under J above.



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SCHEDULE I-B

| ITEM | QUANTITY | UNIT PRICE | TOTAL COST |
|---|---|---|---|
| YEAR 1 | | | |
| Mechanical Freezers (incl freight) | 4 | $5,875.00 | $23,500 |
| Chart Recorders | 4 | $ 540.00 | $ 2,160 |
| Racks, 13-2-C-81 | 154 | $ 81.00 | $12,474 |
| Racks, 8-3.75-C81 | 29 | $ 63.30 | $ 1,836 |
| Racks, Robot | 61 | $ 90.00 | $ 5,490 |
| LN2 Freezer | 1 | $21,285.00 | $21,285 |
| YEAR 1 TOTAL ESTIMATED COST | | | $66,745 |
| OPTION I | | | |
| YEAR 2 Mechanical Freezers (incl freight) | 4 | $6,051.25 | $24,205 |
| Chart Recorders | 4 | $ 556.20 | $ 2,225 |
| Racks, 13-2-C-81 | 154 | $ 83.43 | $12,848 |
| Racks, 8-3.75-C81 | 29 | $ 65.20 | $ 1,891 |
| Racks, Robot | 61 | $ 92.70 | $ 5,655 |
| LN2 Freezer | 1 | $21,923.55 | $21,924 |
| OPTION I TOTAL ESTIMATED COST | | | $68,747 |
| OPTION II | | | |

| | | | |
|---|---|---|---|
| YEAR 3 Mechanical Freezers (incl freight) | 4 | $6,232.79 | $24,931 |
| Chart Recorders | 4 | $ 572.89 | $ 2,292 |
| Racks, 13-2-C-81 | 154 | $ 85.93 | $13,233 |
| Racks, 8-3.75-C81 | 29 | $ 67.15 | $ 1,947 |
| Racks, Robot | 61 | $ 95.48 | $ 5,824 |
| LN2 Freezer | 0 | $ 0.00 | $ 0 |

OPTION II TOTAL ESTIMATED COST $48,228

OPTION III

| | | | |
|---|---|---|---|
| YEAR 4 Mechanical Freezers (incl freight) | 4 | $6,419.77 | $25,679 |
| Chart Recorders | 4 | $ 590.07 | $ 2,360 |
| Racks, 13-2-C-81 | 154 | $ 88.51 | $13,631 |
| Racks 8-3.75-C81 | 29 | $ 69.17 | $ 2,006 |
| Racks Robot | 61 | $ 98.35 | $ 5,999 |
| LN2 Freezer | 1 | $23,238.96 | $23,239 |

OPTION III TOTAL ESTIMATED COST $72,914

OPTION VI

| | | | |
|---|---|---|---|
| YEAR 5 Mechanical Freezers (incl freight) | 4 | $6,612.36 | $26,449 |
| Chart Recorders | 4 | $ 607.77 | $ 2,431 |
| Racks, 13-2-C-81 | 154 | $ 91.17 | $14,040 |
| Racks, 8-3.75-C81 | 29 | $ 71.24 | $ 2,066 |
| Racks, Robot | 61 | $ 101.30 | $ 6,179 |
| LN2 Freezer | 0 | $ 0.00 | $ 0 |

OPTION VI TOTAL ESTIMATED COST $51,166

Schedule I-B Attachment #5

N01-CP-71001

<TABLE>
<CAPTION>

| Item | Descripeion | Mfr. | Model# | Serial# | Gov Decal# | Cost($) |
|---|---|---|---|---|---|---|
| <S> | <C> | <C> | <C> | <C> | <C> | <C> |
| 1 | Mechanical Freezer | Forma | 8158 | 80638-004 | 01029103 | $ 1,780.00 |
| 2 | Mechanical Freezer | Forma | 8158 | 80638-003 | 01029102 | $ 1,780.00 |
| 3 | Mechanical Freezer | Forma | 8158 | 80638-005 | 01029104 | $ 1,780.00 |
| 4 | Mechanical Freezer | Forma | 8358 | 81043-402 | 01029124 | $ 4,680.00 |
| 5 | Mechanical Freezer | Forma | 8358 | 69566-1 | 01029107 | $ 4,539.00 |
| 6 | Mechanical Freezer | Forma | 8158 | 80856-007 | 01029105 | $ 4,850.00 |
| 7 | Mechanical Freezer | Forma | 8358 | 82189-762 | 01029129 | $ 4,729.00 |
| 8 | Mechanical Freezer | Forma | 8358 | 69566-2 | 01029118 | $ 4,539.00 |
| 9 | Mechanical Freezer | Forma | 8358 | 69929-77 | 01029116 | $ 4,539.00 |
| 10 | Mechanical Freezer | Forma | 8158 | 80856-008 | 01029106 | $ 4,850.00 |
| 11 | Mechanical Freezer | Forma | 8358 | 60091-118 | 01029119 | $ 4,539.00 |
| 12 | Mechanical Freezer | Forma | 8358 | 60091-119 | 01029120 | $ 4,539.00 |
| 13 | Mechanical Freezer | Forma | 8358 | 60342-261 | 01029121 | $ 4,732.00 |
| 14 | Mechanical Freezer | Forma | 8358 | 80128-320 | 01029123 | $ 4,680.00 |
| 15 | Mechanical Freezer | Forma | 8358 | 81391-455 | 01029125 | $ 4,680.00 |
| 16 | Mechanical Freezer | Forma | 8358 | 81611-479 | 01029126 | $ 4,680.00 |
| 17 | Mechanical Freezer | Forma | 8358 | 82004-659 | 01029127 | $ 4,275.00 |
| 18 | Mechanical Freezer | Forma | 8358 | 82004-658 | 01029128 | $ 4,275.00 |
| 19 | Mechanical Freezer | Forma | 8358 | 82154-858 | 01029130 | $ 4,857.00 |
| 20 | Mechanical Freezer | Forma | 8358 | 82154-857 | 01029131 | $ 4,857.00 |
| 21 | Mechanical Freezer | Forma | 8358 | 82154-860 | 01029132 | $ 4,857.00 |
| 22 | Mechanical Freezer | Forma | 8458 | 83029-220 | 01029133 | $ 4,743.00 |
| 23 | Mechanical Freezer | Forma | 8458 | 83029-219 | 01029l34 | $ 4,743.00 |
| 24 | Mechanical Freezer | Forma | 8458 | 83071-225 | 01029135 | $ 4,743.00 |
| 25 | Mechanical Freezer | Forma | 8458 | 83071-256 | 01029136 | $ 4,743.00 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 26 | Mechanical Freezer | Solow | SE27-120 | 8889645 | 01023092 | $ 4,503.00 |
| 27 | Mechanical Freezer | Forma | 8458 | 83327-403 | 01029137 | $ 5,028.00 |
| 28 | Mechanical Freezer | Forma | 8458 | 83327-402 | 01029138 | $ 5,028.00 |
| 29 | Mechanical Freezer | Solow | SE27-120 | 8889646 | 01023091 | $ 4,053.00 |
| 30 | Mechanical Freezer | Forma | 8458 | 83510-578 | 00811080 | $ 4,473.00 |
| 31 | Mechanical Freezer | Forma | 8458 | 83510-576 | 00811081 | $ 4,473.00 |
| 32 | Mechanical Freezer | Forma | 8458 | 84200-719 | 00811940 | $ 5,431.00 |
| 33 | Mechanical Freezer | Forma | 8458 | 84200-720 | 00811941 | $ 5,431.00 |
| 34 | Mechanical Freezer | Solow | SE27-120 | 919768 | 00871523 | $ 5,243.00 |
| 35 | Mechanical Freezer | Solow | SE27-120 | 912769 | 00871522 | $ 5,243.00 |
| 36 | Liquid Nitrogen Freezer | MVE | A4500 | 449-B | 01029139 | $ 6,909.00 |
| 37 | Liquid Nitrogen Freezer | MVE | A1500 | 481-B | 01029141 | $ 7,500.00 |
| 38 | Liquid Nitrogen Freezer | MVE | A4500 | 561 | 01029142 | $ 780.00 |
| 39 | Liquid Nitrogen Freezer | MVE | A4500 | 593 | 01029144 | $ 8,952.00 |
| 40 | Liquid Nitrogen Freezer | MVE | A4500 | 595 | 01029143 | $ 8,952.00 |
| 41 | Liquid Nitrogen Freezer | MVE | XLC111O | DKA88J102 | 01029145 | $ 9,500.00 |
| 42 | Liquid Nitrogen Freezer | MVE | A4500 | 274-B | 01029099 | $ 3,720.00 |
| 43 | Liquid Nitrogen Freezer | MVE | A4500 | 272-B | 01029101 | $ 3,720.00 |
| 44 | Liquid Nitrogen Freezer | MVE | A4500 | 276-B | 01029100 | $ 3,720.00 |
| 45 | Liquid Nitrogen Freezer | MVE | A4500 | 448-B | 01029140 | $ 6,909.00 |
| 46 | Liquid Nitrogen Freezer | MVE | XLC111O | DKC89G101 | 01029146 | $10,000.00 |
| 47 | Liquid Nitrogen Freezer | MVE | XLC1110 | DKC89G103 | 01029147 | $10,000.00 |
| 48 | Liquid Nitrogen Freezer | MVE | XLC111O | DKD9OB102 | 01029148 | $ 9,870.00 |

</TABLE>



N01-CP-71001

<TABLE>
<CAPTION>

| Item | Descripeion | Mfr. | Model# | Serial# | Decal# | Cost($) |
|---|---|---|---|---|---|---|
| <S> | <C> | <C> | <C> | <C> | <C> | <C> |
| 49 | Liquid Nitrogen Freezer | MVE | XLC111O | DKD9OB101 | 01029149 | $ 9,870.00 |
| 5O | Liquid Nitrogen Freezer | MVE | XLC111O | DFK9OK110 | 00811082 | $ 10,077.00 |
| 51 | Liquid Nitrogen Freezer | MVE | XLC111O | DFK9lG101 | 00811942 | $ 9,870.00 |
| 52 | Liquid Nitrogen Freezer | MVE | XLC111O | JIA92B101 | 00871521 | $ 9,882.00 |
| 53 | Refirigerator | Puffer Hubbard | LR-201TU | S11138 | 01029114 | $ 880.00 |
| 54 | Liquid Nitrogen Freezer | MVE | XLC111O | JIA93F113 | 01175478 | $ 9,762.00 |
| 55 | Liquid Nitrogen Freezer | MVE | XLC1200 | JUA93M103 | 01096478 | $ 9,492.00 |
| 56 | Liquid Nitrogen Tank | MVE | 160LDura-Lo | L83112112CA | 01029156 | $ 1,295.00 |
| 57 | ControlRateFzr-Cntlr, Chamber | Cryomed | 1010 | 89-2202L | 01029157 | $ 10,754.00 |
| 58 | ControlRateFzr-Cntlr, Chamber | Cryomed | 900 | 810501D | 01029113 | $ 9,870.00 |
| 59 | Laminar Flow Hood(Labgard) | Nuaire, Inc. | NU 408-424 | 4009-MM-A | 01029098 | $ 182.00 |
| 60 | Lannnar Flow Hood(Labgard) | CII | 740 | 13406 | 01029111 | $ 8,952.00 |
| 61 | CPU W/Modem & Software | Compaq | 286 | 4844AM381292 | 01029158 | $ 2,195.00 |
| 62 | Printer | Epson | DFX5OOO | OOG0000823 | 01029184 | $ 1,517.00 |
| 63 | Centrifuge w/Accessories | Sorvall | T-6000D | 9304366 | 01175994 | $ 6,946.00 |
| 64 | Centrifuge | Sorvall | CRU-5000 | 860-1962 | 01029155 | $ 7,325.00 |
| 65 | Water Bath | Precsn Scientific | 184 | 22AM/6 | 01029110 | $ 45O.OO |
| 66 | Coulter Counter | Coulter Electron | ZB-1 | 5632 | 01029112 | $ 650.00 |
| 67 | Mechanical ULT Chest Frz | Forma | 8458 | 85243-970 | 01175129 | $ 5,128.00 |
| 68 | Mechanical ULT Chest Frz | Forma | 8458 | 85243-972 | 01175130 | $ 5,128.00 |
| 69 | ULT Chest freezer | Forma | 8458 | 85471-1017 | 01096558 | $ 4,890.00 |
| 70 | ULT Chest freezer | Forma | 8458 | 85471-1019 | 01096559 | $ 4,890.00 |
| 71 | Chest Freezer | So-Low | C85-27 | 9394788 | 01182917 | $ 4,975.00 |
| 72 | Liquid Nitrogen Dry Shipper | Cryomed | CMD-20 | CMD~20-1 | 00916815 | $ 1,100.00 |
| 73 | Liquid Nitrogen Freezer | MVE | XLC-1830HE | JOA94E101 | 01190560 | $ 18,823.00 |
| 74 | Chest Freezer | So-Low | C85-27 | 9495071 | 01190561 | $ 4,975.00 |
| 75 | Chest Freezer | So-Low | C85-27 | 9495319 | 01190562 | $ 5,075.00 |
| 76 | Chest Freezer | So-Low | C85-27 | 9495320 | 01190563 | $ 5,075.00 |
| 77 | Chest Freezer | So-Low | C85-27 | 9495743 | 00941700 | $ 5,075.00 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 78 | Chest Freezer | So-Low | C85-27 | 9495744 | 00941701 | $ 5,075.00 |
| 79 | LN2 Freezer | MCE/CRYO | XLC1830HE | CDNB95F103 | 00941672 | $ 20,102.00 |
| 80 | Chest Freezer | So-Low | C80-27 | 9596411 | 01250392 | $ 5,845.00 |
| 81 | Chest Freezer | So-Low | C80-27 | 9596412 | 01250393 | $ 5,320.00 |
| 82 | LN2 Freezer | Cryomed | XLC-1830HE | CDN96K101 | 01264045 | $ 21,285.00 |
| 83 | HP Vector P-100 PC, 850mb HD | HP | Vectra Series 4 | US61559762 | 01264046 | $ 1,525.00 |
| 84 | 14" Monitor | HP | 1024 | TW63042334 | 01264047 | $ 350.00 |
| 85 | Power Supply Station | APC | 450AMP | 096097611010 | 01264048 | $ 230.00 |
| 86 | Chest Freezer | So-Low | C80-27 | 9697237 | 01213988 | $ 5,915.00 |
| 87 | Chest Freezer | So-Low | C80-27 | 9697238 | 01213989 | $ 5,915.00 |
| 88 | Diesel Generator | Cummins | 350DFCC | | 01213110 | $ 40,300.00 |
| 89 | Chest Freezer | So-Low | C85-27 | | 01264569 | $ 6,100.00 |
| 90 | Chest Freezer | So-Low | C85-27 | | 01264570 | $ 6,100.00 |
| 91 | Chest Freezer | So-Low | C85-27 | | 01264571 | $ 6,100.00 |
| 92 | Chest Freezer | So-Low | C85-27 | | 01264572 | $ 6,100.00 |
| 93 | Chest Freezer | So-Low | C85-27 | | 01264573 | $ 6,100.00 |
| 94 | Chest Freezer | So-Low | C85-27 | | 01264574 | $ 6,100.00 |
| 95 | Chest Freezer | So-Low | C85-27 | | 01264575 | $ 6,100.00 |
| 96 | Walk-In Refrigerator | Hartford | | | 01264576 | $ 7,776.00 |
| 97 | Walk-In Freezer | Hartford | | | 01264577 | $ 9,250.00 |
| 98 | Printer | Epson | DFX5000 | | 01264578 | $ 1,750.00 |

</TABLE>



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FEDERAL REGISTER / VOL. 56, NO. 8 / FRIDAY, JANUARY 11, 1991 / NOTICES

SYSEMS EXEMPT FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0130

SYSTEM NAME:

Clinical Research: Environmental Epidemiologic Studies in the Division of Cancer Etiology, HHS/NIH/NCI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:
National Institutes of Health, Executive Plaza North, room 443, 6130 Executive Blvd., Bethesda, MD 20892; and National Institutes of Health, Building 12, 9000 Rockville Pike, Bethesda, MD 20892, and at hospitals, medical schools, universities, research institutions, commercial organizations, state agencies, and collaborating governmental agencies. A list of locations and contracts is available upon request from the system manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM
Patients with cancer and other environmentally caused diseases, (e.g., birth defects), patients with other diseases (e.g., heart disease), normal and other persons (e.g., family members) for the purpose of making comparisons.

CATEGORIES OF RECORDS IN THE SYSTEM:
Medical records, progress reports, correpondence, epidemiological computerized data and records on biological specimens (e.g., blood, tumors, urine, etc.).

AUTHORITY FOR MAINTAINANCE OF THE SYSTEM:
42 U.S.C. 241, and 282.

PURPOSES OF THE SYSTEM:

To determine: (1) Factors or substances in the environment which cause cancer; (2) ways in which these factors or substances may cause cancer; (3) characteristics of persons who may be particularly susceptible to the environmental factor(s) or substance(s) and/or to cancer.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to protect such records from improper disclosure.
2. Disclosure may be made to a congessional office from the record of



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an individual in response to an inquiry from the congressional office made at the request of the individual.
3. The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.
4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:
File folders, microfilm, charts, graphs, computer tapes, disks and punch cards.

RETRIEVABILITY:
By name and/or code number.

SAFEGUARDS:
HHS contractors and collaborating researchers are required to comply with the provisions of the Privacy Act and with Department Regulations. Subjects participating in a clinical study are advised that their identity will only be known to those who are involved in conducting the study and that any published findings will be in a format which precludes individual identification.
1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to physicians, scientists and support staff of the National Cancer Institute, collaborating researchers, or HHS contractors, whose duties require the use of such information. Other one-time and special access by other employees is granted on a need to know basis as specifically authorized by the system manager.
2. Physical Safeguards: Data are kept in secured areas with access limited to

authorized personnel (system manager, project officer, contracting officer, collaborating researchers, staff and HHS contractors). Data transmitted to the NCI are in form which precludes individual identification.

3. Proceedural Safeguards: For computerized records, the contractor is required to comply, where appropriate, with Departmental standards, and National Bureau of Standards Guidelines. For example, access is controlled by the use of security codes known only to authorized personnel.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Securites," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1- "Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000 G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

National Cancer Institute, Chief Environmental Epidemiology Branch, Executive Plaza North, room 443, 6130 Executive Blvd., Bethesda, Maryland 20892.

NOTIFICATION PROCEDURE:

To determine if a file exists, write to System Manager and provide the following information:

a. System name: Environmental Epidemiologic Studies in the Division of Cancer Cause and Prevention;
b. Complete Name at time of study;
c. Facility and Home Address at the time the study was undertaken;
d. Date(s) at the time the information was provided (if known);
e. Birth date;
f. Disease type (if known).

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requestor is who he or she claims to be and understands that the knowing and willful request for aquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

Individuals seeking notification of or access to medical records should designate a representative (including address) who may be a physician, other health professional, or other responsible individual who would be willing to review the record and inform the subject individual of its contents, at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Write to System Manager and specify the record sought. The same information required above for notification is also needed for access. Individuals may also request listings of accoutable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to System Manager and Specify the record and the part(s) to be contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

HHS agencies, institutions under contract to the U.S. Government, universities, medical schools, hospitals, research institutions, commercial institutions, state agencies, other U.S. Government agencies, patients and normal volunteers, physicians, research investigators and other collaborating

personnel.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:
None



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PHS 352 223-70 SAFETY AND HEALTH (APRIL 1984)

(a) In order to provide safety controls for protection to the life and health of employees and other persons; for prevention of damage to all property; and for avoidance of work interruptions in the performance of the contract; the Contractor will 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) Recommendations for Prevention of HIV Transmission in Health-Care Settings, Morbidity and Mortality Report, August 21, 1987, Vol. 35, No. 2S.

(3) Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. Morbidity and Mortality Weekly Report, June 24, 1988, Vol. 37, No. 24.

(4) Agent Summary Statement for Human Immunodeficiency Viruses (HIV); Included are GTLV-III, LAV, HIV-1, and HIV-2. Morbidity and Mortality Weekly Report, April 1, 1988, Vol. 37, No. S4.

(5) Recommendations for the Safe Handling of Parentoral Antineoplastic Drugs, NIH Publication No. 83-2621.

(6) NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication No. 81-2385.

The above, (1) - (6), may be obtained from:
Division of Safety
Office of Research Services
National Institutes of Health
Building 31, Room lC02
31 CENTER DR MSC 2260
BETHESDA MD 20892-2260

(7) Guidelines for Research Involving Recombinant DNA Molecules (49 FR 46266 or latest revision) and Administrative Practices Supplemenent. These may be obtained from:

Office of Recombinant DNA Activities
Office of Science Policy and Legislation
National Institutes of Health
Building 31, Room B1C34
31 CENTER DR MSC 2250
BETHESDA MD 20892-2250

(8) Procedures for the Domestic handling and Transport of Diagnostic Specimens and Etiologic Agents, National Committee for Clinical Laboratory Standards, July 17, 1985, Vol. 5. This may be obtained from

National Committee for Clinical Laboratory Standards
771 East Lancaster Avenue
Villanova, Pennsylvania 19085

Further, the Contractor shall take or cause to be taken such additional safety measures as the Contracting Officer may determine to be reasonably necessary; provided, that if compliance with such additional safety measures results in a

material increase in the cost or time of performance of the contract, an equitable adjustment will be made in accordance with the clause of this contract entitled "Changes".



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(b) Prior to commencement of work, the Contractor will submit in writing its plan for complying with the safety and health provisions of this contract, and will meet with the Contracting Officer or his/her designated representative to discuss and develop a mutual understanding relative to administration of the overall safety program.

(c) During the performce of work under this contract, the Contractor shall comply with all procedurres prescribed by the Contracting Officer for the control and safety of persons Visiting the job site and will comply with such requirements to prevent accidents as may be prescribed by the Contracting Officer.

(d) The Contractor will maintain an accurate record of, and report to the Contracting Officer in such manner as the Contracting Officer may prescribe, all accidents and incidents resulting in death, traumatic injury, occupational disease, and/or damage to all property incident to work performed under the contract.

(e) The Contracting Officer shall notify (if otherwise, confirm in writing) the Contractor of any noncompliance with the provisions of this clause and corrective action to be taken. After receipt of such notice, the Contractor shall immediately take such corrective action. (Such notice, when delivered to the Contractor or its representative at the site of the work, shall be deemed sufficient for the purpose.) If the Contractor fails or refuses to comply promptly, the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action has been taken. No part of the time lost due to any such stop order shall be the subject of claim for extension of time or for costs or damages by the Contractor.

(f) The Contractor shall insert the substance of this clause in each subcontract involving the use of hazardous materials or operatians. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)



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PROCUREMENT OF CERTAIN EQUIPTMENT

Notwithstanding any other clause in this contract, the Contractor wil1 not be reimbursed for the purchase, lease, or rental of any item of equiptment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the Contracting Officer.

67 - Photographic Equipment
69 - Training Aids and Devices
70 - General Purpose ADP Equipment, Software, Supplies and Support (Excluding 7045-ADP Supplies and Support Equipment.)
71- Furniture
72 - Household and Commercial Furnishings and Appliances
74 - Office Machines and Visible Record Equipment
77 - Musical Instruments, Phonographs, and Home-type Radios
78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the Contractor and determined essential by the Contracting Officer, the Government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a cost-reimbursement contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

EXHIBIT 11

BOSTON BIOMEDICA, INC. AND SUBSIDIARIES

STATEMENT RE COMPUTATION OF INCOME PER SHARE

WEIGHTED AVERAGE SHARES

| | Quarter Ended March 31, | |
|---|---|---|
| | 1997 | 1996 |
| Average common stock outstanding | 4,380,024 | 2,560,417 |
| Net effect of dilutive common stock equivalents-based on treasury stock method using average market price | 445,558 | - |
| Issuance of "cheap stock" | - | 4,357 |
| | 4,825,582 | 2,564,774 |
| Net income (loss) | $ 147,758 | $ (96,539) |
| Net income (loss) per share | 0.03 | (0.04) |

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