

**Contract Number: HHSN261200800001E**  
**NCI Control Number: N01-CO-2008-00001**

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**PART I - THE SCHEDULE**

**SECTION A - CONTRACT FORM**

**SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

**ARTICLE B.1. INTRODUCTION AND BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

a. Introduction

(1) Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC)

- (a) This major contracted research effort was brought into being on June 26, 1972, by order of then-President Nixon. It was designated as an FFRDC in 1975. It is presently operated under this contract, the primary purpose of which is to provide a unique national resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis and treatment of cancer and AIDS. The research which is supported by this contract is being conducted by both Contractor and NIH scientists. A delineation of the work to be performed under this contract is set forth in SECTION C, ARTICLE C.1.
- (b) This contract constitutes the sponsoring agreement as contemplated in FAR Part 35.017 between Leidos Biomedical Research, Inc. (hereafter "Leidos Biomedical or Contractor") (the operations and technical support contractor for the FNLCR) and the NCI. The FNLCR is a wholly-owned Federal facility.
- (c) This FNLCR contract, currently awarded for a period of ten years, will expire on September 25, 2018. This contract is a performance-based cost-plus-award-fee type and contains the usual general provisions and other special provisions/clauses which are necessary for termination, disposal of assets, settlement of liabilities, etc.
- (d) As an FFRDC, the Contractor cannot compete with any non-FFRDC concern in response to a Federal Agency formal Request for Proposals for other than the operation of an FFRDC. This prohibition is not applicable to the Contractor's parent organization, if any, in its non-FFRDC operations. Also, the Contractor may not accept work from other than the National Cancer Institute (primary sponsor), unless approved by the Contracting Officer.
- (e) All references to the NCI-Frederick (the previous name of this FFRDC) elsewhere in this contract shall be deemed to refer to the FNLCR.

b. Brief Description of Services

For details of the services to be provided, see SECTION C, ARTICLE C.1.

**ARTICLE B.2. ESTIMATED COST AND AWARD FEE CONSIDERATIONS**

- a. The total estimated cost of this contract is **REDACTED**

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- b. The award fee for this contract is: **REDACTED**. The award fee will be paid to the Contractor at regular intervals as defined in subparagraphs d.(1) and (2) below.
- c. The Government's total estimated contract amount represented by the sum of the estimated cost plus the award fee is as follows:

	<b>Estimated Cost (\$)</b>	<b>Available Award Fee (\$)</b>	<b>Estimated Cost Plus Award Fee (\$)</b>
Contract Year (CY) 1	<b>REDACTED</b>	<b>REDACTED</b>	<b>REDACTED</b>
CY 2			
CY 3			
CY 4			
CY 5			
CY 6			
CY 7			
CY 8			
CY9			
CY 10			
Total			\$5,936,717,405

- d. The total potential performance based fee available for this contract is **REDACTED** with the performance based fee amounts and the evaluation periods to be as follows:

<b>Evaluation Period</b>	<b>Available Award Fee (\$)</b>	<b>Award Fee Paid (\$)</b>
<b><u>Contract Year (CY) 1</u></b>	<b>REDACTED</b>	<b>REDACTED</b>
09/26/08 – 03/25/09		
03/26/09 – 09/25/09		
<b><u>CY 2</u></b>		
09/26/09 – 03/25/10		

03/26/10 – 09/25/10		
<b><u>CY 3</u></b>		
09/26/10 – 03/25/11		
03/26/11 – 09/25/11		
<b><u>CY 4</u></b>		
09/26/11 – 03/25/12		
03/26/12 – 09/25/12		
<b><u>CY 5</u></b>		
09/26/12 – 03/25/13		
03/26/13 – 09/25/13		
<b><u>CY 6</u></b>		
09/26/13 – 03/25/14		
03/26/14 – 09/25/14		
<b><u>CY 7</u></b>		
09/26/14 – 03/25/15		
03/26/15 – 09/25/15		
<b><u>CY 8</u></b>		
09/26/15 – 03/25/16		
03/26/16 – 09/25/16		
<b><u>CY 9</u></b>		
09/26/16 – 03/25/17		
03/26/17 – 09/25/17		
<b><u>CY 10</u></b>		
09/26/17 – 03/25/18		
03/26/18 – 09/25/18		
<b>TOTAL</b>		

1. The Contractor is authorized to bill for partial fee payments of available performance based fee amounts at the time each monthly voucher is submitted. Such partial fee payment shall consist of 75% of 1/6 of the total available performance based fee that has been designated as potentially earnable during the then current six-month evaluation period. For example, if the available performance based fee for the current period is \$60,000, the Contractor may bill fee in the amount of  $\$60,000 \times 1/6 \times .75 = \$7,500$ .
2. Methodology for Performance Based Fee Evaluation and Determination
  - (a) The Contractor's performance hereunder will be observed and evaluated continuously by Government monitors. At the end of each evaluation period (set forth in paragraph d. above) a Performance Evaluation Board will review performance based upon criteria established in the PERFORMANCE BASED AWARD FEE EVALUATION PLAN. Such plan will be furnished to the Contractor within thirty (30) days after the contract effective date and may be amended after each evaluation period.
  - (b) The findings of the Performance Evaluation Board will be reported to the NCI Award Fee Determination Official who will determine to what extent the Contractor's performance for each evaluation period warrants payment of the available performance based fee specified in paragraph d. In no event, however, will the unawarded portion of fee for any evaluation period become available for fee award in subsequent periods.
  - (c) The NCI Award Fee Determination Official shall notify the Contractor in writing of the available performance based fee actually earned for a given evaluation period. The decision of the NCI Award Fee Determination Official shall be binding on both parties and not subject to the Disputes Clause provided herein.
  - (d) In the event this contract is terminated prior to a regularly scheduled performance based fee determination, the fee to be paid to the Contractor shall be an appropriate portion of any available performance based fee as may be determined by the NCI Award Fee Determination Official.
3. Any partial payment of performance based fee made to the Contractor pursuant to paragraph d.1. above shall be deducted from the total performance based fee determined by the NCI Award Fee Determination Official. Should the partial payment exceed the performance based fee determination for the applicable period, the excess shall be refunded to the NCI by a credit to the next voucher submitted.

e. Total Estimated Contract Amount

1. The total estimated amount of the contract, represented by the sum of the estimated cost plus the available award fee is **\$5,936,717,405**.
2. Total funds currently available for payment and allotted to this contract are **REDACTED**, of which **REDACTED** represents the estimated costs, and **REDACTED** represents the available award fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2., Authorized Substitutions of Clauses, and ESTIMATED COST - INCREMENTAL FUNDING clause in Article B.5.
3. It is estimated that the amount currently allotted will cover performance of the contract through **REDACTED**
4. The Contracting Officer may allot additional funds to the contract without the concurrence of the

Contractor.

5. Until this contract is fully funded, the requirements of the clause at FAR 52.232-22, Limitation of Funds, shall govern. Once the contract is fully funded, the requirements of the clause at FAR 52.232-20, Limitation of Cost, shall govern.

**ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS**

a. Items Requiring Written Authorization by the Contracting Officer

Notwithstanding the clause, ALLOWABLE COST AND PAYMENT, FAR Clause 52.216-7, 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. Purchase or lease of real property or any interest therein;
2. Any subcontract requirements for facilities renovation, alteration, repair, maintenance, construction, or Architect-Engineer (A-E)/consultant services related to facilities shall be submitted immediately prior to award when the proposed subcontract (or delivery order under a subcontract) amount exceeds that which can be reasonably managed within the total fiscally approved (or concept approved, including any approved changes authorized by the CO through the COA process, in the case of A-E/consultant services) project budget;
3. Foreign and legal services subcontracts (see FAR Clause 52.244-2);
4. Any requirements for advisory and assistance services and any consultant agreements (excluding A&E services referenced above) for which costs will be incurred under this contract, or any use of Leidos Biomedical Research, Inc. personnel in an advisory or assistance service capacity (see B.4.a.(5));
5. Prior notice shall be provided to the Contracting Officer for awards using other than full and open competition made by the Contractor (Leidos Biomedical Research, Inc.) to its parent organization (Leidos, Inc.) or to other NCI Campus at Frederick contractors. This includes all businesses in which these organizations are known to have a controlling interest, including but not limited to affiliates and subsidiaries.
6. Reserved.
7. Reserved.
8. Reserved.
9. Any sale/barter of government furnished or contractor acquired property under this contract;
10. Any changes/renewals or additions to the insurance coverage set in Article B.4. gg;
11. Reserved.
12. The acquisition by lease or purchase of any motor vehicle;
13. All name changes to Leidos Biomedical Research, Inc. labs, programs, centers, etc.
14. Any direct labor positions not approved via the Yellow Task mechanism or through the budget process.

15. Severance pay, early retirement or voluntary termination incentives not otherwise provided for in the approved Contractor retirement plan or other such actions not covered under current FNLCR policy and procedure as incorporated in Article H.8.;
16. All Symposia, Seminars, Conferences and Meetings as per the latest guidance in the HHS Efficient Conference Spending Policy and incorporated guidance on HHS Policy on Use of Appropriated Funds for Conferences and Meeting Space;
17. Food for Meals, Light Refreshments, and Beverages;
18. Promotional Items [includes, but is not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees.]

b. Domestic/Foreign Travel

Only direct travel costs that were not authorized in Article B.4.a.3 shall be submitted for Contracting Officer approval. In addition, all travel which exceeds the authorized per diem requires Contracting Officer approval.

- (1) In the case of travel which exceeds the authorized per diem, the Contractor shall submit a request which sets forth the authorized per diem along with the proposed costs and a justification explaining the necessity to exceed the authorized per diem.
- (2) In the case of foreign travel, Contractor requests shall contain the following information:
  - (a) Meeting(s) and place(s) to be visited, with costs and dates;
  - (b) Names and titles of Contractor personnel to travel, and their functions in the contract;
  - (c) Contract purposes to be served by the travel;
  - (d) How travel of Contractor personnel will benefit or contribute to the accomplishment of the contract, or will otherwise justify the expenditure of contract funds;
  - (e) How such benefits justify the costs for travel and absence from the contract of more than one person, if such is suggested;
  - (f) What additional functions, if any, may be performed by the traveler(s) to accomplish other purposes of the contract and thus provide further benefit to the Government;
  - (g) Justification that absence from the project by Key Personnel and other staff will not delay accomplishing the objectives of the contract; and,
- (3) No funds provided under this contract shall be used for reimbursement of travel expenses incurred by Government employees. Neither shall contract funds provided under this contract be used for travel of other non-contractor employees without the prior approval of the Contracting Officer. The only exceptions are travel associated with subcontracts based on approved purchase requests that include costs for travel, and seminar speaker travel.
- (4) In the event the Contractor employee requesting travel is also employed on another contract, the Contractor must identify the other contracts by Agency and contract number in a letter to the

Contracting Officer. Such letter shall include a written statement from the cognizant Contracting Officer of the other Agency that the employee's travel is for the benefit of this contract and therefore no charges for time or travel will be made to another contract.

**ARTICLE B.4. ADVANCE UNDERSTANDINGS**

a. Costs

Other provisions of this contract notwithstanding, the Contractor is hereby authorized to incur the following costs, within the limits and ceilings as described hereafter:

1. Fringe Benefit Expenses:

- (a) The Fringe Benefits Program described in Subsections 1.1.2.of the Contractor's Business Proposal dated November 13, 2007, and subsequently described in their Final Proposal Revision dated July 14, 2008, is incorporated by reference.
- (b) Changes and notifications relative to the Fringe Benefit Program shall be subject to COA as set forth in Article B.3.a.8.
- (c) Under this contract, fringe benefits shall be approved by the Contracting Officer. Fringe benefit rates established for specific periods of this contract are:

<b>Period</b>	<b>Provisional Rate</b>	<b>Final Rate</b>
	<b>Base – Direct Labor</b>	<b>Base – Direct Labor</b>
<b><u>Contract Year (CY) 1</u></b>		
09/26/08 – 09/25/09		
<b><u>CY 2</u></b>		
09/26/09 – 09/25/10		
<b><u>CY 3</u></b>		
09/26/10 – 09/25/11		
<b><u>CY 4</u></b>		<b>REDACTED</b>
09/26/11 – 09/25/12		
<b><u>CY 5</u></b>	<b>REDACTED</b>	
09/26/12 – 09/25/13		
<b><u>CY 6</u></b>		
09/26/13 – 09/25/14		
<b><u>CY 7</u></b>		

09/26/14 – 09/25/15		
<b><u>CY 8</u></b>		
09/26/15 – 09/25/16		
<b><u>CY 9</u></b>		
09/26/16 – 09/25/17		
<b><u>CY 10</u></b>		
09/26/17 – 09/25/18		

(d) The Contractor shall be required to submit annual fringe benefit rate proposal(s) to the Contracting Officer within 145 calendar days after the end of each contract year. This submission shall include the proposed final fringe benefit rate for the prior year including detailed information to permit evaluation of the elements supporting the rate, along with a proposed provisional rate for the following year. Also, see Paragraph u., Service Contract Act, below.

2. General and Administrative (G&A) Expenses:

The estimated cost of this contract includes the following G&A amounts. The cumulative G&A ceiling in any given Contract Year may not exceed the cumulative amount for the individual Contract Year up to and including the then-current Contract Year. COA is required to increase the G&A pool in any given Contract Year.

<b>Period</b>	<b>G&amp;A Ceilings</b>
<b><u>Contract Year (CY) 1</u></b>	<b>REDACTED</b>
09/26/08 – 09/25/09	
<b><u>CY 2</u></b>	
09/26/09 – 09/25/10	
<b><u>CY 3</u></b>	
09/26/10 – 09/25/11	
<b><u>CY 4</u></b>	
09/26/11 – 09/25/12	
<b><u>CY 5</u></b>	
09/26/12 – 09/25/13	

<b><u>CY 6</u></b>	
09/26/13 – 09/25/14	
<b><u>CY 7</u></b>	
09/26/14 – 09/25/15	
<b><u>CY 8</u></b>	
09/26/15 – 09/25/16	
<b><u>CY 9</u></b>	
09/26/16 – 09/25/17	
<b><u>CY 10</u></b>	
09/26/17 – 09/25/18	
<b>TOTAL</b>	

The above amounts were estimated by the Contractor based on the following types of expenses:

- (a) Management and Administrative. Leidos corporate (home office) will provide management oversight of the OTS contract using both executive and senior managers with knowledge of the OTS Statement of Work (SOW). This will include evaluations of on-site Key personnel, compliance checks for the SOW performance, and meetings with NCI Senior Scientific and Management staff. Leidos management will be tasked by the Leidos Board of Directors to evaluate strategies and provide solutions for specific areas of interest mutually agreed upon with the NCI. The costs for this element include the projected labor costs of both the actual managers and the administrative support to these managers, plus projected Other Direct Costs (ODCs) for such items as travel, communications and postage.
- (b) Human Resources. Leidos will employ the expertise of Human Resources professionals to review and audit Leidos Biomedical policies and procedures, provide advice on federal and state compliance with employment legislation, and train OTS contract Human Resources staff on evolving state of the art Human Resource techniques (as required). Corporate home office support will include working to ensure that the Leidos compensation plan for the OTS contract is consistent with FAR 52.222-46, Evaluation of Compensation for Professional Employees. Leidos Biomedical will also provide ethics training to all OTS contract personnel with the assistance of the corporate Human Resources staff. The costs for this element include the projected labor costs of Human Resources staff plus projected Other Direct Costs (ODCs) for such items as travel, communications and postage.
- (c) Risk Management. Leidos corporate will provide home office support from the corporate Risk Management Office to assess the level of risk for work performed under the contract and make recommendations for managing the risk. This may involve on-site reviews of

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operations, as well as training of managers and supervisors on effective risk management procedures. Audits of industrial operations may be conducted to ensure proper risk management procedures. The costs for this element include the projected labor costs of the Risk Management Office staff plus projected Other Direct Costs (ODCs) for such items as travel, communications, postage, and insurance.

- (d) Environmental Health and Safety (EHS). Leidos corporate may conduct periodic reviews of the OTS contract Safety and Environmental Protection Program (SEPP). Compliance with federal and applicable state regulations will be audited and reports will be issued to NCI indicating the status of compliance. Employee safety and health policies and procedures will be reviewed for currency vis-à-vis industry standards. Guidance on upgrades or improvements will be provided as part of this oversight activity. The costs for this element include the projected labor costs of Environmental Health and Safety staff plus projected Other Direct Costs (ODCs) for such items as travel, communications and postage.
- (e) Legal. Leidos corporate will use the resources of the its corporate legal department to provide advice and consultation on contract-related matters such as contracts, acquisitions, employment law and compliance, insurance, product liability, and other issues requested by the FNLCR. The costs for this element include the projected labor costs of legal department staff plus projected Other Direct Costs (ODCs) for such items as travel, communications, postage, and outside counsel.
- (f) Internal Audit. Leidos will perform audits of OTS contract operations to ensure compliance with Federal Acquisition Regulations, Cost Accounting Standards, the Leidos Biomedical Research Cost Accounting Standards Disclosure Statement, and Generally Accepted Accounting Standards. Audits will cover both operational and incurred costs. The costs for this element include the projected labor costs of internal audit staff plus projected Other Direct Costs (ODCs) for such items as travel, communications, postage, and outside training.
- (g) The Contractor shall provide the Contracting Officer with quarterly reports of General and Administrative expense expenditures. These reports will show expenditures in each of the above six areas. The Government may periodically request detailed back-up data. The first report shall be due on January 15, 2009 covering the period from September 26, 2008 through December 31, 2008. Subsequent reports shall be due on 14 days after the quarter being reported.

3. Travel Costs

- (a) Total annual direct cost expenditures for domestic/foreign travel (transportation, lodging, subsistence, and incidental expenses) are based upon the amounts shown below. The Contractor may adjust and/or re-budget such costs from year-to-year, but such adjustment shall not exceed a given year's allotment, without the prior written approval of the Contracting Officer.

Period	Travel
<b><u>Contract Year (CY) 1</u></b>	<b>REDACTED</b>

09/26/08 – 09/25/09	
<b><u>CY 2</u></b>	
09/26/09 – 09/25/10	
<b><u>CY 3</u></b>	
09/26/10 – 09/25/11	
<b><u>CY 4</u></b>	
09/26/11 – 09/25/12	
<b><u>CY 5</u></b>	
09/26/12 – 09/25/13	
<b><u>CY 6</u></b>	
09/26/13 – 09/25/14	
<b><u>CY 7</u></b>	
09/26/14 – 09/25/15	
<b><u>CY 8</u></b>	
09/26/15 – 09/25/16	
<b><u>CY 9</u></b>	
09/26/16 – 09/25/17	
<b><u>CY 10</u></b>	
09/26/17 – 09/25/18	
<b>TOTAL</b>	

- (b) The cost of travel by privately-owned vehicles (automobile, motorcycle, airplane, etc.) shall be reimbursed at a rate not to exceed the Government mileage rates currently in effect, as amended from time to time, in lieu of actual costs; provided, however, that such reimbursement shall not exceed the otherwise allowable comparative cost of travel by common carrier.
  
- (c) The Contractor agrees that costs for travel including lodging, other subsistence, and incidental expenses shall be allowable only to the extent that they do not exceed the amounts allowed for Federal employees. The Contractor, therefore, shall invoice and be reimbursed for all travel costs in accordance with FAR Subpart 31.205-46, unless otherwise authorized per Article B.3.b. (Domestic/Foreign Travel).

- (d) Notwithstanding the conditions set forth in (a), (b), and (c) above, the Contractor is authorized to reimburse its Leidos Biomedical Research, Inc. employees up to the maximum rates of per diem allowances for travel by personnel in foreign areas, which are delineated in the Department of State Standardized Regulations (ALLOWANCES - 925. Maximum Rates of Per Diem Allowances for travel in Foreign Areas), as updated from time to time. The parties agree that utilization of these rates for foreign travelers will be in lieu of all other subsistence and lodging allowances as may be stipulated herein.

4. Consultant Costs

Total direct costs for consultants are based upon the annual estimates shown below. The Contractor may adjust and/or rebudget such costs from year-to-year, but such adjustment shall not exceed a given year's allotment, without the prior written approval of the Contracting Officer.

Period	Consultant Costs
<b><u>Contract Year (CY) 1</u></b>	<b>REDACTED</b>
09/26/08 – 09/25/09	
<b><u>CY 2</u></b>	
09/26/09 – 09/25/10	
<b><u>CY 3</u></b>	
09/26/10 – 09/25/11	
<b><u>CY 4</u></b>	
09/26/11 – 09/25/12	
<b><u>CY 5</u></b>	
09/26/12 – 09/25/13	
<b><u>CY 6</u></b>	
09/26/13 – 09/25/14	
<b><u>CY 7</u></b>	
09/26/14 – 09/25/15	
<b><u>CY 8</u></b>	
09/26/15 – 09/25/16	
<b><u>CY 9</u></b>	
09/26/16 – 09/25/17	
<b><u>CY 10</u></b>	

09/26/17 – 09/25/18	
<b>TOTAL</b>	

5. Advisory and Assistance Services

Leidos Biomedical Research, Inc. will not provide any advisory and assistance services during OTS contract performance that violate the conditions established under FAR 37.203(c).

6. Honoraria

Honoraria shall not exceed \$400 per day per individual, plus travel expenses consistent with allowable cost principles set forth elsewhere in this contract, unless otherwise approved by the Contracting Officer. For purposes of the contract, "honoraria" may be paid for services provided by guest speakers and lecturers for seminars, non-Government attendees of workshops or meetings held primarily to exchange scientific information, and services provided by non-Government members of review groups or advisory committees.

7. Overtime Premium Expenses

Pursuant to the provisions of FAR Clause No. 52.222-2 - Overtime, the Contractor is hereby authorized to incur, without seeking further approval, total direct overtime premium charges up to but not exceeding the following amounts:

<b>Period</b>	<b>Overtime</b>
<b><u>Contract Year (CY) 1</u></b>	<b>REDACTED</b>
09/26/08 – 09/25/09	
<b><u>CY 2</u></b>	
09/26/09 – 09/25/10	
<b><u>CY 3</u></b>	
09/26/10 – 09/25/11	
<b><u>CY 4</u></b>	
09/26/11 – 09/25/12	
<b><u>CY 5</u></b>	
09/26/12 – 09/25/13	
<b><u>CY 6</u></b>	
09/26/13 – 09/25/14	
<b><u>CY 7</u></b>	

09/26/14 – 09/25/15	
<b><u>CY 8</u></b>	
09/26/15 – 09/25/16	
<b><u>CY 9</u></b>	
09/26/16 – 09/25/17	
<b><u>CY 10</u></b>	
09/26/17 – 09/25/18	
<b>TOTAL</b>	

8. Capitalized Equipment

- a. Total direct costs for capitalized personal property, as defined in the Department of Health and Human Services (DHHS) HHS Contracting Guide for Contract of Government Property, (incorporated herein by reference) are based upon the annual estimates shown below.

The Contractor may adjust and/or rebudget such costs from year-to-year, but such adjustment shall not exceed a given year's allotment, without the prior written approval of the Contracting Officer.

<b>Period</b>	<b>Capital Equipment</b>
<b><u>Contract Year (CY) 1</u></b>	<b>REDACTED</b>
09/26/08 – 09/25/09	
<b><u>CY 2</u></b>	
09/26/09 – 09/25/10	
<b><u>CY 3</u></b>	
09/26/10 – 09/25/11	
<b><u>CY 4</u></b>	
09/26/11 – 09/25/12	
<b><u>CY 5</u></b>	
09/26/12 – 09/25/13	
<b><u>CY 6</u></b>	
09/26/13 – 09/25/14	
<b><u>CY 7</u></b>	

09/26/14 – 09/25/15	
<b><u>CY 8</u></b>	
09/26/15 – 09/25/16	
<b><u>CY 9</u></b>	
09/26/16 – 09/25/17	
<b><u>CY 10</u></b>	
09/26/17 – 09/25/18	
<b>TOTAL</b>	

b. On-Site Corporate Authority

The following listed eight full-time positions must have the authority to represent and commit his/her company in dealing with the Government and other contractors on the NCI Campus at Frederick site on all matters. One of these employees must be available on any given working day of the contract period to perform this function, e.g. to sign contract modifications. **FAILURE TO COMPLY WITH THIS PARAGRAPH SHALL CONSTITUTE A MATERIAL BREACH OF CONTRACT.**

<u>Name of Individual</u>	<u>Position</u>
	President
	Chief Medical Officer
	Chief Operating Officer (Interim)
	Director, Management Support Directorate
	Director, Financial Operations Directorate
	Director, Contracts

c. Parent Company Guarantee

The revised "Parent Company Guarantee", dated October 17, 2013, as submitted in the Contractor's Business Proposal under Section 5.0., Financial Capacity, is incorporated herein as Attachment 5.

d. Space and Resource Assignments

All space and resource assignments shall be made by the COR with the approval of the Contracting Officer.

e. Conferences

All direct costs for symposia, seminars, and conferences at locations other than FNLCR shall require prior written approval (the request shall include the subject matter, participants, cost, date and location thereof) of the COR, and must be submitted to the Contracting Officer for final approval.

All conferences shall be conducted in accordance with the spirit and intent of the NIH policy to include women/ethnic groups/handicapped individuals, and documentation must exist in Contractor files to demonstrate compliance.

f. Work Requirement Resolution

In those situations where one contractor cannot meet the terms of a request(s) by another contractor or by resident intramural staff (e.g., procurement of animals, or the operation of facilities in which animals are held), such request(s), together with appropriate background information supporting the Contractor's position, shall be submitted to the Contracting Officer for resolution.

g. Changes within the Scope

It is agreed that the Contractor may recommend changes in the direction/emphasis of the work within the scope of the contract. These recommended changes shall be submitted to the Contracting Officer for consideration. The Contractor shall take no action on these recommendations without the specific written direction of the Contracting Officer. The procedure for accomplishing such changes is: submission of the recommended change(s), including those from government sources, to the COR for review; transmission through the Contracting Officer to the Contractor; and, back through the Contracting Officer and COR for final disposition.

h. Discretionary Leave

It is understood that the Contractor will be held accountable to complying with the Discretionary Leave Policy approved under **REDACTED** this contract.

i. Property Accountability

It is understood that the Contractor will be held accountable for Government property located in its assigned space in accordance with FAR Clause 52.245-1. All property shall be accountable under this contract whether procured or utilized under either or both of the Contracts. All property utilized under the Contracts shall be maintained on a single inventory and reported in accordance with the requirements of Article G.6.—Government Property. All reports of loss or damage, requests for disposition, sale or barter or other activities related to Government property shall be administered through this contract.

j. Environmental Health and Safety/Regulations at the NCI-Frederick

- (1) The Operations and Technical Support (OTS) Contractor has the primary responsibility for the maintenance and perpetuation of ongoing Safety Programs/Policies and Procedures at the NCI-Frederick in accordance with applicable Federal, State and Local regulations and laws, as well as responsibility for developing new programs/policies and procedures as required. These policies and procedures shall be prepared by the OTS Contractor and shall be approved by the Contracting Officer before implementation. (It is understood that Contracting Officer approval is not required for implementation of orders set forth by the Federal and State regulators with regard to radioactive and hazardous materials because such orders are considered mandatory by those regulators).
- (2) All employees (Federal and Contractor/visitors/guests) shall abide by the approved NCI-Frederick Safety and Environmental Regulations. To monitor compliance with Government-approved safety and environmental requirements, the OTS Contractor's Safety Officer or his/her designated representative has the authority to enter all areas/facilities at the NCI-Frederick to make periodic,

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routine or unannounced inspections. The OTS Contractor will attempt to resolve all deviations in safety and environmental regulations through the appropriate lines of authority. Upon inspection, deviations or discrepancies will be reported to the Laboratory Chief/Manager/Program Head for corrective action within 30 - 45 days. The results of the re-inspection shall be reported to the Contractor Principal Investigator/Project Manager/Key Person or Government authority as appropriate. In cases where deviations or discrepancies are not resolved at the time of re-inspection, the Principal Investigator/Project Manager/Key Person or Government authority shall provide assistance to the Safety Officer to resolve the problem, upon request.

The Contractor will immediately report the following deviations or discrepancies to the Contracting Officer for appropriate action: (a) those requiring submission of a report to regulatory authorities; (b) those involving willful or repeat violations; and, (c) those that the Contractor is unable to resolve after re-inspection.

The Contractor will also submit a quarterly report to the Contracting Officer summarizing all deviations and discrepancies with Safety and Environmental Regulations on or before 10/01, 01/01, 04/01, and 07/01 (see also C.2.a.11). In cases where the OTS Contractor's Safety Officer judges that emergency remedial action is required, he/she is authorized to take such action, including the closing down and evacuation of any area/facility at the NCI-Frederick. The Contracting Officer shall be verbally informed as soon as practicable after any emergency action is taken.

A special report shall be provided to the Contracting Officer and a copy shall be submitted to the Project Officer, within 2 working days thereafter describing the nature of the emergency and corrective action taken.

- (3) The Contracting Officer shall notify (and 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. 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 work order shall be the subject of the claim(s) for extension of time or for costs or damages by the Contractor.

k. Cancer Research Technology Program (CRTP)

All requests for CRTP core services must be routed through the web-based Core Services Accession System (CSAS) (except High-Throughput sequencing requests through the Laboratory of Molecular Technology LIMS). Requests for services will be routed electronically (via e-mail notification) to the appropriate laboratory to review and provide a cost estimate. The response and estimate will be routed electronically to the requestor for consideration. For projects originating from non-NCI customers, or if a request exceeds \$10,000, the NCI Project Office will review the project to ensure the request is consistent with the FNLCR's mission. If approved by the service requestor, and the NCI Project Office when necessary, the Administrative Officer will be notified electronically to review for funds availability. Projects will not commence until all necessary approvals for scientific content and funds availability have been received.

l. Work Orders

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The Contractor shall work closely with the customer to determine needs and priorities associated with its construction (including new buildings and facility upgrades), maintenance, repairs, and other similar requirements. Customer requirements and priorities shall be reduced to writing by the Contractor and formally approved by the customer.

All work orders for renovation or alteration of facilities, construction (including Architect-Engineer (A&E) design), preventative maintenance and repair of facilities estimated to exceed \$50,000 in Materials and Supplies (M&S), labor, or a combination of M&S and labor shall require a single Fiscal Approval (FA) facility Package which requires CO approval. The submission of a fiscal approval package, as required by this article, satisfies the advanced notification requirement of FAR 52.244-2. For projects with higher degrees of complexity or size, the COR may require submission of a Conceptual Approval (CA) Package which requires CO approval. The project package shall provide enough detail to adequately address the requestor's needs and define project requirements to allow project execution upon approval of the package. Projects estimated to cost less than \$50,000 shall require CO determination of funding source. Approval of the cost estimate summary will be required by requester / administrative officer. The simplified package shall contain at a minimum, a scope of work and a cost estimate summary. The simplified package is not required for trouble calls, preventative maintenance activity and routine Special Assists (SAs) under \$50,000 and would apply to the class of work described as Planned Special Assists, which are those SAs executed under the direction of the contractor. The Contractor shall have the authority to manage all aspects of work orders to include, but not limited to, the use of approved project budget, contingency, schedule, and project quality. The Contractor shall keep the customer informed of its progress on a mutually acceptable schedule and format (e-mail, phone, etc.). However, should problems with the initiative develop; responsibility will be released to Leidos and the requestor, unless additional funds are required. Thus changes within the approved Fiscal Approval do not require additional CO and COR approval. When an impact to schedule or performance is identified a request for schedule change shall be submitted to the requestor or end user for approval and the COR shall be notified of the impact. If additional funding is necessitated by the requirements of the approved impact plan, CO approval is required.

The Contractor and NCI designated representatives, as determined by the Contracting Officer, shall hold quarterly Facility Projects Status Report Meeting in January, April, July, and October, at which the status of all facilities projects will be reviewed. Weekly meetings between the Contractor and NCI designated representatives shall be held for the purpose of reviewing all requests for approvals as required under the terms of this contract.

m. Key Personnel Leave

The maximum vacation leave permitted key personnel during any Contract Year is twenty-six (26) working days.

n. Reserved

o. Sale of Contract

Contractor shall not sell, transfer, or otherwise alter the control or ownership of this contract without the approval of the Contracting Officer.

p. Non-Personal Services and Inherently Governmental Functions

1. Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the COR to the Contractor's Project Manager. No Contractor

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employee shall be under the relatively continuous supervision of the Government. All individual employee assignments, and daily work direction, shall be given by the applicable employee supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

The Government and the Contractor understand and agree that the services to be delivered under this contract by the Contractor to the Government are non-personal services and the parties recognize and agree that no employer-employee relationship exists or will exist under the contract between the Government and the Contractor's personnel. It is, therefore, in the best interest of the Government to afford both parties a full understanding of their respective obligations.

The Contractor shall ensure, by appropriate management lines of authority within its contract organization, that within the meaning of FAR Subpart 37.104 no personal services relationships occur. Within the formal assignment of work and staffing allocation to Leidos Biomedical Research, Inc., all Leidos Biomedical Research, Inc. positions shall be assigned to an Leidos Biomedical Research, Inc. organization that justifies the position and selects the employee(s) to perform the work. All Leidos Biomedical Research, Inc. employees shall have an identified Leidos Biomedical Research, Inc. supervisor who is responsible for assignment of their work, assessment of their performance and resulting pay adjustments, and working conditions. The Leidos Biomedical Research, Inc. supervisor is responsible for interacting with the Government customer on the assignment of work, work expectations, and the level of performance provided by the Leidos Biomedical Research, Inc. employees. All employees shall be routinely reminded that they work for Leidos Biomedical Research, Inc. not the Government, and be advised that they must not be supervised and controlled by Government employees on a continuing basis.

The services to be performed under this contract do not require the Contractor or its personnel to exercise personal judgment and discretion on behalf of the Government. Rather the Contractor's personnel shall act and exercise personal judgment and discretion on behalf of the Contractor.

It is the Contractor's, as well as the Government's responsibility to monitor contract activities and notify the Contracting Officer if the Contractor believes that the intent of this clause has been, or may be, violated. Therefore, the Contractor shall notify the Contracting Officer in writing within 30 calendar days from the date the Contractor has reason to believe that the intent of this clause has been, or may be, violated. The notice shall include the date, nature and circumstance of the conduct, the name, function and activity of each Government employee or Contractor official or employee involved or knowledgeable about such conduct, identify any documents or substance of any oral communication involved in the conduct, and the estimate in time by which the Government must respond to this notice to minimize cost, delay or disruption of performance.

The Contracting Officer shall promptly, within 30 calendar days after receipt of notice, respond to the notice in writing. In responding, the Contracting Officer shall either:

- (a) Confirm that the conduct is in violation and when necessary direct the mode of further performance,
- (b) Countermand any communication regarded as a violation,
- (c) Deny that the conduct constitutes a violation and when necessary direct the mode of further performance; or

(d) In the event the notice is inadequate to make a decision, advise the Contractor what additional information is required, and establish the date by which it should be furnished by the Contractor and the date thereafter by which the Government shall respond.

2. Pursuant to FAR 7.5, the Contractor shall not perform any inherently Governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change the contract and that if the other contractor believes this communication to be a direction to change their contract, they should notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.
3. The Contractor shall insure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of the contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

q. Confidentiality of Information (HHSAR 352.224-70)

The findings of studies or research conducted for the Biological Resources Branch (BRB), Biological Testing Branch (BTB), the Screening Technologies Branch (STB), and the Information Technology Branch (ITB), of NCI's Developmental Therapeutics Program (DTP), and the Laboratory of Population Genetics/NCI Center for Bioinformatics are considered confidential information. Therefore, the Contractor is required to provide written advance notice to the Assistant COR for which the work is being performed of its intent to release such data in accordance with HHSAR Clause 352.224-70, Confidentiality of Information (Apr. 1984) which is incorporated into this contract by reference.

r. Product Liability Insurance and Licensing

(1) cGMP Projects (including RAID Projects):

The Contractor in its role as a Federally Funded Research and Development (FFRDC) Contractor, performs cGMP biopharmaceutical developmental and manufacturing activities in support of NIH activities, such as NCI's Biopharmaceutical Development Program, or NIAID Vaccine Research Center (VRC). In some cases, the projects may result in the invention of a product or manufacturing process, reported to NIH on an official Employee Invention Report (EIR), that is determined to have a Contractor employee as an inventor. The intellectual property (IP) ownership of said Contractor invention shall be assigned in accordance with the DEC. The Government may subsequently elect to patent and/or license this technology to a third party for the purpose of manufacturing cGMP products for use in clinical trials or commercialization.

In order to mitigate risks associated with these activities, the following integrated elements of the Contractor's risk management approach are acceptable to the Government: (1) purchase of commercially available medical products liability insurance in the amount of \$50 Million in

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the aggregate (this amount may be changed based on the mutual agreement of NCI and Contractor), (2) review and approval of intramural and extramural projects assigned to the OTS contract to ensure that commercial insurance and contract funding for such insurance is available, (3) restrictions on the quantity of cGMP materials produced to that required to conduct clinical trials and associated pre-clinical studies and monitoring, (4) agreement that cGMP products manufactured during the term of the OTS contract will be used no later than 36 months following the termination date of the contract unless a later date is mutually agreed to by the Government and the Contractor, and (5) inclusion of language (described in paragraph (3), or its equivalent) in any Government licensing agreements with third parties that provides the Government and the contractor, as its FFRDC contractor, with indemnification and a hold harmless agreement. Inclusion of the "Licensing Agreement Wording" or its equivalent as stated in paragraph (3) below will be the general rule unless there is a compelling reason, such as the public health, to change it. The NCI-FFRDC contractor will be notified of any changes to the language in paragraph 3

"Licensing Agreement Wording" which substantially alters the liability to the NCI-FFRDC contractor prior to execution of the License agreement. Under these rare situations, the NCI-FFRDC contractor will be permitted to take other appropriate risk management measures subject to the approval of the Contracting Officer.

The option to include the language described in paragraph (3) below in such NIH licenses will be only in the circumstances described below:

- Technology is invented by Contractor in the performance of the OTS contract;
- An NIH Employee Invention Report (EIR) is submitted in which an Leidos Biomedical Research, Inc. employee is named as an inventor;
- The EIR technology is assigned to the U.S. Government;
- A request to include the language in paragraph (3) below, or its equivalent, is explicitly included in the EIR; and,
- The EIR technology is licensed by a third-party with the intention of using the technology in support of phase 3 clinical trials or commercialization for human use.

- (2) Projects in Support of DoD or other non-NIH activities: The following additional conditions shall apply to projects performed by the Contractor in support of DoD or non-NIH Sponsors:
- (a) The Contractor must be able to obtain a Medical Product Liability insurance policy specific to any cGMP product manufactured on behalf of the Department of Defense (DoD) or other non-NIH sponsor. The limit of insurance to be purchased for each product will be an amount appropriate to the project requested and mutually agreed to by the Parties. Parties are defined to include Leidos Biomedical Research, Inc., the National Cancer Institute, and the Department of Defense (DoD) or other non-NIH sponsor. Alternatively, as an option to the foregoing, and subject to written Contracting Officer Approval, the Contractor may increase its Medical Product Liability insurance policy limits that cover NIH-sponsored products contemplated under this Agreement to an amount to be mutually agreed to by the Parties that provides appropriate protection to the Parties for all products (NIH-sponsored as well as DoD/non-NIH activities) manufactured by the Contractor. The level of insurance will be reviewed for adequacy as part of the conditions of acceptance for each DoD or other non-NIH project or, at a minimum, annually, for adequacy based upon the Contractor's evaluation of the related exposures and any changes in the insurance marketplace. Furthermore the policy

will include a provision for reinstatement of the policy limits, should they be exhausted during the policy year as a result of any claims. Finally, the policy will include an option to purchase extended reporting coverage, which will be exercised at the conclusion of the clinical trials, or at the time the clinical trials are discontinued.

- (b) The DoD or non-NIH sponsor shall agree to (i) fund NCI with an amount necessary for NCI to reimburse the Contractor for the cost of the Medical Product Liability insurance policy or the cost of the additional limits purchased as described above, including any deductibles incurred by the Contractor in connection with the product, (ii) to fund NCI with an amount necessary to reimburse the Contractor for the cost of reinstating policy limits to the extent coverage limits are exhausted during the policy year as a result of claims arising from DoD or non-NIH sponsored products, and (iii) to fund NCI with an amount necessary to reimburse the Contractor for the cost of exercising the extended reporting coverage option at the conclusion of the clinical trials or at the time the clinical trials are discontinued or, if coverage is included in the Contractor's Medical Product Liability insurance program that covers NIH-sponsored products, for a proportional share of the ongoing premium required to continue insuring the DoD or non-NIH sponsored products.
  - (c) The DoD or non-NIH sponsor shall agree to notify the Government and the Contractor of its intended administration of the "cGMP Material" to individuals in clinical trials outside the United States. Should DoD or non-NIH sponsor fail to notify the Government and the Contractor of the use of any "cGMP Materials" outside of the United States, the DoD or non-NIH sponsor agrees to defend and indemnify the Government and the Contractor against any claims relating to the use of the materials outside the United States.
  - (d) The DoD or non-NIH sponsor shall agree to immediately discontinue administering the "cGMP material" to individuals should the Medical Products Liability Insurance referenced herein not be available or funded under the OTS contract.
- (3) **Licensing Agreement Wording:** Licensee shall indemnify and hold PHS and its employees, students, fellows, agents, NCI-FFRDC contractor, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of a) the use by Licensee, its directors, employees, or third parties of any Licensed Intellectual Property or b) the design, manufacture, distribution, or use of any Licensed Products or other products or processes developed in connection with or arising out of the Licensed Intellectual Property. Licensee agrees to maintain a liability insurance program consistent with sound business practice.

s. Intellectual Property

- (1) The deviated FAR Clause 52.227-13 (Deviation) Patent Rights-Acquisition by the Government (DEC 2007) [Patent Rights- OTS Prime Contractor] (Attachment 8) shall apply to the prime Contractor.
- (2) FAR Clause 52.227-11, Patent Rights - Ownership by the Contractor (DEC 2007), is incorporated into this contract by reference. The terms of this FAR Clause shall apply to all subcontractors of all tiers unless one of the deviated clauses applies.

t. Rights in Data

- (1) FAR Clause 52.227-14, Rights in Data General (DEC 2007), is incorporated into this contract by reference. The terms of this FAR Clause shall apply to all subcontractors of all tiers unless one of the deviated clauses applies. Alternates I-V may be substituted into subcontracts at all tiers as appropriate to meet programmatic goals.

NOTE: With regard to Rights in Data, the Contractor is reminded of its obligation to comply with Privacy Act (See Article H.6.) requirements, and HHSAR Clause 352.224-70 Confidentiality of Information clause of this contract, when applicable.

- (2) FAR Clause 52.227-17, Rights in Data - Special Works, (not deviated) is incorporated into this contract by reference. This Clause shall apply when the Contractor is to produce or compile data (other than limited rights data or restricted computer software) for the Government's own use, or when there is a specific need to limit distribution and use of the data and/or to obtain indemnity for liabilities that may arise out of the content, performance, or disclosure of the data. This clause shall apply on a case-by-case basis subject to the mutual agreement of the Contractor and Government.

u. Service Contract Act

Any required changes to fringe benefits brought about by a new Wage Determination that affect the costs to the Contractor, will be the subject of an equitable adjustment pursuant to the "Changes" clause of the contract. The negotiated fee will not be altered by adjustments resulting from such changes.

v. Use of the Internet in Acquisition

The Contractor shall utilize electronic commerce tools to enable Internet procurement to the maximum extent practicable.

w. Cost Efficiencies of Contractor.

The Contractor will have the same buying power as that of its parent, Leidos (Corporate). Other than the normal application of approved overheads and adders, there will be no "mark up" of any costs transferred from Leidos (Corporate) to the Contractor with respect to acquisition of approved insurance policies covering activities under this prime contract. This provision does not apply to intercompany actions to acquire services from Leidos (Corporate) approved under Article B.3. of this contract.

x. Hazardous Materials

In the event it is alleged that Contractor caused environmental releases in or about the place of performance of this contract, or if contract performance gives rise to any similar environmental issue, the following will apply.

- (1) If the Contractor incurs costs, expenses, damages, or liabilities to third parties (third-party liability), to an extent not otherwise compensated by the contract, the protections offered by the combination of in-place operational safety management procedures (to mitigate the effects of the incident), existing (but limited) insurance programs, and HSSAR clause 352.228-7 will be relied upon.
- (2) If the Contractor is required by federal, state, or local government agency or court order to take action, or with NCI approval, takes action in connection with an environmental release, the resulting costs will be allowable and allocable to the contract, and NCI will reimburse the

Contractor for these costs, subject to the limits set forth in FAR 52.232-22, Limitation of Funds. If such actions result in loss or damage to government property, such costs will be allowable only to the extent that the costs are not the direct result of willful misconduct or lack of good faith on the part of the Contractor's directors, officers, or equivalent-level personnel.

- (3) If the Contractor, in the course of performing its obligations under the contract, is assessed fines or penalties as a result of acts or omissions by government personnel or third parties (e.g., other NCI contractors), rather than as a result of its own acts or omissions or those of its subcontractors, the resulting costs will be allowable and allocable to the contract per FAR 31.205-15, and NCI will reimburse the Contractor for these costs, subject to the limits set forth in FAR 52.232-22, Limitation of Funds.

y. Management of Radioactive Materials

The Contractor shall hold radioactive material license(s) from the appropriate regulator (NRC or Agreement State) for use of radioactive material covering FNLCR at both on-site and off-site facilities for which it is performing work under this contract.

If Leidos Biomedical Research, Inc., in the course of performing its obligations under the contract, is assessed fines or penalties as a result of acts or omissions by government personnel or third parties, rather than as a result of its own acts or omissions or those of subcontractors, the resulting costs will be allowable and allocable to the contract in accordance with FAR 31.205-15, and NCI will reimburse the Contractor for these costs, subject to the limits set forth in FAR 52.232-22, Limitation of Funds. The Contractor will ensure that appropriate insurance requirements are flowed down to subcontractors responsible for disposal of these materials.

The Contractor is responsible for disposal of liquid and solid radioactive waste. The Contractor's ability to dispose of liquid and solid radioactive waste is conditioned on the availability of disposal sites. If disposal sites are not available, then changes in the NRC license may be required in order to store materials on-site for longer periods of time.

Liability associated with cleanup of disposal sites will be determined.

z. Management of Hazardous Waste

- (1) The existing Hazardous Waste Generator Permit EPA ID Number MD3 75 083 2062 issued to the FNLCR will continue to be used for the FNLCR hazardous waste program.
- (2) NCI will be identified as the owner of the FNLCR.
- (3) The Contractor will be identified as the point of contact for matters relating to the hazardous waste program and will sign the EPA 8700-12 (as revised) Notification of Regulated Waste Activity, MDE 185 Notification of Special Medical Waste Activity, and other comparable documents related to the operation and administration of the hazardous waste program.

aa. Insurance of Repository Samples

The inventory of samples maintained in the repositories does not fall within the scope of FAR 52.237-2; therefore, in the event of a loss involving the samples, NCI will not look to recover the value of the samples under this clause. However, NCI will notify the Contractor of any samples and their associated value that it determines are to be insured. This insurance requirement will be flowed down to the repository

subcontractor and the cost of this insurance will be included in the subcontractor's annual operating budget. The Contractor and its subcontractors shall be liable under FAR 52.237-2 for the real and personal property associated with the on-site repositories.

bb. New Initiatives

Technical requirements and new initiatives are generally conveyed to the Contractor through the Project Officer/Contracting Officer. As necessary, the Contractor may interface directly with NCI management and scientists and other NCI approved Institutes and Agencies (hereinafter identified as "customer") to discuss potential new scientific initiatives to be added to the contract. Coincident with these discussions, the Contracting Officer and COR shall be made aware by the Contractor or the "customer" of the potential new initiative to determine whether its inclusion in the contract is appropriate and its funding is identified.

Upon preliminary agreement between the Contractor and customer, the Contractor should inform the customer that a request for the services should be submitted to the COR requesting an estimate of costs and time needed for completion of the new initiative. They should also be advised to provide the name(s) of the Contractor personnel with whom they have had preliminary discussion along with a description of the services needed.

If the Contractor is subsequently advised to proceed with the new initiative, the Contractor shall keep the customer informed of its progress on a mutually acceptable schedule and format (e-mail, phone, etc.). However, should problems with the initiative develop, the customer, the Contracting Officer and COR shall be provided written notice of the problem along with a recommendation for its resolution.

In all instances, the Contracting Officer, in consultation with the Project Officer, shall have final approval as to whether the work will be performed under this contract.

cc. Reserved

dd. Make or Buy Program

In carrying out these responsibilities, the Contractor shall ensure that all materials and services are directly provided or as necessary acquired from other sources at the lowest possible cost consistent with the mission requirements of the FNLCR. In making recommendations to the Government on whether to make or buy services and /or supplies, the Contractor will continually review the methods used for work accomplishment and suggest ways to adjust the mix (in-house/out-of-house) as appropriate to meet changing mission requirements while carefully balancing cost and quality.

ee. Special Bank Account (SBA)

The Contractor shall continue utilization of the SBA established under Contract N01-CO-12400 for this follow-on contract beginning September 26, 2008. No Contractor funds will be deposited into this account. Incurred costs for the contract will be allocated based on the center number structure currently in use at NCI Campus at Frederick, and government reimbursement invoices will be issued separately for each contract. The appropriate contract shall thus be billed for the costs incurred under the contract in which they were incurred. As costs are incurred under Contract N01-CO-12400, a credit to the advance will be processed on the SBA invoice for that contract, and an allocation will be made to the Advance Funds on the SBA invoice for the follow-on contract until all advance monies are accounted for under the new contract. (Also see Article H.14.) The SBA shall be used for making payment for all allowable contract costs, inclusive of labor, fringe benefits, materials, supplies, services, equipment, G&A, fee and other direct costs.

ff. Concurrence to Copyright

If Government employee(s) are identified on a publication as a primary author(s) of scientific or technical article(s), then the Contractor shall obtain the concurrence to copyright through the participating Government employee(s). In turn, the Government employee shall be responsible for assuring that appropriate approvals are obtained. If the author(s) are Contractor employees, then the Contractor shall be guided by the contract data rights clauses.

gg. Insurance

In accordance with HHSAR Clause 352.228-7, the Contractor is authorized to acquire the following types of insurance coverage subject to Contracting Officer Authorization (COA) except that any insurance required by law shall not require COA.

1. General Liability (both Domestic and International);
2. Automobile Liability;
3. Umbrella/Excess Liability;
4. Fiduciary Bond;
5. Fidelity Bond;
6. Group Travel;
7. Medical Malpractice;
8. Medical Products Liability for Therapeutics, Diagnostics, and Vaccines;
9. Professional Liability-OHS Clinic;
10. Physicians Malpractice; and
11. Leased Facilities.

hh. Employee Incentives/Bonuses

The contractor is authorized to incur the following amounts per year as discretionary bonuses or incentive payments to non-key employees as a cost element of the indirect rate structure. Bonuses or incentives to key personnel shall not be charged to the contract. The following ceiling amounts do not apply to sign-on bonuses or other bonus arrangements paid in accordance with specific employment agreements the Contractor has made with certain non-key personnel.

Period	Employee Incentives/Bonuses
<b><u>Contract Year (CY) 1</u></b>	<b>REDACTED</b>
09/26/08 – 09/25/09	
<b><u>CY 2</u></b>	
09/26/09 – 09/25/10	
<b><u>CY 3</u></b>	
09/26/10 – 09/25/11	
<b><u>CY 4</u></b>	
09/26/11 – 09/25/12	
<b><u>CY 5</u></b>	
09/26/12 – 09/25/13	
<b><u>CY 6</u></b>	
09/26/13 – 09/25/14	

<b><u>CY 7</u></b>	
09/26/14 – 09/25/15	
<b><u>CY 8</u></b>	
09/26/15 – 09/25/16	
<b><u>CY 9</u></b>	
09/26/16 – 09/25/17	
<b><u>CY 10</u></b>	
09/26/17 – 09/25/18	
<b>TOTAL</b>	

ii. Formal Acceptance of Facility Projects

It is understood and agreed by the parties that renovation projects, alterations of facilities, construction (including Architect-Engineer (A&E) design), preventative maintenance and repair of facilities described in paragraph I. above require formal acceptance by the Contracting Officer prior to final payment.

jj. Approval of Press Releases

All press releases or other dealings with the press must first be approved by the Contracting Officer's Technical Representative. (Also, see Article H.35. Press Releases)

kk. Source Code and Object Code

All source code and object code developed, modified, and/or enhanced under this contract is the property of the Government. Upon termination or expiration of the contract, all such property shall remain in place at FNLCR unless a different disposition is directed by the Contracting Officer.

ll. Defrayment of Idle Facilities and Idle Capacity Costs

The Contractor shall strive to defray the cost of idle facilities and idle capacity as they are defined in FAR 31.205-17. This can be achieved by accepting work or grants from governmental organizations other than NCI or from private sources. The Contractor shall present a proposed course of action to the Contracting Officer before formally soliciting for non-NCI funding. All non-NCI sponsored projects require specific Contracting Officer approval before work is commenced.

mm. Reserved

nn. Steam Production Plants

It is understood and agreed that Steam Generation (North and South) plants constructed and operated by APS Cogeneration on behalf of its parent Potomac Edison, through the Energy Basic Ordering Agreement #97CXS0272A (Delivery Order NCI-2005-07), shall be operated by APS Cogeneration pursuant to its subcontract with the Contractor. It is further acknowledged and agreed that the NCI approval of the COA

dated February 22, 2007, provided NCI's acceptance that this project will be viewed as any other "maintained facility" on the NCI-FNLCR campus in accordance with the terms of this contract, and the Contractor assumes no additional liability beyond that provided for by the provisions of this contract, and for the willful misconduct or gross negligence of the Contractor. Remedies for plant failures are outlined in the Delivery Order modification to the Energy BOA identified above and the Feasibility Study proposal included therein. The Contractor has not acquired any additional insurance to cover losses of the steam facility or related losses due to the loss of steam to operating labs at the NCI Campus at Frederick.

oo. Vaccine Clinical Materials Program (VCMP)

The VCMP complies with U.S. Food and Drug Administration regulations as is appropriate to meet compliance-level requirements for each product manufactured. Projects intended for Phase I clinical trials are manufactured in accordance with the guideline, "Guidance for Industry – cGMP for Phase I Investigational Drugs (July 2008)". Products intended for Phase II and non-pivotal Phase III clinical trials are manufactured following those aspects of 21 CFR Part 211 that apply to investigational use products.

pp. Additional Award Fee Provisions

The Government and the Contractor agree as follows:

- For Year 1 of the contract the total available award fee pool will be comprised of an operational award fee pool of 80% of the available award fee pool, and an innovation award fee pool of 20% of the available award fee pool.
- For Years 2-10 of the contract 100% of the total available award fee pool will be dedicated to evaluation of the Contractor's performance as outlined in the Performance Based Award Fee Plan. The innovation award fee pool will no longer be employed for Years 2-10 of the contract.

Any changes to the Operational Award Fee and Innovation Award Fee Scale (Attachment 20) are subject to the bilateral agreement of the Government and the Contractor.

All other aspects and elements of the Performance Based Award Fee Plan may be changed unilaterally by the Government and are not subject to the bilateral agreement of the Government and the Contractor. The Government intends to provide written notice to the Contractor, at least 30 calendar days prior to the effective date of any unilateral changes to the Award Fee Plan.

qq. Non-severable Projects

The Government intends to fully fund specifically identified non-severable projects performed under this contract. Those projects are identified in Article G.10 and the Limitation of Cost clause identified in Article I.1 shall apply to them immediately upon their placement on the contract. All other contract work (excluding projects funded by royalties under 15 USC 3710c(a)(1)(B)) will be funded incrementally and the Estimated Cost – Incrementally Funded Contract clause identified in Article B.5 shall apply.

rr. OTS Contract Retirement Programs Modification

1. The two Retirement Programs sponsored by the Contractor exclusively for OTS Contractor employees of the Frederick National Laboratory for Cancer Research (FNL) incorporated by reference in the November 13, 2007 Business Proposal and subsequently described in their Final Proposal Revision dated July 14, 2008, is modified, as described below.
2. Retirement Program A is a Qualified Off-Set Arrangement authorized by the Tax Reform Act of 1986, Public Law 99-514, Special Rule for Qualified Off-Set Arrangements, Section 1116(f)(5). A colloquy to Public Law

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99-514 clarifies that the “employer”, in the case of individuals working at the FNLCR would be the facility itself, without regard to the particular contractor in charge of the facility operations. This definition of “employer” is only applicable to Retirement Program A. As a practical application of these statutes, NCI and Leidos Biomedical Research, Inc., as well as each predecessor contractor-operator since Retirement Program A’s establishment in 1986, have agreed, and acted accordingly, that the contractor would adopt and administer it on behalf of the facility.

As a Qualified Off-Set Arrangement, Retirement Program A consists of a Defined Benefit Retirement Plan (DB Plan) and a 401(k) Defined Contribution Plan (Old 401(k)). It was closed to new entrants effective July 1, 2006.

a. The following modification is agreed to:

- i. DB Plan: Effective on or about July 1, 2014, (i.e. the effective date) subject to such restrictions and modifications as may be necessary to satisfy the requirements of the Internal Revenue Code, benefit accruals will cease and be frozen for all participants, other than those who as of the effective date, either: (x) have attained age 55 and 10 years of service, or (y) have attained age 65 and 5 years of service (“Grandfathered Participants”).
- ii. Old 401(k): Effective on or about July 1, 2014 (i.e. the effective date), non-Grandfathered Participants per paragraph 2.a.i. will cease to be eligible to make or receive contributions under the Old 401(k). The matching contribution for Grandfathered Participants under the Old 401(k) will be eliminated; provided, however, that to the extent required by law certain Grandfathered Participants may continue to receive a matching contribution or an additional accrual under the DB Plan.

b. The modification of the DB Plan is not a “curtailment of benefits”, as that term is defined at CAS § 413-30(a)(7), because, subsequent to the modification of the DB Plan, material benefits will continue to accrue under this Plan.

c. It is the intent of the Government, as the plan employer, as that term is defined in the Colloquy to Public Law 99-514, and the Contractor, as the plan administrator pursuant to the terms of the Contract, that the DB Plan continue, the Contractor continue to administer the DB Plan and the government continue to reimburse all allowable DB Plan costs, including plan administration costs, during the term of the OTS Contract. Future benefit modifications or regulatory requirements, however, could arise during the term of the OTS Contract, with respect to the DB Plan that might cause a curtailment, as that term is defined at CAS § 413-30(a)(7), or a future segment closing, as that term is defined at CAS § 413-30(a)(20), might occur. In either circumstance, the Government and the Contractor will seek reasonable modifications to the DB Plan that will avoid a “plan curtailment” or will take reasonable actions to avoid a “segment closing”. Implementation of these reasonable modifications or actions will require the approval of the Government. However, if such reasonable modifications or actions are not available or, if available and not approved, the DB Plan will be handled in one of the following ways:

- i. A pension plan termination, as defined at CAS § 413-30(a)(20), will occur and the required adjustment of pension costs because of a pension plan termination will be measured, assigned and allocated in accordance with the requirements of CAS 413 applicable to a pension plan termination, with NCI’s share of the CAS 413 adjustment amount equaling 100 percent, or
- ii. A curtailment of benefits, as that term is defined at CAS 413.30(a)7), will occur and the required adjustment of pension costs because of a curtailment of benefits will be measured, assigned and

allocated in accordance with the requirements of CAS 413 applicable to a curtailment of benefits, with NCI's share of the CAS 413 adjustment amount equaling 100 percent. Subsequent to such a curtailment and through the date of plan termination, assumption of plan administration by a successor contractor or assumption of plan administration by the Government, the Government will reimburse the Contractor for all allowable yearly plan costs and all yearly plan administration costs. The categories of plan administrative costs post- curtailment would be the same as plan administrative costs before the curtailment with the exception that there would no longer be a cost associated with new benefit accruals.

iii. Other mutually agreeable manner permitted by law and regulation.

3. Retirement Program B is a 401(k) Defined Contribution Plan (New 401(k)). It is the sole retirement program available to OTS Contract employees who accepted an offer of employment on or after July 1, 2006. The following modification is agreed to:
  - a. New 401(k): Effective on or about July 1, 2014 (i.e. the effective date), non-Grandfathered Participants per paragraph 2.a.i. will participate in the New 401(k) on the same terms as other participants in the plan.
4. The Contractor has administered Retirement Programs A and B on behalf of NCI pursuant to requirements of the Contract, and for the exclusive benefit of OTS Contract employees of the FNL and will continue to do so during the term of the OTS Contract. However, the parties agree that after the term of the OTS Contract, the Contractor will no longer administer Retirement Programs A and B on behalf of the Government (the facility employer) or have any other responsibility for these two Retirement Programs whatsoever, absent written mutual agreement to the contrary, with the following sole exception: Notwithstanding a prior plan curtailment, Leidos Biomedical Research, Inc. shall transfer the assets and liabilities of the Retirement Programs A and B to a successor Contractor(s), Government-defined third party(ies), or the Government in accordance with Article H.2.a.(3)(a) or shall terminate the Plan in accordance with Article H.2.a.(3)(b).
5. The Government and the Contractor acknowledge that the OTS Contract, as an FFRDC, is the only final cost objective to which the cost of the Retirement Programs A and B is allocable. Thus, Leidos Research, Inc. contract entitlement is to be reimbursed for the costs of Retirement Programs A and B benefits and administering these Programs incurred through the end of the OTS Contract term, when these costs are measured, assigned and allocated in accordance with the Cost Accounting Standards ("CAS"). Moreover, under Article H.2. the Contractor is entitled to recover from NCI, as of the termination of Retirement Program A or B, or both (whether termination occurs prior to the end of OTS Contract performance, including the circumstances addressed in paragraph 2.c. above, or, as now agreed to, as of the time of the end of the term of the OTS Contract when no successor contractor adopts plan sponsorship, absent written mutual agreement not to terminate Retirement Program A or B at the end of the term of the OTS Contract), all unreimbursed benefit costs of, as well as all unreimbursed administrative costs related to, Retirement Programs A or B, or both. The Government and the Contractor intend under the terms of the OTS Contract, including this Advance Understanding, that the Government is responsible for, and the Contractor is to be reimbursed for, all costs that the Contractor incurs at any time relating to Retirement Programs A and B that are consistent with the terms of this Advance Understanding and do not violate Contractor's responsibilities under the Employee Retirement Income Security Act of 1974, as amended, or the Internal Revenue Code of 1986, as amended.
6. Annual Reporting: Leidos Biomedical Research, Inc. shall submit an annual report about the status of Retirement Programs A and B no later than August 1 of each year. The report shall provide an estimate of plan termination costs as of September 25 of the current Plan Year and information as of the end of most

recent Plan Year regarding the number of participants in each Program, the funding status of the Programs, and an assessment of regulatory or compliance issues that may arise based on participation levels, funding status, other comparable factors, or other data as directed by the Contracting Officer.

7. This Advance Understanding will remain in effect through final payment and closeout of the Contract unless terminated earlier by the mutual written agreement of the parties.

**ARTICLE B.5. ESTIMATED COST- INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-71(June 2010)**

- a. The total estimated cost to the Government for full performance of this contract, including all allowable direct and indirect costs, is **\$5,936,717,405**.
- b. The following represents the schedule\* by which the Government expects to allot funds to this contract:

<b>CLIN, Task, Number, or Description</b>	<b>Start Date of Period or Increment of Performance</b>	<b>End Date of Period or Increment of Performance</b>	<b>Estimated Cost (\$)</b>	<b>Available Award Fee (\$)</b>	<b>Estimated Cost Plus Award Fee (\$)</b>
See SOW	TBD	TBD	TBD	TBD	TBD

\*To be inserted after negotiation

- c. Total funds currently obligated and available for payment under this contract are **REDACTED**
- d. The Contracting Officer may issue unilateral modifications to obligate additional funds to the contract and make related changes to paragraphs b. and/or c., above.

Until this contract is fully funded, the requirements of the clause at FAR 52.232-22, Limitation of Funds, shall govern. Once the contract is fully funded, the requirements of the clause at FAR 52.232-20, Limitation of Cost, shall govern.

(End of Clause)

**SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**

**ARTICLE C.1. STATEMENT OF WORK**

Independently, and not as an agent of the Government, the Contractor shall, in accordance with the terms and conditions hereinafter set forth, exert its best efforts to furnish all personnel, materials, and equipment (other than those furnished by the Government as specified herein) necessary for performance of the work, as set forth in PART III, SECTION J., ATTACHMENT 1, STATEMENT OF WORK.

**ARTICLE C.2. REPORTING REQUIREMENTS**

- a. OPERATIONS AND TECHNICAL SUPPORT

The Contractor shall prepare and submit the following reports in the manner stated below:

- (1) Contract Performance Status Report - semi-annual - within 14 calendar days after the end of each contract year (September 25<sup>th</sup>) and within 14 calendar days after March 25<sup>th</sup> of each contract year.

(2) Annual/Final Technical/Management Reports

The Contractor shall submit an Annual Technical/Management Report documenting the progress/results of the Contractor's technical and management efforts during each year of the contract. The reports shall comprehensively explain the work performed and shall contain, as a portion thereof, a brief summary (not to exceed 200 words) of the salient accomplishments to date. Such reports are due 30 days following the end date of each contract year with the exception of the final year, in which case it will be due on the last day of the contract.

<b>Contract Year</b>	<b>Period</b>	<b>Due Date</b>
1	09/26/08 – 09/25/09	10/25/09 (Annual Report)
2	09/26/09 – 09/25/10	10/25/10 (Annual Report)
3	09/26/10 – 09/25/11	10/25/11 (Annual Report)
4	09/26/11 – 09/25/12	10/25/12 (Annual Report)
5	09/26/12 – 09/25/13	10/25/13 (Annual Report)
6	09/26/13 – 09/25/14	10/25/14 (Annual Report)
7	09/26/14 – 09/25/15	10/25/15 (Annual Report)
8	09/26/15 – 09/25/16	10/25/16 (Annual Report)
9	09/26/16 – 09/25/17	10/25/17 (Annual Report)
10	09/26/17 – 09/25/18	09/25/18

The Contractor shall submit a Final Technical/Management Report which includes a summation of the work and results/progress made during for the entire contract period of performance. A separate Annual Technical/Management Report will not be required for the period when the Final Technical/Management Report is due, however, the report should be separated into a section covering the final contract year which shall comprehensively describe the progress/results achieved during the period; and, a summary of the entire contract period of performance (there is no objection to using appropriately updated summary reports provided with the Annual Technical/Management Reports to fulfill this reporting requirement). Six (6) copies of both the annual and final reports shall be submitted to the Contracting Officer.

(3) For the BDP area only, the following reports shall be required:

- (a) Reports of Major Milestones for Individual Biopharmaceutical Projects - The Contractor shall retain a separate record of major milestones and documentation for each biopharmaceutical project. The Government may periodically request reports of milestone completions and documentation for a given month or months as a special report.

The list of major project milestones and documentation include: Project initiation; Preliminary cost, feasibility and timeline estimate; Project team meetings; Project costs

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and scheduling timelines (estimates and actuals) which shall be updated monthly; Receipt of clones and reagents; Technology transfer of process and assay methodology; Analytical profiles and certificates of analysis; Process methodology; Testing methodology; Validation studies; Batch production records; Clean room activities; Product purification, finishing and

vialing; QC testing of intermediate(s) and final product(s); CMC documentation; Release of product; Post-release testing; Audits; Incidents, deviations and failure investigations; Communications with IND holders; Communications and meetings with regulatory bodies; Inventories of all intermediate and final products, clones and cell banks, process and testing methodology, and documentation.

(b) After the first six (6) months of contract performance, the Contractor shall prepare an updated organizational plan to be submitted for review by the Assistant COR for the BDP.

(4) Reports of Shipment

The Contractor shall retain a record of shipments made during each month. The Government may periodically request reports of shipment for a given month or months as a special report.

(5) Annual Level of Effort Summary

Within thirty (30) days following the end of each annual contract period, the Contractor shall submit a report to the Contracting Officer summarizing the effort expended during such annual period. The effort categories shall be reported in terms of years and the labor disciplines shall correspond with those appearing in ARTICLE F.2. LEVEL OF EFFORT of this contract. The first such report shall encompass the time frame from September 26, 2008 through September 25, 2009. The final level of effort report is due at the time of submission of the Final Technical/Management Report.

(6) Overtime Report – This report will be due at the request of the COR and Contracting Officer.

(7) Incident Reports shall be accomplished upon occurrence of an act of vandalism, discovery of missing/stolen property (involving an estimated loss of Government or person property in excess of \$5,000), OSHA recordable work-related personal injuries, and vehicular accidents.

All incidents involving the loss of life, limb, or requiring hospital admission, or involving an estimated loss of Government or personal property in excess of \$5,000 will be reported to the Contracting Officer immediately (this may be verbally for incidents involving the loss of life, limb, or requiring immediate hospital admission, but must be followed by a written Incident Report within 15 days of OHS learning of the injury).

All OSHA-recordable work-related personal injuries shall be reported to the Contracting Officer within 15 days of the date the injured employee reports to OHS for care. Upon request by the Contracting Officer an Incident Report shall be submitted listing all non-OSHA recordable work-related personal injuries for the preceding contract year or other period specified.

(8) Reserved

(9) Lost Time Reports - All employee lost time will be reported to the Contracting Officer quarterly, or upon request.

(10) Core Services Price Increases

- (a) Reserved.
- b) Price Increases: OD—funded program areas. Requests for price increases for the upcoming fiscal year for any OD-funded Contractor program areas (FME, LASP, SPGM, CSP, and Repository) must be submitted to the COR by March 15<sup>th</sup> of the current contract year for review by the Office of Scientific Operations.

(11) Report on Adherence to Safety and Environmental Regulations

The Contractor shall provide a quarterly report on all deviations or discrepancies in Safety and Environmental Regulations as well as the status of all regulatory/licensing requirements as appropriate. The report shall be submitted to the Contracting Officer and COR on or before 10/01, 01/01, 04/01, and 07/01 (see also B.4.j.2.).

- (12) Reports of Alternative Sources - - The report of alternative sources is intended to evaluate cost effectiveness and efficiency in the use of contract resources. The Contractor selects the approach for completion of assigned activities based on cost but also available capacity and expertise; e.g., cell culture production and virus vector development. For the completed activities that allow a direct cost comparison the Contractor shall provide cost comparison reports between services provided within the Biopharmaceutical Development Program and those similar services provided from the commercial sector. Individual reports are to be provided periodically within 60 days from the completion of services to the Assistant COTR for Support to the Biological Resources Branch (BRB), DTP, DCTD, NCI.

- (13) Report on Adherence to cGMP Guidelines and Regulations - The Contractor shall provide a monthly report on all deviations from cGMP guidelines and regulations. The report shall be submitted to the Contracting Officer and BDP Assistant COR by the 15th day of the month following the period being reported. The Contractor shall make reports to the FNLCR BDP Quality Board on results of all audits (whether internal or external), failure investigations, and communications from regulatory bodies. Reports on other quality-related issues shall be submitted as required.

(14) List of Business Interests

Within thirty (30) calendar days after contract award, the Contractor shall furnish a complete listing of all businesses in which it has an ownership interest, including but not limited to affiliates and subsidiaries. The Contractor shall update the list as variances in business interests occur and furnish one (1) copy to the Contracting Officer.

- (15) Reserved.

(16) Table of Employee Distribution

The Contractor shall maintain a table setting forth the distribution of employees through the organization on an FNLCR WEB-site. The report should include the following elements: Division, Budgeted FTEs, current FTEs, and distribution breakdown into LOE categories. The table should also include an accounting of open/budget positions and an indication of which positions are actually being recruited. The WEB-site shall be kept up-to-date at least weekly or more frequently and the date of up-date should be shown on the WEB-site.

Information related to names, salaries, hirings and terminations will not be placed on the above-referenced WEB-site. This information will be provided to the Contracting Officer on an as-needed basis.

(17) Staffing Plan

At the request of NCI, the Contractor shall provide, within the requested timeframe, a schedule including, but not limited to, the distribution/organization of all employees, their present grade/step, salary, and date of eligibility for next increase.

Information related to names, salaries, hirings and terminations will not be placed on the above-referenced WEB-site. This information will be provided to the Contracting Officer on an as-needed basis.

(18) Space Reports

The Contractor shall provide one (1) copy of a bi-annual space report to the NCI Contracting Officer and one (1) copy to the COR. The first report will be due on March 26, 2009. The format and content shall be stipulated by the FNLCR Project and Contracting Officer.

(19) Financial/Management Reports:

- (a) Cost Status Reports (CSR) shall be WEB-based and be kept up-to-date on a daily workday basis, i.e. the report shall be posted on the WEB-site at the end of each work day. The report shall include items which may be changed periodically by the Contracting Officer, as deemed necessary.

The report shall include the following information for each item: Account Number; Account Description; Actuals; Commitments; Encumbrances; Total Cost; Total Budget; and, Variance.

(b) Funding versus Cost Analysis Report:

After each quarterly contract funding modification, the Contractor shall provide to the Assistant COR for Financial Analysis and the Contracting Officer, a funding vs cost analysis for each NCI Division/Center and other major NIH Institutes/Centers. These reports shall be due May 1, August 1, November 1, and February 1.

(c) Initial Detailed Operating Budget and Capital Equipment List

Within thirty (30) days following contract award, the Contractor shall review the Final Annual Detailed Budget prepared by its predecessor (if applicable) and submit to the Contracting Officer any suggested revisions for approval. Given the NCI budget planning and approval cycle, any revisions must be within the previously determined total budget amount.

Until the Contractor is notified that the budget is approved, a level budget (i.e. expenditure of funds at the same level of the previous year or other direction based on information from the Division Administrative Officer) shall apply.

(d) Annual Detailed Budget from Year 2 through Contract Termination:

**Contract Number: HHSN261200800001E**  
**NCI Control Number: N01-CO-2008-00001**

The Contractor shall submit a full draft of the Annual Detailed Budget for each additional contract year, after the initial contract year, by September 1<sup>st</sup> and a Final Proposed Annual Detailed Budget after discussion and meetings between NCI and Leidos Biomedical Research, Inc. staff. Draft and Final Proposed Annual Detail Budgets shall be submitted in six (6) hard copies or DVDs per NCI's instructions, plus one (1) electronic submission of the entire document, including supporting material. Such budgets shall follow a format acceptable to the Contracting Officer, and will serve as a basis for the additional allocation of funds under this contract, pursuant to the attached clause entitled "LIMITATION OF FUNDS". All such budgets shall be subject to the approval of the Contracting Officer.

Until the Contractor is notified that the budget is approved, a level budget (i.e. expenditure of funds at the same level of the previous year or other direction based on information from the Division Administrative Officer) shall apply.

Subsequent to the approval of the annual operating budget, the Contractor shall provide to the COR and Contracting Officer a quarterly accounting of open positions and the unexpended funds resulting from these positions.

(e) Contract Year Estimate-to-Complete

A report setting forth the Contractor's "estimate-to-complete" shall be submitted each contract year by February 14<sup>th</sup>. The report shall provide a breakdown following the format of the Cost Status Report under Financial/Management Reports described in Article C.2. and shall set forth the costs to date and the estimated costs to be incurred through September 25<sup>th</sup> of the previous year. A prioritized list of projects/equipment purchases, against which any excess funding could be used, shall be provided by the Contractor.

(f) AIDS Cost Report

The Contractor shall submit, on the dates delineated below, an AIDS obligations report (breakdown of expenditures for OD-Frederick-funded AIDS Projects). The report shall be provided to the Assistant COR for Financial Analysis on January 5<sup>th</sup>, April 5<sup>th</sup>, July 5<sup>th</sup>, and October 5<sup>th</sup>.

(g) Subcontracting Report

In addition to the Subcontracting Reports required under Article H.29., Subcontracting Provisions, the Contractor shall provide to the Contracting Officer a separate subcontracting reports by no later than October 15 (covering the period from April 1 through September 30, except for the last year of the contract which ends on September 25) and April 15 (covering the period from October 1 through March 31). Such reports shall provide information similar to that provided in the Subcontracting Report for Individual Contracts, SF-294. Additionally, the Contractor shall state whether the goals were met for each small business area where goals have been established. In cases where goals were not met, provide an explanation and describe corrective action to be taken to assure that goal(s) will be accomplished by contract completion.

(20) Steam Meter Readings

The Contractor shall retain a record of readings from steam metering equipment of the NCI Campus at Frederick. Minimum information to be retained shall include identification of each

meter/location, previous month's meter reading, current reading, date of reading, consumption for the month, and year to date consumption.

(21) Report of Deviations to Patents and Data Clauses

The Contractor shall provide a bi-annual report on October 15<sup>th</sup> and April 15<sup>th</sup> identifying all subcontracts which the Contractor included (after the Government provides notification of DEC and/or deviated clause approval) a clause which deviates from FAR Clause 52.227-11, 52.227-14, and/or 52.227-17. The report shall include the subcontract number, name of subcontractor, name of program and requester for which the subcontract was prepared, reason for need to deviate, and an extract of the

language from the subcontract in which the subcontractor has agreed to accept a future deviated clause, or, the actual deviated clause (or title of deviated clause) included in the subcontract. One copy of the report shall be submitted to the Contracting Officer and one copy shall be submitted to the COR for Intellectual Property.

(22) List of Off-Site Employees

The Contractor shall provide, as requested, one (1) copy of a report to the FNLCR Contracting Officer of all Contractor employees assigned to any of the off-site locations. The report shall include the name of the area to which assigned, name of employee, title, lab/department, location, phone number, supervisor and phone number, and Division.

(23) Source Code and Object Code

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

(24) Contractor Goals and Objectives Statement - semi-annually working draft submitted no later than two (2) weeks prior to the start of the current evaluation period, revised document (if necessary) submitted within five (5) calendar days of receipt of Contracting Officer comments, and final within two weeks after receipt of additions/revisions from the Government.

(25) Reserved.

(26) DCEG-Specific Projects

On the 15<sup>th</sup> of each month following the closing of each quarter, i.e., January 15<sup>th</sup>, April 15<sup>th</sup>, July 15<sup>th</sup>, and October 15<sup>th</sup>, the Contractor shall submit a quarterly report on DCEG-specific projects. The report is to be delivered to Ms. Marianne Henderson, Chief, Office of Division Operations and Analysis, DCEG, Room 7E424, 9609 Medical Center Drive, Rockville, Md. 20850. This report shall cover applicable reporting requirements under this provision for this contract.

(27) Invoice Processing

The Contractor shall submit a written report on October 15<sup>th</sup> of each year, based on funding through the prior fiscal year, which provides the balance of remaining funds that are over three years old. For example, the October 15, 2008 report will provide a balance of funding for years prior to 2006. This report shall be submitted to the OSO Finance and the Contracting Officer.

(28) Budget Submissions

The Contracting Officer shall be provided with copies of all budget submissions. In addition, all budget revisions requested by the Division Administrative Officers will be forwarded to the Contracting Officer on a quarterly basis.

29) Miscellaneous

The Contractor shall submit such other reports, in the time frames specified, pertaining to the contract effort as may be requested by the Contracting Officer or his duly authorized representatives.

(30) Reserved

(31) Electronic reports shall be submitted in accordance with the requirements outlined in the Electronic contract Reporting Requirements Summary, found in Attachment 18 to the Contract.

(32) Reporting of Financial Conflict of Interest (FCOI)

All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in Electronic format. Thereafter, reports shall be due in accordance with the regulatory compliance requirements in 45 CFR Part 94.

45 CFR Part 94 is available at: <http://ecfr.gpoaccess.gov/cgi/t/text/text-dx?c=ecfr&rgn=div5&view=text&node=45:1.0.1.1.52&idno=45> . See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

(Reference ARTICLE H.48., (paragraph g), INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST in SECTION H of this contract.)

(33) All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

Unless otherwise specified, submissions shall be directed to the Contracting Officer or the COR as indicated above at the following addresses:

Mr. Stephen Davis  
Contracting Officer  
FNLCR  
Building 427, Room 10

Frederick, Maryland 21702-1201

Dr. Craig Reynolds  
COR  
FNLCR  
Building 427, Room 8

Frederick, Maryland 21702-1201

**ARTICLE C.3. INVENTION REPORTING REQUIREMENT**

All reports and documentation required by FAR Clause 52.227-11 (or deviation thereof), including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be

directed to the Division of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, a copy of the annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract. The first annual utilization report shall be due on or before October 6, 2009. Thereafter, reports shall be due on or before the tenth working day following the reporting period. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer, National Institutes of Health  
National Cancer Institute  
NCI Campus at Frederick  
Building 427, Room 10  
Frederick, Maryland 21702-1201

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (<http://www.iedison.gov>), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

#### **SECTION D - PACKAGING, MARKING AND SHIPPING**

Packaging, marking and shipping shall be accomplished in accordance with FNLCR Policy and Procedures.

#### **SECTION E - INSPECTION AND ACCEPTANCE**

Inspection and acceptance shall be performed at the FNLCR, Frederick, Maryland, by the Project Officer/Contracting Officer for those items required under reporting requirements set forth in PART I, SECTION C., ARTICLE C.2., REPORTING REQUIREMENTS.

- a. 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**

- a. The base period of performance of this contract shall be from September 26, 2008 through September 25, 2018.
- b. Should the Contractor fail to succeed itself as a result of recompetition, or for other reason, the Contractor hereby agrees to an extended period of not less than thirty (30) days within the context of ARTICLE H.2., CONTINUITY OF SERVICES.

**ARTICLE F.2. LEVEL OF EFFORT**

- a. In accomplishing the work set forth in the OTS contract, the Contractor agrees to provide an estimated 21,992 labor years during the periods defined below. The labor years include all paid absences. The labor years are as follows:

<b>Labor Category</b>	<b>Contract Year (CY) 1</b>	<b>CY 2</b>	<b>CY 3</b>	<b>CY 4</b>	<b>CY 5</b>
Key Personnel	6.00	6.00	6.00	6.00	6.00
Other Professional	581.19	602.19	623.19	644.19	665.19
Scientific Tech Support	568.93	583.93	598.93	613.93	628.93
Other Support	773.08	797.08	821.08	845.08	869.08
<b>TOTAL</b>	<b>1929.20</b>	<b>1989.20</b>	<b>2049.20</b>	<b>2109.20</b>	<b>2169.20</b>

<b>Labor Category</b>	<b>CY 6</b>	<b>CY 7</b>	<b>CY 8</b>	<b>CY 9</b>	<b>CY 10</b>
Key Personnel	6.00	6.00	6.00	6.00	6.00
Other Professional	686.19	707.19	728.19	749.19	770.19
Scientific Tech Support	643.93	658.93	673.93	688.93	703.93
Other Support	893.08	917.08	941.08	965.08	989.08
<b>TOTAL</b>	<b>2,229.20</b>	<b>2,289.20</b>	<b>2,349.20</b>	<b>2,409.20</b>	<b>2,469.20</b>

- b. A labor year shall constitute 100% of a given employee's time. For example, an employee counted as a full time equivalent (FTE) shall give 100% of his/her time to the performance of these contracts, regardless of whether such employee works more than 40 hours per week.
- c. For the contract period, the Contractor shall have satisfied the requirements herein if it furnishes not less than 85% nor more than 115% of the total direct labor years specified herein, or the equivalent value thereof as determined by the Contracting Officer, and the Contractor has otherwise met all other terms and conditions of the contract.
- d. The Contractor shall promptly notify the Contracting Officer at any time it anticipates non-compliance with this Article. Such notification shall explain the reason(s) therefore, and, where possible, recommend action(s) to resolve the non-compliance, regardless if such is attributable to the Contractor, the Government, or other sources.

**ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)**

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSES:

52.242-15, Stop-Work Order (Aug1989) with Alternate I (April 1984)

52.247-35, F.o.b. Destination Within Consignees Premises (April 1984).

**SECTION G - CONTRACT ADMINISTRATION DATA**

**ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)/ASSISTANT AND ALTERNATE CORs)**

- a. The following CORs/Alternate and Assistant (CORs) will represent the Government for the purposes of this contract:

<u>Name</u>	<u>Areas of Responsibility</u>
Dr. Craig Reynolds	COR
Dr. Kristin L. Komschlies	Alternate COR Technical and Scientific Support.
Vacant	Assistant COR for Financial Analysis.
Dr. Sara Hook	Assistant COR for the Cancer Research Technology Program
Dr. Janelle Cortner	Assistant COR for CCR Basic Research.
Dr. Karen E. Pitt	Assistant COR for Support to DCEG.
Dr. Stephen P. Creekmore	Assistant COR for Support to the Biological Resources Branch (BRB), DTP, DCTD, NCI.
Ms. Linda Blumenauer	Assistant COR for Support to the Biological Testing Branch (BTB), DTP, DCTD, NCI, including <i>in vivo</i> models, animal production and repositories.
Ms. Julie Metcalf	Assistant COR for Support to the National Institute of Allergy and Infectious Diseases (NIAID), NIH, Clinical Research.
Dr. Richard Schwartz	Assistant COR for Support to the Vaccine Research Center, NIAID, NIH.
Ms. Laura McNay	Assistant COR for Clinical Trials Support for NIAID
Dr. Daniela S. Gerhard	Assistant COR for the Office of Cancer Genomics
Dr. Piotr Grodzinski	Assistant COR for the Nanocharacterization Laboratory
Dr. Jeffrey Thomas	Assistant COR for Intellectual Property
Mr. Frank Bell	Assistant COR for Facilities Maintenance and Engineering
Mr. Sam Denny	Assistant COR for Environment, Health and Safety
Dr. Walter Hubert	Assistant COR for the Advanced Biomedical Computing Center and the Advanced Technology Partnerships Initiative
Ms. Dianna Kelly	Assistant COR for Information Systems

- b. The COR 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.
- c. 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 for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.
- d. The Assistant CORs are responsible for the above-described functions for those areas of responsibility set forth above.
- e. The Government may unilaterally change the COR/Assistant COR designations.

- f. Detailed delineation of the duties of the COR is contained in ARTICLE H.1. - AUTHORITIES AND RESPONSIBILITIES OF THE PRINCIPAL PARTIES TO THIS CONTRACT.

**ARTICLE G.2. KEY PERSONNEL, HHSAR 352.242-70 (Jan 2006)**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individual(s) is/are considered to be essential to the work being performed hereunder:

<u>NAME</u>	<u>TITLE</u>
	President
	Chief Science Officer
	Chief Medical Officer
	Chief Operating Officer (Interim)

**ARTICLE G.3. PROPERTY ADMINISTRATOR**

The Property Administrator for this contract is the MOSB Contracting Officer, who is located in Building 428, NCI Campus at Frederick.

**ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST**

- a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR 32.9, Prompt Payment.
1. Payment requests shall be submitted as follows:
    - (a) An electronic copy in either Adobe Portable Document Form (PDF) or Microsoft Excel (.xls and .xlsx) uploaded to [ncibranchdinvoices@mail.nih.gov](mailto:ncibranchdinvoices@mail.nih.gov). Subject line of the e-mail shall read: "Deliverable\_HHSN261200800001E\_Leidos\_Invoice.X\_2014".
    - (b) an original to the following designated billing office:

National Institutes of Health  
Office of Financial Management  
Commercial Accounts  
2115 East Jefferson Street, Room 4B-432, MSC 8500  
Bethesda, MD 20892-8500
  - (b) One hard copy to the approving official:

Contracting Officer, National Institutes of Health

**Contract Number: HHSN261200800001E**  
**NCI Control Number: N01-CO-2008-00001**

National Cancer Institute at Frederick  
Building 427, Room 10  
Frederick, Maryland 21702-1201

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:
  - (a) Name of the Office of Acquisitions. For the purpose of this contract, the Office of Acquisitions is **NCI Office of Acquisitions**
  - (b) Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is: **NCI Branch D Invoices**.
  - (c) Vendor Identification Number: This is the 7-digit number that appears after the Contractor's name in Block 7 of Standard Form 26, i.e., **1107088**.
  - (d) DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract, and as registered in SAM.gov.
  - (e) This contract requires a **Two-Way Match**
- b. Inquiries regarding payment shall be directed to the designated billing office, (301) 496-6452.
- c. Number, content, and date for payment of invoices:

The OTS Contractor is authorized to prepare up to three (3) invoices/financing requests per month each for: 1) appropriated funds expenditures; and 2) American Recovery and Reinvestment Act funds as follows:

1. Financing requests will be prepared approximately every 14 days to include the costs incurred and paid for through the Special Bank Account for all contract related costs (inclusive of labor, fringe benefits, materials and supplies, travel, equipment, G&A, fee, and other direct costs). These financing requests will be prepared by the Contractor and submitted to the addresses listed in a.2.(a) and (b) above. The Contractor shall have an authorized signatory on site for this purpose. The payment of the financing requests will be assigned to the Special Bank Account established by the Contractor for liquidating the obligations of these costs.
  2. The date for payment under this contract is twenty (20) calendar days after the date of receipt, in the office designated in a.(1) above, of a correct and properly documented invoice/financing request.
- d. In lieu of submission of a financing request, a Completion/Final Invoice shall be submitted promptly upon completion of the work.
  - e. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in ARTICLE H.31. of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract."

**ARTICLE G.5. INDIRECT COST RATES**

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

Contracting Officer  
Management Operations & Support Branch  
NCI Campus at Frederick  
Building 428, Room 59  
Frederick, Maryland 21702-1201

**ARTICLE G.6. GOVERNMENT PROPERTY**

a. General

In addition to the requirements of Clause 52.245-1 - GOVERNMENT PROPERTY of the General Provisions, the Contractor shall comply with the provisions of the DHHS Publication entitled, "HHS Contracting Guide for Contract of Government Property" (hereinafter called the "Guide"), which is incorporated into this contract by reference. This document can be accessed at:

[http://ncioa.cancer.gov/oa-internet/reference/Appendix\\_Q\\_HHS\\_Contracting\\_Guide-508.pdf](http://ncioa.cancer.gov/oa-internet/reference/Appendix_Q_HHS_Contracting_Guide-508.pdf)

The Guide is modified for purposes of FNLCR as follows:

The Contractor is required to provide a biennial inventory as set forth in the Guide and other periodic inventories as requested by the MOSB Property Administrator. The first biennial inventory shall begin with Fiscal Year 2010 and shall be provided by November 30 every two years thereafter.

Notwithstanding the above, the final authority for Government property accountable under this contract shall vest with the Contracting Officer.

b. Contractor-Acquired Government Capital Equipment

- (1) The Contractor shall screen all existing NIH and NCI Campus at Frederick excess property prior to any capital equipment acquisitions. All new capital equipment is hereby incorporated into the contract by reference.
- (2) The Contractor is hereby authorized to credit the proceeds of any sale of contractor inventory to the price or cost of the work covered by this contract. The gross proceeds from the sale of such property shall be deposited to the FNLCR Special Bank Account.

c. Government-Furnished Property

- (1) Additionally, pursuant to Clause No. 52.245-1 - GOVERNMENT PROPERTY of the General Provisions, the Contractor is hereby given custody of the property listed as of 9/26/08 on the Operations and Technical Support Contract decaled equipment list as well as all other non-decaled property for which the Contractor is responsible for use in direct performance of the contract. Accountability for the items shown on the referenced decaled equipment list and located in the Contractor's areas of responsibility is hereby transferred to this contract from the predecessor contract(s), under which these items were provided by the Government. It is understood that this property is transferred without confirming audit by the contractor. At such time as a confirming audit is performed, the contractor will recommend appropriate adjustment to the contract for any inventory discrepancies identified. Any additional equipment purchased for use under this

contract will automatically be considered contractor acquired Government property at the time it is added to the list of capital equipment in possession of the Contractor.

- (2) By November 30<sup>th</sup> of each contract year, The Contractor agrees to forward to the Contracting Officer four (4) copies of the capital equipment list covering all government furnished property and property acquired for use in the performance of this contract, as provided by the Government Property clause and the instructions contained in the "HHS Contracting Guide for Contract of Government Property" issued in 2007. This report is required to be submitted under this contract and must identify under which contract the property was acquired.
- (3) The OTS Contractor's Property Department shall provide any needed guidance to the co-located NCI-Frederick contractors pertaining to preparation and submission of the list. Title to this property shall remain vested in the Government.

**ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

a. Contractor Performance Evaluations:

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, one interim evaluation will be prepared annually, beginning September 2011.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

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

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

<https://www.cpars.gov>

**ARTICLE G.8. CONTRACTING OFFICER'S REPRESENTATIVE (CORs) FOR INTELLECTUAL PROPERTY**

The Contracting Officer's Technical Representative (CORs) for review and approval of intellectual property (see ARTICLE H.1.(e)) are:

Jeffrey Thomas, Ph.D.  
Senior Advisor  
Technology Transfer Center (TTC)  
8490 Progress Drive  
Riverside 5, Room 4050  
Frederick, Maryland 21701  
Telephone: 301-624-8775

**ARTICLE G.9. "AUTHORITY HAVING JURISDICTION", FREDERICK NATIONAL LABORATORY**

The current Authority Having Jurisdiction for Fire Protection and Life Safety for the FNLCR is:

The NIH Fire Marshal, Division of Fire Marshal (DFM)

As defined in NIH Policy Manual Chapter 1370 (Release Date: 08/16/2013) Fire Protection and Life Safety Building Permit Process, the Authority Having Jurisdiction is responsible for, as quoted in Manual Chapter 1370: "Proper fire protection and life safety in ensured in construction projects, renovations or major equipment installations through oversight by the local fire safety Authority Having Jurisdiction (AHJ) at various stages of the project. The NIH Division of Fire Marshal (DFM) Office of Security and Emergency Response (SER), Office of Research Services (ORS), as the designated AHJ for all fire-safety matters at the NIH, accomplishes this mission through: (1) design reviews, (2) fire protection construction submittal reviews and (3) construction inspections, both in-progress and at the completion of the project." Any questions or clarifications regarding fire and life safety shall be addressed to the Authority Having Jurisdiction.

The contractor, in consultation with the COR, is responsible for matters exclusive of fire and life safety (e.g. interpretations and applications of National Electrical Code, State/Local Building Codes, NIH Design Requirements Manual, etc.).

**ARTICLE G.10., ACCOUNTING and APPROPRIATION DATA IDENTIFICATION ON INVOICE SUBMITTAL**

The contractor agrees to add the CAN/Accounting and appropriation data (to work invoiced under the contract as specified below.

<p align="center"><b>Period of Funds Availability for Severable Projects</b></p> <p align="center">(Funds may be expended against associated severable work under this contract for up to 12 months after the effective date of this modification and may be billed against commitments made within that 12 month period until expended)</p>	<p align="center"><b>Period of Funds Availability for Non-Severable Projects</b></p> <p align="center">(Funds may be expended against associated non-severable work under this contract from the effective date of this modification until the "End Date" listed on the CAN page(s) list and may be billed against commitments until expended)</p>	<p align="center"><b>CAN/Accounting and Appropriation Data</b></p> <p align="center">(See CAN page(s) list for this modification)</p>

The Contractor shall include the above information on all invoices submitted as of the date of this modification. Invoices must identify the proper accounting and appropriation data to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

**SECTION H - SPECIAL CONTRACT REQUIREMENTS**

**ARTICLE H.1. AUTHORITIES AND RESPONSIBILITIES OF THE PRINCIPAL PARTIES TO THIS CONTRACT**

The contract principal parties are as follows:

- a. COR, OSO
- b. Contractor
- c. Contracting Officer, MOSB
- d. Property Administrator, MOSB
- e. Contracting Officer's Representative (COR) for Intellectual Property, NCI-TTB
- f. Reserved

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None of the subsequent statements diminish the authorities and responsibilities reserved by law, regulation and/or Executive Order, to the Contracting Officer.

a. COR, OSO

- (1) Serves as the senior technical point of contact in residence at NCI Campus at Frederick;
- (2) Is responsible for establishing requirements;
- (3) Delegates responsibilities to the Assistant CORs as appropriate;
- (4) Coordinates space management at the NCI Campus at Frederick;
- (5) Monitors the utilization of Contractor resources and their allocation in accordance with NCI priorities, and assists in the resolution of differences among ICD's interests;
- (6) Together with the Contracting Officer, prepares the Performance Based Award Fee Evaluation Plan;
- (7) Monitors the Contractor's technical progress and reports significant performance deficiencies to the C.O.; and,
- (8) Performs technical inspections and acceptances, as required.

b. Contractor

- (1) Accomplishes contract work statement in accordance with the terms and conditions of the contract.
- (2) Communicates with the COR concerning technical/scientific matters.
- (3) Directs to the Contracting Officer all non-technical/scientific matters requiring interface with the U.S. Army, other contractors, or with NCI/NIH personnel at NCI Campus at Frederick; as well as all business management recommendations, etc. that will improve Contract performance.
- (4) Directs to the Contracting Officer all business management matters.
- (5) Directs to the Contracting Officer all written communications requiring approval under the contract.

c. Contracting Officer, MOSB

- (1) Serves as exclusive agent for the purpose of negotiation, award and administration for all contract and intra/interagency matters between NCI, the Contractor, the U.S. Army, and other Government entities as necessary, in accordance with the Federal Acquisition Regulations.
- (2) Is solely responsible for obtaining legal input related to the contract, and intra/interagency agreements.
- (3) Acquires cost data and cost analysis information associated with this contract, and any intra/interagency agreements.
- (4) Is the exclusive authority for all business matters, to include all overhead-type matters.

d. Property Administrator, MOSB

- (1) Administers the contract requirements and obligations related to government property and is responsible for all property administration functions from acquisition of the property to final disposition.

- (2) Coordinates property issues with the COR and Contracting Officer.
- (3) Reviews and approves the property control system and notifies the contractor when the property control system does not meet DHHS requirements.

e. Contracting Officer's Representatives (COR) for Intellectual Property, NCI-TTB

Subject to the terms and conditions of this contract, the COR(s) review and approve/disapprove issues associated with intellectual property including unmodified and modified Material Transfer Agreements (MTAs), Simple Letter Agreements for Material Transfer, Confidential Disclosure Agreements (CDAs), and Uniform Biological Materials Transfer Agreements (UBMTAs). Additionally, only Dr. Stackhouse shall review and approve CRADAs as provided for in this contract. See Articles G.8 and H.16.

f. Reserved

**ARTICLE H.2. CONTINUITY OF SERVICES**

- a. In recognition of the fact that the functions covered under this contract are in support of NCI programs, and require uninterrupted performance; that upon expiration of this contract, the services hereunder may be provided by a successor Contractor and any successor will require phase-in training; that the retention of personnel experienced in the work covered hereunder by any successor is important to the Government; and that a successor's ability to retain such personnel may be significantly enhanced if such personnel can remain without unreasonable loss of earned fringe benefits; the Contractor agrees as follows:
- (1) To provide, as an allowable cost, the necessary resources to complete those work items commenced during the period of this contract or any renewal thereof, which would not otherwise have been completed within such a period;
  - (2) To provide phase-in, phase-out services for a period not less than thirty (30) days, and up to the period of time set forth in FAR 52.237-3(b), commencing the day after expiration of the contract, to the extent required by the Government, and expeditiously negotiate an equitable adjustment to the estimated cost of the contract for such services, to be provided by continuing the assignment of qualified personnel then currently assigned to the contract.
  - (3) The Contractor shall transfer to any successor Contractor(s) all accrued employment benefits, both vested and non-vested, and, where applicable and as discussed below, the funds accrued for those benefits and any personnel data for those incumbent employees who become employees of the successor Contractor. This transfer shall include, but not necessarily be limited to, all accrued sick leave, vacation, pension benefits, and other employee-related benefits and data as may be required to provide for the uninterrupted accrual and administration of the employees' personnel and fringe benefits program.

Vacation Benefits: The Contractor shall transfer funds to the successor Contractor(s) in an amount equal to the dollar value of the accrued vacation liability assumed by the successor Contractor(s).

Retirement Programs:

- (a) In the event there is a successor Contractor: The successor Contractor shall adopt, as plan sponsor and employer, the OTS Contract Employee Savings Plan and the defined benefit Retirement Plan and the Leidos Biomedical 401(k) Plan (*the "Plans"*). The successor Contractor shall also assume sponsorship of the Plans' respective Trusts and assets. The successor Contractor shall become solely responsible for any and all obligations to participants in the Plans as a result of the transfer in total to the successor Contractor of assets and liabilities of the Plans

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In regard to Cost Accounting Standards (CAS), Sections 412 and 413, any CAS pre-payment credit shall be returned to the predecessor Contractor by the successor Contractor; and any amount the predecessor Contractor accumulated in accordance with 48 CFR 9904.412-50(a)(2) shall be payable by the predecessor Contractor to the successor Contractor in a timely manner. As described in Section 1116(f)(5) of the Tax Reform Act of 1986, Public Law 99-514, Special Rule for Qualified Offset Arrangements, the employer is the FNLCR.

The amount of pension liability shall be based on the most recent actuarial calculation completed by the plan actuary. The amount of the assets that shall be transferred by the Contractor to the successor Contractor shall equal the assets in the Plans' respective Trusts. The Government shall approve assets and liabilities as being properly calculated in compliance with applicable Cost Accounting Standards.

The Government shall include in any successor contract such terms and conditions as are needed to give this Article H.2.a.(3) full force and effect.

- (b) In the event there is not a successor Plan Sponsor: At the end of this contract, if the contract is not extended or renewed and there is no successor contract or a successor Contractor is not required to assume Sponsorship of the Plans, or upon a "segment closing", a plan "termination" or a plan "curtailment," as these three terms are defined in Cost Accounting Standard 413, this Standard shall determine the requirements for measuring, assigning and, allocating pension costs. The Government and the Contractor acknowledge that as an FFRDC, the Contractor has only one objective which is to operate the FFRDC; therefore, when the contractor is required to measure, assign and allocate an adjustment amount, the government's participation level is expected to be 100%.

- b. Furthermore, the parties recognize that due to the long-term nature of the FFRDC's research mission, there may be activities, including acquisitions, initiated under the current contract that will extend into the term of a successor contract. Examples of these activities include i) agreements such a Cooperative Research and Development Agreements (CRADAs), ii) subcontracts for alterations, renovations, and research support services, and iii) cGMP quality biopharmaceutical products manufactured under the current contract that will be used in clinical studies during the term of the successor contract. Accordingly, the following conditions will apply under this contract and will be included as a requirement in any Request for Proposal for a successor contract:

- The phase-in support services referred to in this Article shall apply to the situations described above and other comparable OTS contract activities that will continue under a successor contract.
- The successor contractor shall maintain a Medical Products Liability Insurance program that includes the predecessor Contractor as a named insured and provides a comparable level of coverage and protection as that which is in effect under the current OTS contract and meets the conditions or Article B.4.r., Product Liability Insurance and Licensing.
- The successor OTS contractor shall assume responsibility for bringing acquisitions initiated by the predecessor Contractor to an orderly conclusion.

- c. Within thirty (30) days after contract award by the Government to a successor contractor, the current Contractor shall jointly prepare with said successor a mutually agreeable plan for phase-in, phase-out operations. The plan shall set forth in detail the training program for the successor with a proposed date by which the successor will assume responsibility for work performance. Prior to said date the current Contractor shall retain full responsibility for work performed. Upon request, this plan shall be submitted to the NCI Contracting Officer for approval.

- d. This plan shall include all LBR employee payrolls, health benefits, pension plans, etc.
- e. The Contractor shall transfer to any successor Contractor(s) all non-proprietary or privileged internally and externally generated technical, business, financial, administrative, and engineering manuals, user guides, documentation, studies, reports, patent applications, business records, Standard Procedures (SPs), Standard Operating Procedures (SOPs), produced and paid for under this Contract or acquired by the Contractor from any predecessor Contractor of this FFRDC. This requirement will cover both physical and electronic media. The Contractor also agrees to make all of the above available for review by the Contracting Officer upon request.

**ARTICLE H.3. INTERFACE WITH OTHER NCI CAMPUS AT FREDERICK CONTRACTORS AND THE GOVERNMENT**

- a. The Contracting Officer shall be the focal point for all interface matters concerning the NCI Campus at Frederick. This includes interface between Contractors, and between Contractors and the Government, both individually and collectively.
- b. All Contractor employees for each Contractor shall, in all communications (both internal and external to NCI Campus at Frederick), include as a part of his/her title, the name of his/her employer. This requirement covers all dissemination and/or publication of information, in written or oral form, generated in part or in whole, as a result of funds expended in support of this contract. Regardless of the source of funds, all individuals employed under this contract who purport to represent their affiliation with the NCI Campus at Frederick, must also include the name of their employer as part of that representation.
- c. The Contractor agrees to have its Principal Investigator, and other staff as appropriate, participate in meetings/conferences called by the Contracting Officer or COR, FNLCR. It is understood that there may be some meetings/conferences which may take place at locations other than the NCI Campus at Frederick.
- d. It is anticipated that Policies and Procedures involving interface between contract areas will be formulated through discussions with the various NCI Campus at Frederick Contractors and intramural laboratories, as appropriate. All new or revised proposed Policies and Procedures shall be prepared and submitted by the OTS contractor as directed by the Contracting Officer. Final approval of Policies and Procedures shall be by the Contracting Officer.

**ARTICLE H.4. OPERATIONS AND TECHNICAL SUPPORT RESPONSIBILITY**

Notwithstanding any other terms, provisions and conditions of this contract, the Contractor shall be responsible for providing technical/administrative support as delineated in the Statement of Work and for maintaining the buildings and facilities as delineated in Attachment 19, entitled LISTING OF BUILDING RESPONSIBILITY, for this contract, as well as all other Government contracts collocated at the NCI Campus at Frederick, except for those services provided by the U.S. Army through its Interagency Agreement with NCI.

**ARTICLE H.5. HUMAN SUBJECTS**

Some research activities conducted hereunder require participation of human subjects or the use of human source materials. These research activities must be conducted in accordance with the guidelines set out under the Contractor's Federal-wide Assurance (FWA) which assures compliance with DHHS regulations detailed in 45 CFR Part 46. The Contractor shall observe the requirements specified in the FWA in effect during the term of the contract. Written notice of the IRB protocol approval or exemption determination, and any changes thereto by the IRB must be provided by the NCI-Frederick Contracting Officer. Failure to comply with this requirement shall result in the implementation of corrective procedures, including the possibility of termination, as defined in Title 45 Part 46 of the Code of Federal Regulations (45 CFR 46).

Additional contract requirements and responsibilities concerned with Protection of Human Subjects are found in PART II, SECTION I, ARTICLE I.3.b., HHSAR 352.270-4(b) Protection of Human Subjects.

**ARTICLE H.6. PRIVACY ACT, HHSAR 352.224-70 (Jan 2006))**

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)).

The contract work statement: (a) Identifies the system(s) of records and the design, development, or operation work to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: [http://www.access.gpo.gov/nara/cfr/waisidx\\_06/45cfr5b\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html)

The Privacy Act Systems of Records applicable to this project are incorporated into this contract as Attachment 3a-3i, in SECTION J of this contract. This document is also available at: <http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm> . Link does not work, this link works: <http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm>

**ARTICLE H.7. HUMAN MATERIALS**

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

**ARTICLE H.8. POLICY AND PROCEDURE (P&P)**

The Contractor shall adhere to the FNLCR Policy and Procedure Online Manual which is incorporated herein by reference and made a part hereof. It shall be modified/updated as current requirements and trends dictate. Copies of all current P&Ps are available from the Contracting Officer. In the event of any contradiction/conflict between the FNLCR Policy and Procedure Online Manual and the terms and conditions of this contract, the contract shall prevail.

**ARTICLE H.9. OBSERVANCE OF FORT DETRICK REGULATIONS**

Because the FNLCR is located adjacent to Fort Detrick, the Contractor and its employees shall observe the rules and regulations as prescribed by the authorities of that installation. In the event the Contractor deems such rules and regulations to be not applicable or inappropriate, written relief or deviation thereto shall be requested from the Contracting Officer. The Contractor is reminded that the DOD Police have official arresting authority if outside of the confines of HHS property on Fort Detrick

**ARTICLE H.10. UNAUTHORIZED INSTRUCTIONS FROM GOVERNMENT PERSONNEL**

The Contractor will not accept any instructions issued by any person employed by the U.S. Government or otherwise, other than the Contracting Officer, or the COR(s)/Assistant COR(s), acting within the limits of their authority as set forth in ARTICLE H.1 of this contract

**ARTICLE H.11. CONTRACT IDENTIFICATION**

Consistent with current NIH procurement procedures, the contract identification number "Contract No. HHSN261200800001E" shall be used on all official documents and correspondence relating to and/or referencing this contract.

**ARTICLE H.12. CONTRACT FEE DESIGNATION**

The parties agree that any references throughout the contract to "fixed-fee" appearing in the General and Additional Provisions may also be interpreted to mean "performance based fee" for the purposes of this contract, if applicable.

**ARTICLE H.13. NOVATION AND CHANGE OF NAME AGREEMENTS**

- a. The transfer of a Government contract is prohibited by law (41 U.S.C. 15). However, the Government may, if it is in its best interest, recognize a third party as the successor in interest to a Government contract when the third parties' interest in the contract arises out of the transfer either of all the assets of the Contractor or of all of that part of the Contractor's assets involved in the performance of the contract.
- b. The portion of the Act which prohibits the transfer of contracts is intended for the Government's protection, thus giving an agency discretion in acting to ensure that protection.
- c. When requested to concur in a novation agreement, the Government's main concerns are (1) whether the proposed transferee is, in fact, a successor in interest to the Government contract, and (2) whether it is consistent with the Government's interest to concur in the novation agreement. Accordingly, the Government has the discretion to either (i) treat the contract as originally executed, or (ii) recognize the assignment if it is in the Government's best interest.
- d. In order to provide for continuation of services and in accordance with this ARTICLE, and ARTICLE H.2., Continuity of Services, (except as directed by the Contracting Officer) all subcontracts having anticipated completion dates beyond the expiration date of the Contract shall be novated/transferred to the successor contractor.

**ARTICLE H.14. ADVANCE PAYMENT**

- a. Amount of Advance

At the request of the Contractor, and subject to the conditions hereinafter set forth, the Government may make an advance payment, or advance payments from time-to-time, to the Contractor. No advance shall be made: (1) without the approval of the office administering advance payments (hereinafter called the "Contracting Officer" and designated in I.(4) hereof) as to the financial necessity therefor; (2) in an amount which together with all advance payments theretofore made, shall exceed the amount stated in paragraph I.(4) hereof: and (3) without a properly certified invoice(s). Failure to adhere to these material provisions will be considered an event under the paragraph entitled Default Provisions of this Clause.

- b. Special Bank Account

Until all advance payments made hereunder, and interest charges if applicable, are liquidated and the Contracting Officer approves in writing the release of any funds due and payable to the Contractor, all advance payments under the contract shall be made to the Contractor and be marked for deposit only in an interest-bearing Special Bank Account with the bank designated in paragraph I.(2) hereof. Interest earned by this account will be paid directly to the Government by the bank under the procedure described in paragraph f. of this ARTICLE. No part of the funds in the Special Bank Account shall be mingled with other funds of the Contractor prior to withdrawal

thereof from the Special Bank Account as hereinafter provided. Except as hereinafter provided, each withdrawal shall be made only by check of the Contractor countersigned on behalf of the Government by the Contracting Officer, or such other person(s) as he may designate in writing (hereinafter called the "Countersigning Agent"). Until otherwise determined by the Contracting Officer, countersignature on behalf of the Government will not be required.

c. Use of Funds

The funds in the Special Bank Account may be withdrawn by the Contractor solely for the purposes of making payments for allowable contract cost (inclusive of labor, fringe benefits, materials, supplies, service, equipment, G&A, fee and other direct costs) under this contract, or to reimburse the Contractor for such items of allowable cost, and for such purposes as the Contracting Officer may approve in writing. Any interpretation required as to the proper use of funds shall be made in writing by the Contracting Officer.

d. Return of Funds

The Contractor may at any time repay all or any part of the funds advanced hereunder. Whenever so requested in writing by the Contracting Officer, the Contractor shall repay to the Government such part of the unliquidated balance of advance payments as shall, in the opinion of the Contracting Officer, be in excess of current requirements or (when added to total advances previously made and liquidated) in excess of the amount specified in paragraph l.(1) hereof. In the event the Contractor fails to repay such part of the unliquidated balance of advance payments when so requested by the Contracting Officer, all or any parts thereof may be withdrawn from the Special Bank Accounts to the Treasurer of the United States signed solely by the Countersigning Agent and applied in reduction of advance payments then outstanding hereunder.

e. Maximum Payment

When the sum of all unliquidated advance payments, unpaid interest charges, and other payments equal the total estimated cost of \$45,000,000 for the work under this contract, the Government shall withhold further payments to the Contractor. Upon completion or termination of the contract, the Government shall deduct from the amount due to the contractor all unliquidated advance payments. The Contractor shall pay any deficiency to the Government upon demand. For purposes of this paragraph, the estimated cost shall be considered to be the stated estimated cost, less any subsequent reductions of the estimated cost, plus any increases in the estimated costs that do not, in the aggregate, exceed \$45,000,000. The estimated cost shall include, without limitation, any reimbursable cost (as estimated by the Contracting Officer) incident to a termination for the convenience of the Government. Any payments withheld under this paragraph shall be applied to reduce the unliquidated advance payments. If full liquidation has been made, payments under the contract shall resume.

f. Interest

The Contractor will not be required to pay the Government interest in accordance with the exemption for contracts solely for the management and operation of Government-owned plants (FAR Subpart 32.407(d)(2)). However, the Special Bank Account will be an interest-bearing account. Interest payment, less administrative costs to maintain the account, will be paid monthly by Leidos Biomedical Research, Inc. to the Government by check made payable to the U.S. Treasury and mailed to:

Office of Financial Management, NIH  
2115 E. Jefferson Street  
Room 4B-430  
Bethesda, Maryland 20892

For purposes of making interest payments to the Government, Leidos Biomedical Research, Inc. will use Tax Identification # 52-0599027.

**g. Bank Agreement**

Before an advance payment is made hereunder, the Contractor shall transmit to the Contracting Officer, in the form prescribed by such officer, an Agreement in triplicate from the bank in which the Special Bank Account is established, clearly setting forth the special character of the bank thereunder. Whenever possible, such bank shall be a member bank of the Federal Reserve System, or an "insured" bank within the meaning of the Act creating the Federal Deposit Insurance Corporation (Act of Aug. 23, 1935, 49 Sta. 684, as amended; 12 U.S.C. 364).

**h. Lien on Special Bank Account**

The Government shall have a lien, paramount to all other liens, upon (1) the credit balance in the special bank account, (2) any supplies contracted for, (3) any material or property acquired for performance of the contract, which lien shall secure the repayment of any advance payments made hereunder together with interest charges thereon, and (4) interest earned by the account but not yet paid to the Government by the bank.

**i. Insurance**

The Contractor represents and warrants that it is now maintaining with responsible insurance carriers, (1) insurance upon its own plant and equipment against fire and other hazards to the extent that like properties are usually insured by others operating plants and workmen's compensation laws. The Contractor agrees that, until work under this contract has been completed and all advance payments made hereunder have been liquidated, it will maintain such insurance and furnish such certification with respect to its insurance as the Administering Office may from time-to-time require.

**j. Default Provisions**

Upon the happening of any of the following events of default, (1) termination of this contract by reason of fault of the Contractor; (2) a finding by the Contracting Officer that the Contractor (i) has failed to observe any of the covenants, conditions, or warranties of these provisions or has failed to comply with any material provision of this contract, or (ii) has so failed to make progress, or is in such unsatisfactory financial condition as to endanger performance of this contract, or (iii) has allocated inventory to this contract substantially exceeding reasonable requirements, or (iv) is delinquent in payment of taxes or of the costs of performance of this contract in the ordinary course of business; (3) appointment of a trustee, receiver or liquidator for all or a substantial part of the Contractor's property or institution of bankruptcy, reorganization, arrangement or liquidation proceedings by or against the Contractor; (4) service of any writ of attachment, levy of execution, or commencement of garnishment proceedings with respect to the Special Bank Account; or (5) the commission of an act of bankruptcy; the government without limiting any rights which it may otherwise have, may, in its discretion and upon written notice to the Contractor; withhold further withdrawals from the Special Bank Account and withhold further payment under this contract. Upon the continuance of any such events of default for a period of thirty (30) days after such written notice to the Contractor, the Government may, in its discretion, and without limiting any other rights which the Government may have, take the following additional actions as it may deem appropriate under the circumstances:

- (1) Withdraw all or any part of the balances in the Special Bank Account by checks payable to the Treasurer of the United States signed solely by the Countersigning Agency and apply such amounts in reduction of advance payments then outstanding hereunder and in reduction of any other claims of the Government against the Contractor.

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- (2) Charge interest on advance payments outstanding during the period of any such default at the rate established by the Secretary of Treasury pursuant to Public Law 92-41, 85 Stat. 97 for the Renegotiation Board.
- (3) Demand immediate repayment of the unliquidated balance of advance payments hereunder.
- (4) Take possession of and, with or without advertisement, sell at public sale at which the Government may be the purchaser, or at a private sale, all or any part of the property on which the Government has a lien under this contract and, after deducting any expenses incident to such sale, apply the net proceeds of such sale in reduction of the unliquidated balance of advance payments hereunder and in reduction of any other claims of the Government against the Contractor.

k. Information - Access to Records

The Contractor shall furnish to the Administering Office a monthly report, due on the 20<sup>th</sup> day of the month following the period being reported, on the operation of the Special Bank Account in prescribed form, and such other information concerning the operation of the Contractor's business as may be requested. The Contractor shall afford to authorized representatives of the Government proper facilities for inspection of the Contractor's books, records, and accounts.

l. Designations and Determinations

(1) Amount

The aggregate amount of advance payments to be made hereunder (less the aggregate amounts paid or withdrawn pursuant to paragraph d.) shall not exceed \$45,000,000.

- (2) Depository - The bank designated for the deposit of payments made hereunder shall be Citibank.
- (3) Interest Charge - No interest shall be charged for advance payments made hereunder, except interest during a period of default as provided in paragraph j(2) and as provided in paragraph f. of the ARTICLE.
- (4) Administering Office - The office administering advance payments is designated as NCI Management Operations and Support Branch, Building 427, NCI Campus at Frederick, Frederick, Maryland 21702-1201.

m. Other Security

The terms of this contract shall be considered adequate security for advance payments hereunder, except that if at any time the Administering office deems the security furnished by the Contractor to be inadequate, the Contractor shall furnish such additional security as may be satisfactory to the Administering Office, to the extent that such additional security is available.

n. Representations and Warranties

To include the making of the advance payments, the Contractor represents and warrants that:

- (1) The Contractor's financial statements, included in their Final Proposal Revision, dated July 14, 2008, fairly reflects the Contractor's financial condition as of this date and since said date there has been no material adverse change in the financial condition of the Contractor.
- (2) No litigations or proceedings are presently pending or threatened against the Contractor, except as shown in the above statements.
- (3) The contractor, apart from liability resulting from the renegotiation of defense production contracts, has no contingent liabilities not provided for or disclosed in the financial statements furnished to the Administering Office.
- (4) None of the provisions herein contravenes or is in conflict with the authority under which the Contractor is doing business with the provision of any existing indenture or agreement of the Contractor.

- (5) The Contractor has the power to enter into this contract and accept advance payments hereunder, and has taken all necessary action to authorize such acceptance under the terms and conditions of his contract.
- (6) None of the assets of the Contractor are subject to any lien or encumbrance of any character except for current taxes not delinquent, and except as shown in the financial statements furnished by the Contractor to the Administering Office.
- (7) All information furnished by the Contractor to the Contracting Officer in connection with each request for advance payment is true and correct.
- (8) These representations and warranties shall be continuing and shall be deemed to have been repeated by the submission of each invoice for advance payments.

o. Prohibition Against Assignment

Notwithstanding any other provision of this contract, the Contractor shall not transfer, pledge, or otherwise assign advance payments made under this ARTICLE, or any interest therein, or any claim arising thereunder, to any party or parties, bank, trust company, or other financing institution, except the Depository as designated in paragraph l.(2) of this ARTICLE.

**ARTICLE H.15. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS**

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the Electronic and Information Technology Accessibility Standards set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the Access Board) in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at <http://www.access-board.gov/news/508-final.htm>. The standards applicable to this requirement are set forth in 36 CFR Part 1194.21 through 26.

**ARTICLE H.16. TECHNOLOGY TRANSFER**

The following terms and conditions reflect procedures the Contractor shall follow for Technology Transfer activities including presenting CRADAs, Joint work Statements (JWSs), and other types of technology transfer agreements and planning documents to the Government for approval.

a. Technology Transfer

(1) Definitions

- (a) GOCO Laboratory means the entire GOCO (FFRDC) laboratory research effort of the Contractor at the FNLCR. Contractor may be substituted herein for GOCO Laboratory
- (b) GOCO Laboratory Director means the Contractor employee, who has supervision over all of the operations of the GOCO Laboratory. The Laboratory Director role will be carried out by the Chief Executive Officer identified in Article G.2.
- (c) GOCO Research Laboratory refers to the Contractor laboratory, in which a laboratory scientist has been identified for serving as Principal Investigator solely for the purpose of leading the effort specified in the technology transfer agreement.

- (d) Intellectual Property means patents, trademarks, copyrights, mask works, and other forms of comparable property rights protected by Federal law.
- (e) Cooperative Research and Development Agreement (CRADA) means any agreement pursuant to 15 U.S.C. 3710a between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories (e.g. the GOCO Laboratory), provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory; except that such term does not include a procurement contract or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of title 31 of the United States Code.
- (f) Government CRADA means a CRADA, where at least one Government scientist participates jointly with GOCO Laboratory personnel to perform CRADA work. Government CRADAs are entered into by Government and an outside CRADA party to directly advance the Government's research and development objectives.
- (g) Contractor CRADA means a CRADA, where only GOCO Laboratory personnel perform CRADA work that meets the GOCO Laboratory's core mission. No Government employees participate in such Contractor CRADA projects.
- (h) Joint Work Statement (JWS) means a proposal prepared for a Federal agency by the director of a GOCO laboratory describing the purpose and scope of a proposed CRADA, and assigning rights and responsibilities among the agency, the GOCO Laboratory, and any other party or parties to the proposed agreement.
- (i) PHS Model CRADA means the then current version of the model CRADA or similar document (i.e. Materials-CRADA) approved by the PHS Technology Transfer Policy Board which by this reference is incorporated herein. This model or other approved CRADA document and any approved changes will be used for Government CRADAs. Model CRADAs can be viewed here: [http://www.ott.nih.gov/forms\\_model\\_agreements/forms\\_model\\_agreements.aspx](http://www.ott.nih.gov/forms_model_agreements/forms_model_agreements.aspx)
- (k) OFFICE OF RESEARCH TECHNOLOGY APPLICATIONS (ORTA) means that Contractor office which shall be the office of record for all GOCO Laboratory technology transfer matters and records which do not involve the Government directly. This office will also act as the liaison to the Government and the COR for Intellectual Property for all technology transfer and intellectual property matters. The office designated shall be subject to mutual agreement of the GOCO Laboratory Director and the Contracting Officer consistent with the policy, principles and purposes of 15 U.S.C. 3710.

(2) Technology Transfer Authority

- (a) In order to ensure the full use of results of the research and development efforts and the capabilities of the GOCO Laboratory, technology transfer (including CRADAs) is established as a mission of the GOCO Laboratory consistent with the policy, principles and purposes of 15 U.S.C. sections 3701, 3702, and 3710a, as amended, Executive Order 12591 of April 10, 1987, and the PHS Technology Transfer Policy Statement.

(b) In pursuing the technology transfer mission, the GOCO Laboratory, subject to the obligations herein, will coordinate its efforts through a COR for Intellectual Property or through a designated process to conduct the following activities: transfer selected proprietary materials and information for research purposes; identify and protect intellectual property; enter into CRADAs and licenses consistent with the Contractor's obligations to the Government and relevant statutes with respect to intellectual property; provide technical consulting and personnel exchanges; conduct science education activities; and, provide information exchanges and the use of laboratory facilities. It is fully expected that the GOCO Laboratory shall, to the extent permitted by this ARTICLE and the Contracting Officer, use all of the mechanisms available to it to accomplish this technology transfer mission, including, but not limited to, the use of laboratory facilities, science education activities, consulting, and personnel exchanges.

(3) Allowable Costs

(Applies only to the performance of technology transfer activities under this ARTICLE.) The costs associated with the conduct of technology transfer activities by the Contractor, including activities associated with obtaining and maintaining intellectual property rights, increasing the potential for the transfer of technology, and the widespread notice of technology transfer opportunities, shall be deemed allowable provided that such costs are otherwise allowable consistent with the terms of this contract.

(4) Conflicts of Interest - Technology Transfer

The GOCO Laboratory shall develop implementing procedures that seek to avoid employee and organizational conflicts of interest, or the appearance of conflicts of interest, in the conduct of its technology transfer activities. For Contractor CRADAs, a conflict of interest review specific to the individual CRADA will be considered by the Contracting Officer when approving a proposed Contractor CRADA.

(5) Fairness of Opportunity

In conducting its technology transfer activities, the GOCO Laboratory will take all reasonable measures to ensure widespread notice of availability of technologies suited for transfer and opportunities for licensing and joint research arrangements.

(6) U.S. Industrial Competitiveness

In the interest of enhancing U.S. Industrial Competitiveness, the GOCO Laboratory shall give preference in such a manner so as to enhance the accrual of economic and technological benefits to the U.S. domestic economy.

(7) Indemnity

The GOCO Laboratory agrees that all Contractor CRADAs authorized by this ARTICLE, will contain a requirement to the extent permitted by law that the U.S. Government, as well as the Contractor, be indemnified and held harmless from all damages, costs, and expenses, including attorneys' fees, arising from the commercialization or utilization of any Intellectual Property transferred by the U.S. Government or the GOCO Laboratory, including, but not limited to, the making, using, selling, or

exporting of products, processes, or services derived from the transferred technology, unless directed otherwise by the Contracting Officer.

- (8) Disposition of Contractor CRADA Funds and Royalty Income from Contractor CRADAs: (Applies only to technology transfer activities under this ARTICLE.)
- (a) Any funds received by the GOCO Laboratory under a CRADA entered into under this ARTICLE, shall be reported to the Contracting Officer within 30 days of receipt of such funds and used by the appropriate GOCO Research Laboratory in accordance with the terms of the CRADA. A separate cost center itemizing costs expended shall be maintained for each CRADA.
  - (b) Any royalty funds received by the GOCO Laboratory under this ARTICLE, shall be reported to the Contracting Officer within 30 days of receipt of such funds and used in accordance with 15 U.S.C. 3710a and the guidelines found in Attachment 29 herein.
- (9) Reporting of CRADA and Licensing Activities
- (a) The GOCO Laboratory shall, within 30 calendar days following the end of each contract year, provide to the Contracting Officer, a report on the progress of active Contractor CRADAs and a separate accounting of how CRADA funds were expended, in accordance with the format and content of the Cost Status Report required to be submitted by the Contractor as set forth elsewhere in this contract.
  - (b) The GOCO Laboratory shall, within 30 calendar days following the end of each contract year, provide to the Contracting Officer, licenses let, royalty funds collected, and a separate accounting of how such royalty funds were used. Financial reports will be in accordance with the format and content of the Cost Status Report required to be submitted by the Contractor as set forth elsewhere in this contract.
- (10) Transfer of Intellectual Property Rights Upon Contract Termination or Expiration
- In the event of termination or expiration of this Contract or termination of the OTS Contractor CRADA program, ownership and management of intellectual property, CRADA funds, royalty funds, rights to uncollected royalties and related records shall be transferred to a successor Contractor or the Government as required by FAR 52.227-11 (Deviation) Patent Rights Ownership by the Contractor (Dec. 2007) [OTS Contractor CRADAs] and in Attachment 29.
- (11) Technology Transfer Export
- (a) The GOCO Laboratory is responsible for coordinating with a COR for Intellectual Property to ensure that technology is transferred in accordance with applicable law, NIH Policies and Procedures (as appropriate), and other executed transactional agreements, and is consistent with its obligations under this Contract.
  - (b) The GOCO Laboratory shall include in all Contractor CRADAs and related documents, notice to third parties that the export of goods and/or Technical Data from the United States may require an export control license from the U.S. Government and that, failure to obtain such export control license, may result in criminal liability under U.S. laws.
- (12) Records

The GOCO Laboratory shall maintain appropriate records of all its technology transfer activities. The GOCO Laboratory shall forward reports of all records of its technology transfer activities in a manner and to the extent satisfactory to each of the Contracting Officer's Representatives (CORs) for Intellectual Property for review. Records which are not required to be part of this report would include those handled separately by the Government. However, said reports should include any other technology transfer-related agreements, such as MTAs, CDAs, Contractor CRADAs, beta test agreements, collaboration agreements, software agreements, etc. Reports of the foregoing shall be provided to the CORs for Intellectual Property on an annual basis with a due date of February 15th and cover the previous calendar year. Such reports shall be prepared in a format to be agreed upon between the GOCO Laboratory and the CORs for Intellectual Property, and in such a format which will serve to adequately inform DHHS of the GOCO Laboratory's technology transfer activities.

(13) Technology Transfer Plan

The GOCO Laboratory is required to submit to the Contracting Officer, annually, a technology transfer plan for conducting its technology transfer functions for the upcoming year. This plan shall be provided to the Contracting Officer on or before the first business day of each calendar year.

(14) Oversight and Appraisal

The GOCO Laboratory is responsible for developing and implementing effective internal controls for all technology transfer activities consistent with the audit and record requirements of this Contract. The GOCO Laboratory performance in implementing the technology transfer mission and the effectiveness of GOCO Laboratory procedures will be evaluated by the NCI as part of its award fee evaluation process.

(15) Invention Reporting

The Contractor will report inventions made by its employees consistent with its obligations under the appropriate FAR clauses and any other terms of this contract on the current NIH Employee Invention Report (EIR) form. An approved OTS Contractor Coversheet will accompany such EIRs as appropriate.

b. Types of Technology Transfer Agreements

(1) Material Transfer Agreements (MTA)

The transfer of proprietary material belonging to an outside party into FNLCR or the transfer of NCI proprietary material out of the FNLCR for research purposes will be documented under a Material Transfer Agreement (MTA) or other similar agreement.

- (a) Inbound Materials-Sole GOCO Laboratory Use: After consultation with a COTR for Intellectual Property or through another approved process, the GOCO Laboratory may execute a Contractor MTA for the purposes of transferring proprietary materials from outside sources into FNLCR that will be used solely by GOCO Laboratory employees and not provided to Government employees.
- (b) Inbound Materials -Joint Government and GOCO Laboratory Use: Proprietary materials from outside sources transferred into the FNLCR that will be used by both Government and GOCO Laboratory employees will be documented under a Government MTA. The GOCO Laboratory may also be a signatory on such Government MTAs as appropriate.

- (c) All Government proprietary materials transferred out of the FNLCR will be documented under a Government MTA unless other approved procedures are in place and described elsewhere or is approved on a case-by-case basis by the Contracting Officer through a COTR for Intellectual Property.
- (d) To the extent that the Contractor produces research materials under an OTS Contractor CRADA, it is expected that the Contractor will share such materials for research purposes to the greatest extent possible under an appropriate MTA.

(2) Confidential Disclosure Agreements (CDA)

The transfer of proprietary or confidential information belonging to an outside party into NCI-Frederick or the transfer of Government proprietary or confidential information out of the NCI-Frederick for research purposes will be documented under a Confidential Disclosure Agreement (CDA) or other similar agreement.

- (a) Inbound Confidential Information-Sole GOCO Laboratory Use: After consultation with a COR for Intellectual Property, the GOCO Laboratory may execute a CDA for the purposes of transferring proprietary or confidential information for research purposes from outside sources into FNLCR that will be used solely by GOCO Laboratory employees and not provided to Government employees.
- (b) Inbound Confidential Information -Joint Government and GOCO Laboratory Use: Proprietary or confidential information from outside sources transferred into the FNLCR that will be used by both Government and GOCO Laboratory employees will be documented under a Government CDA. The GOCO Laboratory may also be a signatory on such Government CDAs as appropriate.
- (c) All Government proprietary or confidential information transferred out of the FNLCR will be documented under a Government CDA. The Contractor may also be a signatory on such Government CDAs as appropriate. A COR for Intellectual Property does not need to be consulted or the CDA approved for activities of the Contractor related to its internal business, financial or other areas not related to the GOCO Laboratory's research mission.

(3) Collaboration Agreements (CA)

Collaboration Agreements are designed to document selected collaborative research projects which do not involve a promise of advanced intellectual property rights to the outside collaborator nor involve the exchange of funds. Accordingly a CA is not a CRADA and does not operate under the authority of 15 U.S.C. 3710a. Under a CA proprietary materials and information from all parties may be exchanged, research data produced and shared among the collaborating parties.

- (a) GOCO Laboratory CAs: The GOCO Laboratory may execute a CA for research purposes after consultation with a COR for Intellectual Property and appropriate approval by the Contracting Officer. Government employees are not involved in GOCO Laboratory CAs and accordingly are not provided any outside proprietary materials or information obtained by the GOCO Laboratory under the CA.
- (b) Government CAs: If Government employees are involved in the research covered by a CA or if Government employees receive outside proprietary materials or information then the CA must be a Government CA. The GOCO Laboratory may also be a signatory on such Government CAs as appropriate.

(4) CRADA Agreements

Pursuant to the CRADA statute (15 U.S.C. 3710a) the Government and the GOCO Laboratory each have the authority to independently enter into a CRADA. Accordingly the GOCO Laboratory may participate in two (2) types of CRADAs:

- (a) Government CRADAs in which the GOCO Laboratory assists the Government in the Government's research and development objectives, and the GOCO Laboratory assigns its rights to inventions to the Government pursuant to the OTS contract DEC and FAR 52.227-13 (Deviation) Patent Rights--Ownership by the Government (DEC 2007) [Patent Rights-OTS Prime Contractor] as amended.
- (b) The GOCO Laboratory may enter into Contractor CRADAs independent of the Government pursuant to 15 U.S.C. 3710a and consistent with the terms of this Contract to advance its core mission. Contractor CRADAs and associated inventions are governed by the FAR 52.227-11 (Deviation) Patent Rights Ownership by the Contractor (Dec. 2007) [OTS Contractor CRADAs] and the procedures found in Attachment 29. Contractor CRADAs must be approved by the Contracting Officer. The Contractor manages inventions resulting from the CRADA, licenses such inventions and collects royalties as consistent with the terms herein, CRADA statute (15 U.S.C. 3710a) (including Attachment 29). Contractor CRADAs may not directly support or involve an NIH program.

c. Contractor Process for Government CRADAs

- (1) The Contractor may participate in Government CRADAs in which there are Government employees or in which the Contractor is directly supporting the Government's research enterprise.
- (2) The Contractor will work under the Government CRADA within the Government's CRADA policies and procedures consistent with its rights and obligations under this contract.
- (3) The Contractor will establish internal policies to ensure that any real or apparent conflicts of interest of the Contractor or its employees participating in the Government CRADA are appropriately addressed.

d. Review and Approval of Contractor CRADAs

Pursuant to 15 U.S.C 3710a, a GOCO contractor may enter into CRADAs independent of the Government. Such CRADAs require the approval of the Contracting Officer. Contractor CRADAs will be approved according to the following.

- 1) The Contractor will establish a standard operating procedure (SOP) to develop potential collaborative projects. This SOP will include a preliminary evaluation of the project to determine if circumstances are favorable for a Contractor CRADA or other collaborative interaction.
- 2) A JWS and accompanying Contractor CRADA documentation shall be submitted through to the Contracting Officer for approval. All terms in the Contractor CRADA Agreement must be consistent with the Contractors obligations herein and the CRADA statute (15 U.S.C. 3710a).

- 3) Within thirty (30) days after submission of a JWS, the Contracting Officer shall approve, disapprove or request modification to the JWS. If a modification is required, the Contracting Officer shall approve or disapprove any resubmission of the JWS within thirty (30) days of its resubmission.

e. Selection of Participants

The GOCO Laboratory Director or his designee, in deciding what Contractor CRADA(s) to propose shall work with the COR for Intellectual Property to:

- 1) Give special consideration to small business firms, and consortia involving small business firms;
- 2) Comply with the Conflicts of Interest requirements
- 3) Provide Fairness of Opportunity;
- 4) Grant U.S. preference in accordance with the licensing and assignment requirements.

f. Withholding of Data

(1) Consistent with the Contractors obligations herein and the CRADA statute (15 U.S.C. 3710a), the GOCO Laboratory may provide for appropriate protection against dissemination of data produced as a result of research and development activities conducted under a Contractor CRADA, for a period of up to five (5) years from the time the data are first produced. In addition, protection against dissemination should apply to both proprietary information provided by an outside collaborator and to data first- produced as a result of research and development activities under the Contractor CRADA.

(2) All proprietary information provided by an outside collaborator and data first-produced under a Contractor CRADA, in accordance with this provision, is freely available to the Contracting Officer, FNLCR upon request. To the extent permitted by law, it is the Government's intention to abide by the restrictions against private use and further dissemination which are consistent with the GOCO Laboratory's obligations under the subject Contractor CRADA as provided by the GOCO Laboratory pursuant to (1) above.

**ARTICLE H.17. ANIMAL CARE PROCEDURES**

Animal care procedures shall conform to the NIH Guide for the Care and Use of Laboratory Animals as well as all PHS Animal Welfare Policies. Research and technical functions are dependent upon the ability of the Government to provide access to controlled substances when necessary.

**ARTICLE H.18. INTRODUCTION OF RODENTS AND RODENT PRODUCTS**

The animal program at the FNLCR is exempt from NIH policy as described in NIH Policy Manual 3043-1, Introduction of Rodents and Rodent Products, due to FNLCR's separate PHS Assurance and AAALAC accreditation. The Contractor shall adhere to FNLCR Policies and Procedures which relate to rodents and rodent products.

**ARTICLE H.19. DISPOSITION OF ANIMALS AT FNLCR**

- a. Research animals, on Animal Care and Use Committee protocols and maintained in Laboratory Animal Sciences Program facilities (including Receiving and Quarantine), shall be sacrificed ONLY with the approval of the Contracting Officer of the protocol or his/her designee.
- b. In rare cases, when the attending veterinarian determines that an animal is experiencing so much pain or distress that immediate euthanasia is required, every reasonable attempt should be made

to contact the principal investigator (or designee) before the animal is sacrificed. If such contact cannot be made, the principal investigator (or designee) should be informed as soon as possible. Each animal facility should have protocol-specific standard operating procedures to cover such eventualities.

- c. Records should be maintained on all animals requiring treatment and/or euthanasia.

**ARTICLE H.20. ANIMAL WELFARE**

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at <http://grants1.nih.gov/grants/olaw/references/phspol.htm>

**ARTICLE H.21. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES**

In the performance of any research and/or development under this contract involving recombinant DNA molecules, the Contractor agrees to abide by all NIH Guidelines relating to such activities, that are now current, or as may be updated from time-to-time. The Institutional Biosafety Committee (IBC) serves to interpret the application of NIH guidance to the NCI and its Contractors. A copy of these Guidelines will be provided to the Contractor by the Contracting Officer.

**ARTICLE H.22. SAFETY STANDARDS**

All work with hazardous biological materials will be conducted in compliance with the publication,

Biosafety in Microbiological and Biomedical Laboratories. Also, see Article B.4.j., Environmental Health and Safety/Regulations at the FNLCR and the attached HHSAR Clause 352.223-70, Safety and Health (Deviation) (JAN 2006).

**ARTICLE H.23. CONSULTANT OR OTHER COMPARABLE EMPLOYMENT SERVICES OF CONTRACTOR EMPLOYEES**

The Contractor shall require all employees who are receiving 50 percent or more of their regular annual compensation under the terms of this contract to disclose to the Contractor all consultant or other comparable employment services which the employees propose to undertake for others. The Contractor shall advise the Contracting Officer of all information obtained from such disclosures (which information shall be treated with confidentiality by the Contracting Officer); and shall specifically advise the Contracting Officer of the nature and extent of any work such employees are undertaking under any other contract the Contractor may be performing for the Department of Health and Human Services (DHHS).

With respect to any employee who will be employed on a full-time annual basis on the work under this contract, the Contractor will require, as a condition of his/her employment on such work, that the employee will not perform consultant or other comparable employment services for another contractor under a cost-reimbursement type contract with the DHHS, except with the prior approval of the Contractor who shall notify the Contracting Officer of such approval.

**ARTICLE H.24. COMMITTEE RESPONSIBILITIES**

- a. The Contractor shall establish, maintain, operate and chair the following FNLCR committee in support of government and contractor programs at NCI Campus at Frederick:

(1) Radiation Safety Committee to review and approve all activities involving radioisotopes.

b. The Contractor shall assist the chairperson, who shall be appointed by the Project Officer, in the maintenance and operation of the following FNLCR committees:

(1) Animal Care and Use Committee for review and approval of animal protocols.

(2) Institutional Biosafety Committee for review and approval of protocols involving recombinant molecules or other potentially hazardous materials.

#### **ARTICLE H.25. SCIENTIFIC COLLABORATION**

The Contractor shall make every effort to promote collaboration between and among all scientific activities at the FNLCR. This includes the sharing of research objectives, research results, and all research resources at their disposal; to include labor, materials and supplies, equipment, experimental media, and non-scientific support services. These initiatives should take place between individuals at all levels of the organization. In the event such collaboration shall require research resources not presently available at the FNLCR, the subject shall be brought to the attention of the respective contract Principal Investigator or appropriate Government supervisor, who shall then meet with the Project Officer and the Contracting Officer shall resolve the matter.

#### **ARTICLE H.26. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

#### **ARTICLE H.27. NEEDLE DISTRIBUTION**

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

#### **ARTICLE H.28. OMB CLEARANCE**

In accordance with HHSAR 352.201-70, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

**ARTICLE H.29. SUBCONTRACTING PROVISIONS**

a. Small Business Subcontracting Plan

- (1) The Contractor's Individual Subcontracting Plan (Attachment 7) which outlines its Small Business and Small Disadvantaged Business subcontracting goals, is incorporated into and made a part of the contract to cover the period from 9/26/08 through 9/25/18. The Contractor may revise the Subcontracting Plan to more accurately reflect plan goals based on more complete knowledge of subcontracting needs. Revised Subcontracting Plans shall be submitted to the Contracting Officer for review and approval by September 1 of each year. Refer to PART III, LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS, SECTION J - LIST OF ATTACHMENTS.
- (2) The failure of the Contractor or its subcontractor(s) to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the Electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>.

(1) Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

April 30<sup>th</sup>  
October 30<sup>th</sup>  
Expiration Date of Contract

(2) Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

October 30<sup>th</sup>

For both the Individual and Summary Subcontract Reports, the Contract Specialist shall be included as a contact for notification purposes at the following e-mail address: [whitep@ncifcrf.gov](mailto:whitep@ncifcrf.gov).

**ARTICLE H.30. SUBCONTRACTING**

Notwithstanding the other provisions of this contract pertaining to subcontracting, the Contractor shall, to the maximum extent practicable, use performance-based contracting methods in its subcontracts for services as described in FAR Subpart 37.6 and Office of Federal Procurement Policy Letter 91.2 which provides guidance concerning the development and use of performance-based contracting concepts.

The Contractor's progress in the above area shall be a factor in the bi-annual performance based fee evaluation.

**ARTICLE H.31. Reserved**

**ARTICLE H.32. INFORMATION SECURITY**

The Statement of Work (SOW) requires the Contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the Contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

a. Information Type

[X] Administrative, Management and Support Information  
See Attachment 15.

[X] Mission Based Information

N/A

[X] Security Categories and Levels

See Attachment 15

c. Position Sensitivity Designations

1. The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI). The following positions under the contract are determined to fall under Level 5C.

**Advanced Biomedical Computing Center: Mgr, Telecom/Network; LAN/Network Spec II, III; and, IT Security Analyst I**

**Financial and Administrative Systems: LAN/Network Spec II, III.**

**NIAID Support: LAN/Network Specialist III.**

**In addition to the above, other positions may be evaluated in conjunction with the Project Officer and Contracting Officer for inclusion.**

Level 1: Non Sensitive (Requires Suitability Determination with an NACI). Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI). **There are currently no IC positions.**

2. The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: <http://ais.nci.nih.gov/forms/Suitability-roster.xls> .

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov> .

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

3. Contractor/Subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/Subcontractor employees may begin work under the contract after the Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

d. Information Security Training

The Contractor shall ensure that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by Contractor/Subcontractor staff shall be included on this listing. [The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.]

Contractor/Subcontractor staff shall complete the following additional training prior to performing any work under this contract:

e. Rules of Behavior

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior ( <https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx>), which are contained in the NIH Information Security Awareness Training Course <http://irtsectraining.nih.gov> .

f. Personnel Security Responsibilities

Contractor Notification of New and Departing Employees Requiring Background Investigations

4. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer within five working days before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.
5. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.

6. Departing employees:

- Provide the name, position title, and security clearance level held by or pending for the individual.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

7. Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose information that has been designated as non-public or confidential to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

2. Commitment to Protect Non-Public Information – Contractor Agreement

Each Contractor/Subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement.

h. NIST SP 800-53 Self-Assessment

The contractor shall annually update and re-submit its Self-Assessment required by NIST SP 800-53, *Recommended Security Controls for Federal Information Systems* . ( <http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The Contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the Contractor's/Subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the Contractor's/Subcontractor's facility.

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer [For option contracts: no later than the completion date of the period of performance/ for all other contracts: indicate due date as determined by the Project Officer/Contracting Officer ].

i. Information System Security Plan

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*. ( <http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf> ). The details contained in the Contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The Contractor shall include similar information for any subcontractor performing under the SOW with the Contractor whenever the submission of an ISSP is required.

j. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

- k. Contractor employees are authorized limited personal use of NIH IT resources in accordance with NIH Policy Manual Chapter 2806 and subject to all applicable policies regarding limited personal use and the terms of this contract.

**ARTICLE H.33. RESERVED**

**ARTICLE H.34. 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 acknowledgment substantially as follows:

- a. For Manuscripts (Use of NCI Funds):

"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. HHSN261200800001E. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government."

For Abstracts: (due to space limitations): Funded by NCI Contract No. HHSN261200800001E

For Manuscripts (Use of NIH funds):

"This research was supported [in part] by the National Institutes of Health"

- b. Authors of manuscripts/abstracts have the option of using any or all of the following affiliations:

- Option 1) Government laboratory name
- Option 2) Contractor laboratory name
- Option 3) Contractor directorate name

The selected option(s) shall be inserted into the following statement:

Authors Name, (Option 1, 2, 3), Leidos Biomedical Research, Inc., NCI Campus at Frederick, Frederick, Maryland 21702.

- c. The following additional statement is to be included in manuscripts when animal studies have been performed:

"NCI-Frederick is accredited by AAALAC International and follows the Public Health Service Policy for the Care and Use of Laboratory Animals. Animal care was provided in accordance with the procedures outlined in the >Guide for Care and Use of Laboratory Animals= (National Research Council; 1996; National Academy Press; Washington, D.C.)."

- d. Reserved.

**ARTICLE H.35. PRESS RELEASES**

Pursuant to the current HHS annual appropriations act, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

**ARTICLE H.36. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE**

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

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

**ARTICLE H.37. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act (21 U.S.C. 812), except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

**ARTICLE H.38. ORGANIZATIONAL CONFLICTS OF INTERESTS**

- a. Purpose. The purpose of this article is to ensure that the Contractor) (1) is not biased because of its financial, contractual, organizational, or other interests which relate to the work under this contract, and (2) does not obtain any unfair competitive advantage over other parties by virtue of its performance of this contract.
- b. Scope. The restrictions described herein shall apply to performance or participation by the Contractor when it uses any of its affiliates or their successors in interest in the activities covered by this article as a subcontractor, co-sponsor, joint venturer, consultant, or in any similar capacity. For the purpose of this article, affiliation occurs when a business concern is controlled by or has the power to control another or when a third party has the power to control both.
- c. Background. The Contractor is required to conduct its business in a manner befitting its special relationship with the Government, to operate in the public interest with objectivity and independence, to be free from organizational conflicts of interest, and to have full disclosure of its affairs to the Government. FAR 9.502 (c) states: "An organizational conflict of interest may result when factors create an actual or potential conflict of interest on an instant contract, or when the nature of the work to be performed on the instant contract creates an actual or potential conflict of interest on a future acquisition."

Due to the requirements and unusual (sometimes unique) nature of the work performed under this contract, and the fact that the Contractor is operating an FFRDC in Government owned facilities, the Government must maintain a special, close relationship with the Contractor's personnel in various important areas (e.g., access to Government and supplier data, including sensitive and proprietary data, employees and facilities, safety, security, cost control, and site conditions). This relationship has the potential to give the Contractor access to information that the Government considers privileged, including proprietary information of third parties and non-public Government deliberations, recommendations, and advice. Examples include, but are not limited to, NIH and NCI program plans, policies, reports, studies, and financial plans that are not publicly available. The Contractor shall not use this privileged information or access to facilities to compete with the private sector for other Government contracts.

- d. Restrictions. FAR 35.017-1 (c) (4) states that an FFRDC sponsoring agreement must address the following: "A prohibition against the FFRDC competing with any non-FFRDC concern in response to a Federal agency request for proposal for other than the operation of an FFRDC. This prohibition is not required to be applied to any parent organization or other subsidiary of the parent organization in its non-FFRDC operations. Requests for information, qualifications or capabilities can be answered unless otherwise restricted by the sponsor." In this instance, the Contractor (Leidos Biomedical Research, Inc.) is a wholly owned subsidiary of Leidos, Inc. As a result, this prohibition does not apply to the parent organization (Leidos, Inc.) or other subsidiary of the parent organization in its non-FFRDC operations.

1. Use of Contractor's Work Product

- i. The Contractor shall be ineligible to participate in any capacity in Government contracts, subcontracts, or proposals therefore (solicited and unsolicited) which stem directly from the Contractor's performance of work under this contract for a period of one (1) year after the completion of this contract. Furthermore, unless so directed in writing by the Contracting Officer, the Contractor shall not perform any advisory and assistance services work under this contract on any of its products or services or the products or services of another firm if the Contractor is or has been substantially involved in their development or marketing. Nothing in this subparagraph shall preclude the Contractor from competing for follow-on contracts.
- ii. If, under this contract, the Contractor prepares a complete or essentially complete statement of work or specifications to be used in competitive acquisitions, the Contractor shall be ineligible to perform or participate in any capacity in any contractual effort which is based on such statement of work or specifications. The Contractor shall not incorporate its products or services in such statement of work or specifications unless so directed in writing by the Contracting Officer, in which case the restriction in this subparagraph shall not apply.
- iii. Nothing in this Article shall preclude the Contractor from offering or selling its standard and commercial items to the Government, or from competing for a Cooperative Research and Development Agreement (CRADA).

2. Access to and use of information

- i. If the Contractor, in the performance of this contract, obtains access to information, such as Government plans, policies, reports, studies, financial plans, internal data protected by the Privacy Act of 1974 (5 U.S.C. 552a), or data which has not been released or otherwise made available to the public, the Contractor agrees that without prior written approval of the Contracting Officer it shall not—
  - A. use such information for any private purpose unless the information has been released or otherwise made available to the public;

- B. compete for work for the Government based on such information for a period of one (1) year after either the completion of this contract or until such information is released or otherwise made available to the public, whichever is first;
  - C. submit an unsolicited proposal to the Government which is based on such information until one year after such information is released or otherwise made available to the public; and
  - D. release such information unless such information has previously been released or otherwise made available to the public by the Government.
- ii. In addition, the Contractor agrees that to the extent it receives or is given access to proprietary data, data protected by the Privacy Act of 1974 (5 U.S.C. 552a), or other confidential or privileged technical, business, or financial information under this contract, it shall treat such information in accordance with any restrictions imposed on such information.
  - iii. The Contractor may use technical data it first produces under this contract for its private purposes consistent with paragraphs (b)(2)(i) (A) and (D) of this clause and the patent, rights in data, and security provisions of this contract.
- e. Disclosure after award. The Contractor shall make an immediate and full disclosure in writing to the Contracting Officer of any new organizational conflicts of interest that may arise during performance of this contract or any material changes to those previously identified. Such disclosure may include a description of any action which the Contractor has taken or proposes to take to avoid, neutralize, or mitigate any resulting conflict of interest.
  - f. Waiver. Requests for waiver under this clause shall be directed in writing to the Contracting Officer and shall include a full description of the requested waiver and the reasons in support thereof. If it is determined to be in the best interests of the Government, the Contracting Officer may grant such a waiver in writing.

**ARTICLE H.39. RESERVED**

**ARTICLE H.40. PERFORMANCE-BASED AWARD FEE PLAN**

The parties agree to augment the Performance-Based Award Fee Plan with specific goals and objectives as outlined in the Goals and Objectives Statement. The Goals and Objectives will be submitted according to the schedule outlined in the Plan. The Goals and Objectives are intended to maximize Contractor performance in such areas as cost and/or operating efficiency; environment, safety and health; new business development; technology transfer; technical performance; or any other areas of contract performance which are appropriate. It is the Government's intention that any additions and/or revisions to the Goals and Objectives Statement will be adopted and incorporated by mutual agreement between the Contractor, Project Officer and Contracting Officer; however, the Government reserves the right to unilaterally incorporate Goals and Objectives that the Government deems to be of value to the contract and FNLCR.

**ARTICLE H.41. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)**

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: <http://www.usfa.fema.gov/hotel/index.htm>

**ARTICLE H.42. POSSESSION, USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS**

Work involving select biological agents or toxins shall not be conducted under this contract until the contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the NIH that a process equivalent to that described in 42 CFR 73 (<http://www.cdc.gov/od/sap/docs/42cfr73.pdf>) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the contractor should provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes concise summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at <http://www.cdc.gov/od/sap/>.

**ARTICLE H.43. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL**

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user.

**ARTICLE H.44. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH**

Beginning April 7, 2008, NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: <http://www.pubmedcentral.nih.gov>.

Additional information is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>

**ARTICLE H.45. EXCEPTION TO THE DETERMINATION OF EXCEPTIONAL CIRCUMSTANCES - NANOTECHNOLOGY MAGNETIC RESONANCE IMAGING**

Pursuant to the Exception to the Determination of Exceptional Circumstances (DEC) signed on September 15, 2005 by the NIH Director, Contractor agrees to include and suitably modify to identify the parties, e.g., subcontractors, FAR Clause 52.227-11 Patent Rights- Retention by the Contractor (Short Form) (June 1997) in large business subcontracts, such that FAR Clause 52.227-11 will apply only to those subcontractor inventions that are directly related to the subcontractor's core magnetic resonance imaging (MRI) hardware and software technology used for imaging nanoparticles as part of the NCI's Nanotechnology Characterization Laboratory (NCL). The Contractor will also modify paragraph (f) of this clause to include the requirements in FAR 27.303 (a)(2)(i) through (iv). The frequency of reporting in (i) will be annual. This Exception explicitly does NOT change the DEC with respect to the nanoparticles characterized during the MRI development project. The majority of the nanoparticles will be submitted to the NCL by third-party collaborators. Accordingly, the provisions of the OTS DEC that direct inventions to the Government or to a collaborator designated by the Government will continue to be in effect for all other inventions. Accordingly, the Contractor will include FAR Clause 52.227-13 (Deviation) Patent Rights Acquisition by the Government [Patent Rights-Prime Contractor and Large Business Subcontractors] which will apply to all other inventions except for the subcontractor's core magnetic resonance imaging (MRI) hardware and software technology noted above.

**ARTICLE H.46, REQUIRED LANGUAGE FOR SUBCONTRACTS INVOLVING THIRD PARTY PROPRIETARY MATERIALS/DATA**

The Contractor will use the following language in all future subcontracts in support of the Translational Research Initiative for the Cancer Therapy Evaluation Program, NCI and any and all such future subcontracts where third party proprietary materials/data, identified in Section C: Statement of Work, are provided:

**Use of Deviated FAR Clause 52.227-11, Third Party Materials or Data**

Whereas, rights to inventions made under this subcontract using third-party proprietary materials or data are subject to the Deviated FAR Clause 52.227-11, Third Party Materials, of the prime contract between NCI and Leidos Biomedical Research, Inc. The Clause flows down to this subcontract from the prime contract and it is hereby incorporated by reference. The Deviated FAR Clause requires subcontractor to assign to the Government, or a third-party (NCI Collaborator) designated by the Government, subcontractor's rights in inventions made under the subcontract.

Whereas, the implementing Determination of Exceptional Circumstances executed by NIH Director Elias Zerhouni on September 5, 2004 anticipated the importance to the Government of the capability to direct the assignment of rights in subcontractor inventions developed using third-party proprietary materials and data to the NCI Collaborator as appropriate (Determination of Exceptional Circumstances, p. 7, copy provided).

NCI has determined that it is in the Government's interest, and appropriate under the present circumstances, to allow the subcontractor to retain rights in subject inventions pursuant to section 35 U.S.C. ' 202, subject to the requirements of that section and subject further to the subcontractor=s compliance with the requirements set forth herein below, including the subcontractor=s agreement to grant and granting of the following license and option to NCI Collaborators.

**License to NCI Collaborators of Proprietary Material and Data**

Subcontractor agrees to promptly notify the NCI and NCI Collaborator in writing of any inventions, discoveries or innovations (hereinafter "Subcontractor Inventions") made by the Subcontractor's principal investigator or any other employees or agents of Subcontractor, whether patentable or not, which are conceived or first actually reduced to practice in the performance of this study using NCI Collaborator's Study Drug or Agent.

Subcontractor agrees to grant and hereby grants to NCI Collaborator: (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Subcontractor Inventions for research purposes only; and (ii) a time-limited first option to negotiate an exclusive, or co-exclusive if applicable, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Subcontractor Inventions on terms to be negotiated in good faith by NCI Collaborator and Subcontractor. NCI Collaborator shall notify Subcontractor, in writing, of its interest in obtaining an exclusive license to any Subcontractor Invention within six (6) months of NCI Collaborator's receipt of notice of such Subcontractor Invention(s). In the event that NCI Collaborator fails to so notify Subcontractor, or elects not to obtain an exclusive license, then NCI Collaborator's option shall expire with respect to that Subcontractor Invention, and Subcontractor will be free to dispose of its interests in such Subcontractor Invention in accordance with Subcontractor's policies. If Subcontractor and NCI Collaborator fail to reach agreement within ninety (90) days, (or such additional period as NCI Collaborator and Subcontractor may agree) on the terms for an exclusive license for a particular Subcontractor Invention, then for a period of six (6) months thereafter Subcontractor shall not offer to license the Subcontractor Invention to any third party on materially better terms than those last offered to NCI Collaborator without first offering such terms to NCI Collaborator, in which case NCI Collaborator shall have a period of thirty (30) days in which to accept or reject the offer.

Subcontractor agrees that notwithstanding anything herein to the contrary, any inventions, discoveries or innovations, whether patentable or not, which are not Subject Inventions as defined in 35 USC 201(e)<sup>1</sup>, arising out of any unauthorized use of the NCI Collaborator's Study Drug and/or any modifications to the Study Drug, shall be the property of the NCI Collaborator (hereinafter "NCI Collaborator Inventions"). Subcontractor will promptly notify the NCI Collaborator in writing of any such NCI Collaborator Inventions and, at NCI Collaborator's request and expense, Subcontractor will cause to be assigned to NCI Collaborator all right, title and interest in and to any such NCI Collaborator Inventions and provide NCI Collaborator with reasonable assistance to obtain patents (including causing the execution of any invention assignment or other documents). Subcontractor may also be conducting other more basic research using the Study Drug under the authority of a separate Material Transfer Agreement (MTA), or other such agreement with the NCI Collaborator. Inventions arising thereunder shall be subject to the terms of the MTA or other such agreement, and not to this clause.

### **Combination Intellectual Property Option to NCI Collaborator**

For clinical studies involving combinations of investigational agents provided by more than one NCI Collaborator, Subcontractor agrees to grant and hereby grants a non-exclusive, fully paid and royalty-free license to Subcontractor Inventions incorporating such combination of investigational agents for all purposes, including commercial purposes, to each Third Party Provider providing an investigational agent for that study.

### **Protection of Proprietary Data**

"Clinical Data and Results and Raw Data will be provided exclusively to the NCI, the NCI Collaborator(s), and the FDA, as appropriate and unless additional disclosure is required by law or court order. Additionally, all Clinical Data and Results and Raw Data will be collected, used and disclosed consistent with all applicable federal statutes and regulations for the protection of human subjects, including, if applicable, the Standards for

Privacy of Individually Identifiable Health Information set forth in 45 C.F.R. Part 46. This provision shall not affect the investigators right to publish or present as described in the NCI/DCTD Standard Protocol Language." This statement ensures that data generated using an investigational agent proprietary to NCI Collaborator(s) will be kept confidential and shared only with the NCI, the FDA, and the NCI Collaborator. Furthermore, as described in the above-referenced NCI/DCTD Standard Protocol Language, this addresses the needs of the NCI Collaborator to have access to the patient records and raw data; it has no effect on the investigator's right to publish.

#### **ARTICLE H.47. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

#### **ARTICLE H.48. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS**

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: [http://www.ecfr.gov/cgi-bin/text-idx?SID=85cdadec111cc76a5995455e895e7c6e&tpl=/ecfrbrowse/Title45/45cfr94\\_main\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?SID=85cdadec111cc76a5995455e895e7c6e&tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl)

#### **ARTICLE H. 49. EXCHANGE OF CONFIDENTIAL INFORMATION AND RESEARCH MATERIALS**

##### Confidentiality

Pursuant to federal law (18 U.S.C. 1905, 15 U.S.C. 3710(a), 5 U.S.C. 552 (b) (4), 45CFR 46) and NIH policy (Standards of Ethical Conduct for Employees of the Executive Branch, 2635.703), NCI employees are obligated to maintain confidential information in confidence as part of their official duties. OTS contractor employees are hereby required to maintain confidential information confidential in their official duties to the same extent as NCI employees. Therefore, other sections of this contract notwithstanding, OTS contractor employees will keep information identified as or reasonably known to be confidential, including but not limited to, information belonging to the Government or information provided to the Government under a properly executed agreement (e.g., MTA, CDA, CRADA, MCRADA, CTA, Collaboration Agreement). Such obligations are documented in such transactional agreements substantially similar to those agreements currently found on the NCI Technology Transfer Center website (<http://ttc.nci.nih.gov>). Furthermore, the OTS contractor will flow down this obligation in its subcontracts and other agreements as appropriate. NCI agreements while not signed by the Contractor will reflect the potential for the Contractor to receive materials or information provided to NIH and that such materials and information will be handled by the Contractor consistent with its obligations herein.

The OTS contractor may independently receive third-party confidential information that was not originally intended to be shared with the NCI or other Government users of the OTS contract as part of the OTS contract management (e.g., pursuant to FAR 52.215-2 Audits & Records). In the course of managing the OTS contract, if

the OTS contractor identifies such third-party confidential information as confidential, NCI and other Government users of the OTS contract will keep such third-party confidential information confidential to the best of its ability according to policy and to the extent permitted by law.

No party will be obligated to keep information confidential: (i) that can be demonstrated to have been in the public domain or publicly known at the time of disclosure; or (ii) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to such Party from another source prior to the disclosure; or (iii) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by such Party; or (iv) that can be demonstrated as independently developed or acquired by such Party without reference to or reliance upon such Confidential Information; or (v) that is required to be disclosed by law or court order.

#### Third-party Materials Provided to NIH

Pursuant to federal law (15 U.S.C. 3710(a), 42 U.S.C., 241(a), 282(c), 284 (b)(1)(F)) and NIH policy (PHS Technology Transfer Manual, Chapters 400 & 500), NCI employees are obligated to retain appropriate control over third-party materials provided to NIH as part of their official duties. Such obligations are documented in transactional agreements (e.g., MTA, CRADA, MCRADA, CTA, Collaboration Agreement) substantially similar to those agreements currently found on the NCI Technology Transfer Center website (<http://ttc.nci.nih.gov>). OTS contractor employees are hereby required to maintain control over third-party materials provided through NIH from such third parties as part of their official duties to the same extent as NCI employees.

#### **ARTICLE H.50. NCI CAMPUS AT FREDERICK INFORMATION SYSTEM SECURITY OFFICER REQUIREMENT**

The Contractor will be responsible for, and have authority over, all Information System Security Officer (ISSO)-related functions at NCI Campus at Frederick, with support from the Scientific Program Office. The NCI Campus at Frederick ISSOs will be authorized to enforce applicable security requirements and policies for all information technology systems operating on the NCI Campus at Frederick network. This includes the authority to revoke access to and shut down systems on the NCI Campus at Frederick network in accordance with NIH and NCI security policies, whether the equipment is operated by federal personnel or their contractors. ISSO responsibilities are based on the NIH "ISSO IT Security Responsibilities" document at <http://irm.cit.nih.gov/security/ISSO%20Responsibilities.doc> and include, but are not limited to:

1. Serve as the principal contact for coordination, implementation, and enforcement of InfoSec policies with the NCI ISSO, the NIH Chief Information Security Officer (CISO), and the NIH senior ISSO.
2. Act as the contact for receiving and reporting abnormal alert reports, scan reports, security incidents and compromises, and other notifications from the HHS and NIH incident response teams (IRTs).
3. Represent the NCI Campus at Frederick's information-security (InfoSec) interests to NCI.
4. Stay informed about NCI Campus at Frederick's InfoSec needs.
5. Be familiar with federal, Department of Health and Human Services, NIH, and NCI InfoSec directives, policies, procedures, guidelines, and standards. See the following Web sites:
  - DHHS - [http://intranet.hhs.gov/infosec/policies\\_guides.html](http://intranet.hhs.gov/infosec/policies_guides.html)
  - NIH - <http://www.cit.nih.gov/security-policies.asp>
  - NIST - <http://csrc.nist.gov/publications/nistpubs/index.html>
6. Implement federal InfoSec directives and policies.
7. Keep up-to-date on policy changes.

8. Educate staff on policies and directives. Inform staff when there are changes.
9. Oversee development, implementation, and promulgation of objectives, goals, policies, standards, guidelines, and other InfoSec requirements.
10. Recommend improvements and updates to policies and procedures.
11. Inform management about the development of InfoSec system and application policies, guidelines, standards, requirements, and procedures.
12. Request exceptions to HHS, NIH, or NCI policies and procedures, if exclusion from the standard requirements is warranted.

**ARTICLE H.51. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352-270-5(b) (October 2009)**

- (a) Before undertaking performance of any contract involving animal related activities, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.
- (b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 through 2.11, or from a source that is exempt from licensing under those sections.
- (c) The Contractor agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and the pertinent laws and regulations of the United States Department of Agriculture ( see 7 U.S.C. 2131 *et seq.* and 9 CFR Subchapter A, Parts 1 - 4). In case of conflict between standards, the more stringent standard shall be used.
- (d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved PHS Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

(End of Clause)

**ARTICLE H.52. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD**

The Contractor shall not use contract funds to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

A listing of the conferences and/or meetings containing the following information that have been approved by the Contracting Officer and are hereby authorized under this contract are contained in the official contract file:

Conference or Meeting Title	Conference or Meeting Location	Federal/NonFederal Space	Date of Conference	Not to Exceed Estimate Cost
		<input type="checkbox"/> Federal <input type="checkbox"/> NonFederal		

**ARTICLE H.53. REGISTRATION FEES FOR CONFERENCES, WORKSHOPS AND MEETINGS**

A Non-Federal entity co-sponsoring a conference with an Institute/Center (IC) under a contract may charge and collect a registration fee from all participants for the purpose of defraying its portion of the expenses of the conference. Under these circumstances, the Contractor shall document that the registration fees associated with the event are being charged, collected and used solely by the co-sponsor.

Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government's estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted by the Contractor from the total cost of the conference.

In addition, prior to each conference, the Contractor shall provide the following information and documentation to the Contracting Officer's Representative (COR) and Contracting Officer:

1. Co-sponsor's name
2. Conference name, location, dates, times
3. Copy of the agenda
4. A completed "Contractor Pre-Conference Expense Offset Worksheet" (See 6. below).
5. After the conference is held, the Contractor shall submit a completed "Post-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the COR and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the COR and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the Contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury. If the registration fees collected are in excess of the uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.

Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the "Post-Conference Expense Offset Worksheet" has been approved by the COR.

6. Conference Expense Offset Worksheets

Contractor Pre-Conference Expense Offset Worksheet, dated 3/2008, 1 page. Located at:  
<http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Pre-Conf-worksheet.pdf>

Post Conference Expense Offset Worksheet, dated 3/2008, 2 pages. Located  
at: <http://oamp.od.nih.gov/DGS/FORMS/Post-Conf-worksheet.pdf>

**ARTICLE H.54. REGISTRATION FEES FOR NIH SPONSORED SCIENTIFIC, EDUCATIONAL, AND RESEARCH-RELATED CONFERENCES**

In accordance with the NIH Reform Act of 2006, P.L. 109-482, the NIH may authorize a Contractor procured to assist in the development and implementation of a scientific, educational or research-related conference to collect and retain registration fees from Non-HHS Federal and Non-Federal participants to defray the costs of the contract.

Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government's estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted from the total cost of the conference.

Prior to each conference, the Contractor shall submit a completed "Contractor Pre-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the Contracting Officer's Representative (COR) and Contracting Officer. After the conference is held, the Contractor shall submit a completed "Post-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the COR and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the COR and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury.

If the registration fees collected are in excess of the uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.

Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the "Post-Conference Expense Offset Worksheet" has been approved by the COR.

**ARTICLE H.55. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES**

Pursuant to the NIH Revitalization Act (P.L. 103-43, Section 206), which adds Section 402(b) to the Public Health Service Act, it is required that NIH, "in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." In addition, Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 require reasonable accommodations to be provided to individuals with disabilities.

It is NIH policy that organizers of scientific meetings should make a concerted effort to achieve appropriate representation of women, racial/ethnic minorities, and persons with disabilities, and other individuals who have been traditionally underrepresented in science, in all NIH sponsored and/or supported scientific meetings.

Therefore, it is the contractor's responsibility to ensure the inclusion of women, minorities, and persons with disabilities in all events when recruiting speakers and/or participants for meetings or conferences funded by this contract.

See the policy announcement for additional details and definitions at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html>

Therefore, it is the contractor's responsibility to ensure the inclusion of women, minorities, and persons with disabilities in all events when recruiting speakers and/or participants for meetings or conferences funded by this contract.

See the policy announcement for additional details and definitions at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html>

#### **ARTICLE H.56. USE OF FUNDS FOR PROMOTIONAL ITEMS**

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

#### **ARTICLE H.57. Bring Your Own Device (BYOD) Policy**

All authorized Contractor employees using their own personal mobile device to conduct government business shall follow the contractor's internal Standard Operating Procedures (SOPs). The SOP shall be in accordance with all applicable NIH IT security requirements and contract Article H.32, Information Security. The cost associated with the initial application for each individual related to the implementation of the BYOD Policy is an allowable cost, applicable to the provisions of FAR 52.216-7, Allowable Cost and Payment, incorporated into this contract.

#### **ARTICLE H.58. REVIEW OF MANUSCRIPTS**

In order to balance the oversight responsibility of the National Cancer Institute (NCI) with the authorization provided to the Contractor by the Rights in Data clause, 52.227-14 of this contract, the NCI does not require contractors to seek the Institute's approval of manuscripts and abstracts; however Government review of manuscripts and abstracts is required. This review process applies to Contractor authored or co-authored manuscripts and abstracts. Government authored or co-authored manuscripts and abstracts do not follow this review process.

The Contractor shall provide advance notice of intent to submit a manuscript to a peer reviewed journal for publication at least 10 business days prior to submission to the publisher to the appropriate Division, Office, or Center (DOC) Point of Contact. The advance notice should briefly describe the plans for publication of the

manuscript and include a copy of the manuscript Manuscripts are defined as – a scientific or technical report or abstract to be submitted to a peer-reviewed journal or conference for publication.

The Contractor shall provide advance notice of intent to submit an abstract to a conference for publication at least 2 business days prior to submission to the publisher to the appropriate Division, Office, or Center (DOC) Point of Contact. The advance notice should briefly describe the plans for publication of the abstract and include a copy of the abstract. An abstract is defined as any document that summarizes a professional publication, i.e. research article, thesis, review, conference proceeding or any in-depth analysis of a particular subject or discipline.

Any comments from the DOC Point of Contact will be provided in writing within the 10 business day review period for manuscripts and within the 2 business day review period for abstracts. In the event that no comments are received in the specified timeframes allotted above, it will result in “review with no comments” and the Contractor may proceed with submittal. Comments expressed by the DOC Point of Contact about the manuscript shall not be a cause for action under the Disputes clause of the contract by either NCI or the Contractor.

**PART II - CONTRACT CLAUSES**

**SECTION I - CONTRACT CLAUSES**

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP. **ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT**

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: <https://www.acquisition.gov/far/>. HHSAR Clauses at: <http://www.hhs.gov/policies/hhsar/subpart352.html>.

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

<b><u>FAR CLAUSE NO.</u></b>	<b><u>DATE</u></b>	<b><u>TITLE</u></b>
52.202-1	Jan 2012	Definitions (Over \$100,000)
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over \$100,000)
52.203-7	Oct 2010	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of

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<b><u>FAR</u></b> <b><u>CLAUSE NO.</u></b>	<b><u>DATE</u></b>	<b><u>TITLE</u></b>
		Whistleblower Rights.
52.203-99	Feb 2015	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements (DEVIATION)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over \$100,000)
52.204-10	Jul 2013	Reporting Executive Compensation and First-Tier Subcontract Awards (\$25,000 or more)
52.204-13	July 2013	System for Award Management Maintenance
52.209-6	Dec 2010	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$30,000)
52.215-2	Oct 2010	Audit and Records - Negotiation (Alternate 1 (MAR 2009) [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over \$100,000 funded exclusively with non-Recovery Act funds.]
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data (Over \$700,000)
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over \$700,000)
52.215-14	Oct 2010	Integrity of Unit Prices (Over Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over \$700,000)
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)
52.216-7	Jun 2011	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.219-8	Oct 2014	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
52.219-9	Oct 2014	Small Business Subcontracting Plan (Over \$650,000, \$1,500,000 for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$650,000, \$1,500,000 for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (Note: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor

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<b><u>FAR</u></b> <b><u>CLAUSE NO.</u></b>	<b><u>DATE</u></b>	<b><u>TITLE</u></b>
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Apr 2015	Equal Opportunity
52.222-35	Jul 2014	Equal Opportunity for Veterans (Over \$100,000)
52.222-36	Jul 2014	Affirmative Action for Workers with Disabilities
52.222-37	Jul 2014	Employment Reports on Veterans (Over \$100,000)
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Aug 2013	Employment Eligibility Verification
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-1	Feb 2009	Buy American Act – Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Dec 2007	Rights in Data – General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest (Over Simplified Acquisition Threshold)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer--Central Contractor Registration
52.233-1	Jul 2002	Disputes

<b><u>FAR</u></b> <b><u>CLAUSE NO.</u></b>	<b><u>DATE</u></b>	<b><u>TITLE</u></b>
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2014	Penalties for Unallowable Costs (Over \$700,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over \$100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Oct 2010	Subcontracts, Alternate I (June 2007) (Over the Simplified Acquisition Threshold)
52.244-5	Dec 1996	Competition in Subcontracting (Over the Simplified Acquisition Threshold)
52.244-6	Apr 2015	Subcontracts for Commercial Items
52.245-1	Apr 2012	Government Property
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over the Simplified Acquisition Threshold)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

<b><u>HHSAR</u></b> <b><u>CLAUSE NO.</u></b>	<b><u>DATE</u></b>	<b><u>TITLE</u></b>
352.202-1	Jan 2006	<i>Definitions - with Alternate paragraph (h) (Jan 2006)</i>
352.203-70	Mar 2012	<i>Anti-Lobbying</i>
352.216-70	Jan 2006	<i>Additional Cost Principles</i>
352.222-70	Jan 2010	<i>Contractor Cooperation in Equal Employment Opportunity Investigations</i>

<b><u>HHSAR CLAUSE NO.</u></b>	<b><u>DATE</u></b>	<b><u>TITLE</u></b>
352.227-70	Jan 2006	Publications and Publicity
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.233-71	Jan 2006	Litigation and Claims
352.242-70	Jan 2006	Key Personnel
352.242-73	Jan 2006	Withholding of Contract Payments
352.242-74	Apr 1984	Final Decisions on Audit Findings

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT- Rev. 10/2013].

**ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES**

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

1. 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 therefore. [NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]
  
2. Alternate I (March 2009) of FAR Clause 52.215-2, Audit and Records--Negotiation (March 2009) is added.

**ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES**

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

- a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES
  1. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (April 2010).
  2. FAR Clause 52.203-14, Display of Hotline Poster(s) (December 2007).

"...(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From
HHS Contractor Code of Ethics and Business Conduct Poster	<a href="http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf">http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf</a>

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3. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
4. FAR Clause **52.209-10, Prohibition on Contracting with Inverted Domestic Corporations** (Dec 2014).
5. FAR Clause **52.210-1, Market Research** (April 2011).
6. FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).
7. Reserved
8. Reserved
9. FAR Clause 52.222-4, Contract Work Hours and Safety Standards Act - Overtime Compensation - General (December 2010).
10. FAR Clause 52.223-3, Hazardous Material Identification and Material Safety Data (January 1997), with Alternate I (July 1995).
11. FAR Clause 52.223-5, Pollution Prevention and Right-to-Know Information (May 2011).
12. FAR Clause 52.223-10, Waste Reduction Program (May 2011).
13. FAR Clause 52.223-12, Refrigeration Equipment and Air Conditioners (May 1995).
14. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).
15. FAR Clause 52.223-16, IEEE 1680 Standard for the Environmental Assessment of Personal Computer Products (December 2007).
16. FAR Clause **52.223-19, Compliance with Environmental Management Systems** (May 2011)
17. FAR Clause 52.224-1, Privacy Act Notification (April 1984).
18. FAR Clause 52.224-2, Privacy Act (April 1984).
19. FAR Clause 52.225-8, Duty-Free Entry (February 2000).
20. FAR Clause 52.226-1, Utilization of Indian organizations and Indian-owned Economic Enterprises (June 2000).
21. FAR Clause 52.227-16, Additional Data Requirements (June 1987).
22. FAR Clause 52.227-17, Rights in Data--Special Works (December 2007).
23. FAR Clause 52.227-19, Commercial Computer Software License (December 2007).
24. FAR Clause 52.230-2, Cost Accounting Standards (May 2012).
25. FAR Clause 52.230-6, Administration of Cost Accounting Standards (June 2010).

26. FAR Clause 52.237-2, Protection of Government Buildings, Equipment and Vegetation (April 1984).
27. FAR Clause 52.239-1, Privacy or Security Safeguards (August 1996).
28. FAR Clause 52.244-5, Competition in Subcontracting (December 1996).
29. FAR Clause 52.247-63, Preference for U.S. Flag Air Carriers (June 2003).
30. FAR Clause 52.247-64, Preference for Privately Owned U.S. Flag Commercial Vessels (February 2006).
31. FAR Clause 52.248-1, Value Engineering (October 2010).
32. FAR Clause 52.251-1, Government Supply Sources (April 2012)
33. FAR Clause **52.203-15, Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009** (June 2010)

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

1. HHSAR Clause **352.223-70, Safety and Health** (January 2010).
2. Reserved.
3. HHSAR Clause **352.231-70, Salary Rate Limitation** (January 2010). *For FY2015, the Consolidated Appropriations Act, 2015 (Public Law 113-235) signed into law on January 17, 2014, restricts the amount of direct salary to Executive Level II of the Federal Executive Pay scale. The Executive Level II salary has increased to \$183,300 effective January 11, 2015.*
4. HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).
5. HHSAR Clause **352.270-4(b), Protection of Human Subjects** (January 2006).
6. Reserved.
7. HHSAR Clause **352.270-13, Tobacco-Free Facilities** (January 2006).
8. HHSAR Clause **352.270-7, Conference Sponsorship Request and Materials Disclaimer** (Jan 2010)

**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 52.227-13 (Deviation) Patent Rights-Acquisition by the Government (DEC 2007) [Patent Rights- OTS Prime Contractor]. See Attachment 8.

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- b. FAR 52.227-11 (Deviation) Patent Rights--Ownership by the Contractor (DEC 2007) [Patent Rights-Use of Third-party Technology and Information by OTS Subcontractors]. See Attachment 9.
- c. FAR 52.227-11 (Deviation) Patent Rights--Ownership by the Contractor (DEC 2007) [Patent Rights-NCI Full-length cDNA Initiative]. See Attachment 10.
- d. FAR 52.227 11, (Deviation) Patent Rights --Ownership by the Contractor (DEC 2007) [Patent Rights--NCI Initiative for Chemical Genetics (ICG)] (formerly called the Molecular Targets Laboratories (MTL) Initiative). See Attachment 11.
- e. FAR (Deviation) 52.227-14 Rights in Data-General (DEC 2007) [Rights in Data-NCI Full-length cDNA Initiative]. See Attachment 12.
- f. FAR 52.227-14 (Deviation) Rights in Data-General (DEC 2007) [Initiative for Chemical Genetics (ICG)] (formerly called the Molecular Targets Laboratories (MTL) Initiative).See Attachment 13.
- g. FAR 52.227-17 (Deviation) Rights in Data--Special Works (DEC 2007) [Rights in Data-Use of Third-party Technology and Information]. See Attachment 14.
- h. FAR Clause 52.203-15, Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (March 2009)

(a) The Contractor shall post notice of employees rights and remedies for whistleblower protections provided under section 1553 of the American Recovery and Reinvestment Act of 2009 (Pub.L. 111-5).

(b) The Contractor shall include the substance of this clause including this paragraph (b) in all subcontracts.

(End of Clause)

FAR Clause 52.204-11, American Recovery and Reinvestment Act--Reporting Requirements (March 2009) - **REMOVED**

(a) *Definitions.* As used in this clause--

*Contract*, as defined in FAR 2.101, means a mutually binding legal relationship obligating the seller to furnish the supplies or services (including construction) and the buyer to pay for them. It includes all types of commitments that obligate the Government to an expenditure of appropriated funds and that, except as otherwise authorized, are in writing. In addition to bilateral instruments, contracts include (but are not limited to) awards and notices of awards; job orders or task letters issued under basic ordering agreements; letter contracts; orders, such as purchase orders, under which the contract becomes effective by written acceptance or performance; and bilateral contract modifications. Contracts do not include grants and cooperative agreements covered by 31 U.S.C. 6301, et seq. For discussion of various types of contracts, see FAR Part 16.

*First-tier subcontract* means a subcontract awarded directly by a Federal Government prime contractor whose contract is funded by the Recovery Act.

*Jobs created* means an estimate of those new positions created and filled, or previously existing unfilled positions that are filled, as a result of funding by the American Recovery and Reinvestment Act of 2009 (Recovery Act). This definition covers only prime contractor positions established in the United States and outlying areas (see definition in FAR 2.101). The number shall be expressed as "full-time equivalent" (FTE), calculated cumulatively as all hours worked divided by the total number of hours in a full-time schedule, as defined by the contractor. For instance, two full-time employees and one part-time employee working half days would be reported as 2.5 FTE in each calendar quarter.

*Jobs retained* means an estimate of those previously existing filled positions that are retained as a result of funding by the American Recovery and Reinvestment Act of 2009 (Recovery Act). This definition covers only prime contractor positions established in the United States and outlying areas (see definition in FAR 2.101). The number shall be expressed as "full-time equivalent" (FTE), calculated cumulatively as all hours worked divided by the total number of hours in a full-time schedule, as defined by the contractor. For instance, two full-time employees and one part-time employee working half days would be reported as 2.5 FTE in each calendar quarter.

*Total compensation* means the cash and noncash dollar value earned by the executive during the contractor's past fiscal year of the following (for more information see 17 CFR 229.402(c)(2)):

- (1) *Salary and bonus* .
- (2) *Awards of stock, stock options, and stock appreciation rights* . Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.
- (3) *Earnings for services under non-equity incentive plans*. Does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
- (4) *Change in pension value*. This is the change in present value of defined benefit and actuarial pension plans.
- (5) *Above-market earnings on deferred compensation which is not tax-qualified*. (6). *Other compensation*. For example, severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property if the value for the executive exceeds \$10,000.

(b) This contract requires the contractor to provide products and/or services that are funded under the American Recovery and Reinvestment Act of 2009 (Recovery Act). Section 1512(c) of the Recovery Act requires each contractor to report on its use of Recovery Act funds under this contract. These reports will be made available to the public.

(c) Reports from contractors for all work funded, in whole or in part, by the Recovery Act, and for which an invoice is submitted prior to June 30, 2009, are due no later than July 10, 2009. Thereafter, reports shall be submitted no later than the 10th day after the end of each calendar quarter.

(d) The Contractor shall report the following information, using the online reporting tool available at <http://www.FederalReporting.gov> .

- (1) The Government contract and order number, as applicable.
- (2) The amount of Recovery Act funds invoiced by the contractor for the reporting period. A cumulative amount from all the reports submitted for this action will be maintained by the government's on-line reporting tool.
- (3) A list of all significant services performed or supplies delivered, including construction, for which the contractor invoiced in this calendar quarter.
- (4) Program or project title, if any.
- (5) A description of the overall purpose and expected outcomes or results of the contract, including significant deliverables and, if appropriate, associated units of measure.
- (6) An assessment of the contractor's progress towards the completion of the overall purpose and expected outcomes or results of the contract (i.e., not started, less than 50 percent completed, completed 50 percent or more, or fully completed). This covers the contract (or portion thereof) funded by the Recovery Act.
- (7) A narrative description of the employment impact of work funded by the Recovery Act. This narrative should be cumulative for each calendar quarter and only address the impact on the contractor's workforce. At a minimum, the contractor shall provide--
  - (i) A brief description of the types of jobs created and jobs retained in the United States and outlying areas (see definition in FAR 2.101). This description may rely on job titles, broader labor categories, or the contractor's existing practice for describing jobs as long as the terms used are widely understood and describe the general nature of the work; and
  - (ii) An estimate of the number of jobs created and jobs retained by the prime contractor, in the United States and outlying areas. A job cannot be reported as both created and retained.
- (8) Names and total compensation of each of the five most highly compensated officers of the Contractor for the calendar year in which the contract is awarded if--
  - (i) In the Contractor's preceding fiscal year, the Contractor received--
    - (A) 80 percent or more of its annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants) and cooperative agreements; and
    - (B) \$25,000,000 or more in annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants) and cooperative agreements; and
  - (ii) The public does not have access to information about the compensation of the senior executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986.
- (9) For subcontracts valued at less than \$25,000 or any subcontracts awarded to an individual, or subcontracts awarded to a subcontractor that in the previous tax year had gross income under \$300,000, the Contractor shall only report the aggregate number of such first tier subcontracts awarded in the quarter and their aggregate total dollar amount.
- (10) For any first-tier subcontract funded in whole or in part under the Recovery Act, that is over \$25,000 and not subject to reporting under paragraph 9, the contractor shall require the subcontractor to provide the information described in (i), (ix), (x), and (xi) below to the contractor for the purposes of the quarterly report. The contractor shall advise the subcontractor that the information will be made available to the public as required by section 1512 of the Recovery Act. The contractor shall provide detailed information on these first-tier subcontracts as follows:
  - (i) Unique identifier (DUNS Number) for the subcontractor receiving the award and for the subcontractor's parent company, if the subcontractor has a parent company.
  - (ii) Name of the subcontractor.

- (iii) Amount of the subcontract award.
- (iv) Date of the subcontract award.
- (v) The applicable North American Industry Classification System (NAICS) code.
- (vi) Funding agency.
- (vii) A description of the products or services (including construction) being provided under the subcontract, including the overall purpose and expected outcomes or results of the subcontract.
- (viii) Subcontract number (the contract number assigned by the prime contractor).
- (ix) Subcontractor's physical address including street address, city, state, and country. Also include the nine-digit zip code and congressional district if applicable.
- (x) Subcontract primary performance location including street address, city, state, and country. Also include the nine-digit zip code and congressional district if applicable.
- (xi) Names and total compensation of each of the subcontractor's five most highly compensated officers, for the calendar year in which the subcontract is awarded if--

(A) In the subcontractor's preceding fiscal year, the subcontractor received--

- (1) 80 percent or more of its annual gross revenues in Federal contracts (and subcontracts), loans, grants (and subgrants), and cooperative agreements; and
- (2) \$25,000,000 or more in annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants), and cooperative agreements; and

(B) The public does not have access to information about the compensation of the senior executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986.

(End of clause)

a. FAR Clause 52.225-21, Required Use of American Iron, Steel, and Manufactured Goods-Buy American Act--Construction Materials (October 2010)

(a) *Definitions* . As used in this clause—

*Construction material* means an article, material, or supply brought to the construction site by the Contractor or a subcontractor for incorporation into the building or work. The term also includes an item brought to the site preassembled from articles, materials, or supplies. However, emergency life safety systems, such as emergency lighting, fire alarm, and audio evacuation systems, that are discrete systems incorporated into a public building or work and that are produced as complete systems, are evaluated as a single and distinct construction material regardless of when or how the individual parts or components of those systems are delivered to the construction site. Materials purchased directly by the Government are supplies, not construction material.

*Domestic construction material means --*

(1) An unmanufactured construction material mined or produced in the United States (The Buy America Act applies)

(2) A manufactured construction material that is manufactured in the United and, if the construction material consists wholly or predominantly of iron or steel, the iron or steel was produced in the United States. (Section 1605 of the Recovery Act applies.)

*Manufactured construction material* means any construction material that is not unmanufactured construction material.

*Steel* means an alloy that includes at least 50 percent iron, between .02 and 2 percent carbon, and may include other elements.

*United States* means the 50 States, the District of Columbia, and outlying areas.

*Unmanufactured construction material* means raw material brought to the construction site for incorporation into the building or work that has not been--

- (1) Processed into a specific form and shape; or
- (2) Combined with other raw material to create a material that has different properties than the properties of the individual raw materials.

(b) *Domestic preference.* (1) This clause implements--

- (i) Section 1605 of the American Recovery and Reinvestment Act of 2009 (Recovery Act) (Pub. L. 11-5), by requiring, unless an exception applies, that all iron, steel, and other manufactured goods used as construction material in the project is manufactured in the United States and, if the construction material consists wholly or predominantly of iron or steel, the iron or steel was produced in the United States (produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, except metallurgical processes involving refinement of steel additives); and
- (ii) The Buy American Act (41 U.S.C. 10a-10d) by providing a preference for unmanufactured construction material mined or produced in the United States over unmanufactured construction material mined or produced in a foreign country.

(2) The Contractor shall use only domestic construction material in performing this contract, except as provided in paragraph (b)(3) and (b)(4) of this clause.

(3) This requirement does not apply to the construction material or components listed by the Government as follows:   none  

*[Contracting Officer to list applicable excepted materials or indicate "none"]*

(4) The Contracting Officer may add other foreign construction material to the list in paragraph (b)(3) of this clause if the Government determines that--

- (i) The cost of domestic construction material would be unreasonable.

(A) The cost of domestic manufactured construction material, when compared to the cost of comparable foreign manufactured construction material, is unreasonable when the cumulative cost of such material will increase the cost of the contract by more than 25 percent

(B) The cost of domestic unmanufactured construction material is unreasonable when the cost of such material exceeds the cost of comparable foreign unmanufactured construction material by more than 6 percent;

(ii) The construction material is not mined, produced, or manufactured in the United States in sufficient and reasonably available quantities and of a satisfactory quality; or

(iii) The application of the restriction of section 1605 of the Recovery Act to a particular manufactured construction material would be inconsistent with the public interest or the application of the Buy American Act to a particular unmanufactured construction material would be impracticable or inconsistent with the public interest.

(c) *Request for determination of inapplicability of Section 1605 of the Recovery Act or the Buy American Act.* (1)(i) Any Contractor request to use foreign construction material in accordance with paragraph (b)(4) of this clause shall include adequate information for Government evaluation of the request, including--

A description of the foreign and domestic construction materials;

(B) Unit of measure;

(C) Quantity;

(D) Cost;

(E) Time of delivery or availability;

(F) Location of the construction project

(G) Name and address of the proposed supplier; and

(H) A detailed justification of the reason for use of foreign construction materials cited in accordance with paragraph (b)(4) of this clause.

(ii) A request based on unreasonable cost shall include a reasonable survey of the market and a completed cost comparison table in the format in paragraph (d) of this clause.

(iii) The cost of construction material shall include all delivery costs to the construction site and any applicable duty.

(iv) Any Contractor request for a determination submitted after contract award shall explain why the Contractor could not reasonably foresee the need for such determination and could not have requested the determination before contract award. If the Contractor does not submit a satisfactory explanation, the Contracting Officer need not make a determination.

(2) If the Government determines after contract award that an exception to section 1605 of the Recovery Act or the Buy American Act applies and the Contracting Officer and the Contractor negotiate adequate consideration, the Contracting Officer will modify the contract to allow use of the foreign construction material. However, when the basis for the exception is the unreasonable cost of a domestic construction material, adequate consideration is not less than the differential established in paragraph (b)(4)(i) of this clause.

(3) Unless the Government determines that an exception to section 1605 of the Recovery Act or the Buy American Act applies, use of foreign construction material is noncompliant with section 1605 of the American Recovery and Reinvestment Act or the Buy American Act.

(d) *Data* . To permit evaluation of requests under paragraph (c) of this clause based on unreasonable cost, the Contractor shall include the following information and any applicable supporting data based on the survey of suppliers:

**FOREIGN AND DOMESTIC CONSTRUCTION MATERIALS PRICE COMPARISON**

<b>Construction Material Description</b>	<b>Unit of Measure</b>	<b>Quantity</b>	<b>Price (dollars)*</b>
Item 1			
Foreign construction material			
Domestic construction material			
Item 2			
Foreign construction material			
Domestic construction material			

*[ List name, address, telephone number, and contact for suppliers surveyed. Attach copy of response; if oral, attach summary.] [ Include other applicable supporting information.]*

*[\* Include all delivery costs to the construction site.]*

(End of clause)

b. FAR Clause 52.225-23, Required Use of American Iron, Steel, and Other Manufactured Goods--Buy American Act--Construction Materials Under Trade Agreements (April2012)

(a) *Definitions* . As used in this clause--  
*Construction material* means an article, material, or supply brought to the construction site by the Contractor or subcontractor for incorporation into the building or work. The term also includes an item brought to the site preassembled from articles, materials, or supplies. However, emergency life safety systems, such as emergency lighting, fire alarm, and audio evacuation systems, that are discrete systems incorporated into a public building or work and that are produced as complete systems, are evaluated as a single and distinct construction material regardless of when or how the individual parts or components of those systems are delivered to the construction site.

*Designated country* means any of the following countries:

- (1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Aruba, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway,

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Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, or United Kingdom);

(2) A Free Trade Agreement (FTA) country (Australia, Bahrain, Canada, Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Morocco, Nicaragua, Oman, Peru, or Singapore);

(3) A least developed country (Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, East Timor, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Laos, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Tanzania, Togo, Tuvalu, Uganda, Vanuatu, Yemen, or Zambia); or

(4) A Caribbean Basin country (Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, British Virgin Islands, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Netherlands Antilles, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, or Trinidad and Tobago).

*Designated country construction material* means a construction material that is a WTO GPA country construction material, an FTA country construction material, a least developed country construction material, or a Caribbean Basin country construction material.

*Domestic construction material* means the following--

(1) An unmanufactured construction material mined or produced in the United States (The Buy American Act applies.)

(2) A manufactured construction material that is manufactured in the United States and, if the construction material consists wholly or predominantly of iron or steel, the iron or steel was produced in the United States. (Section 1605 of the Recovery Act applies.)

*Foreign construction material* means a construction material other than a domestic construction material.

*Free trade agreement (FTA) country construction material* means a construction material that--

- (1) Is wholly the growth, product, or manufacture of an FTA country; or
- (2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in an FTA country into a new and different construction material distinct from the materials from which it was transformed.

*Least developed country construction material* means a construction material that--

- (1) Is wholly the growth, product, or manufacture of a least developed country; or
- (2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a least developed country into a new and different construction material distinct from the materials from which it was transformed.

*Manufactured construction material* means any construction material that is not unmanufactured construction material.

*Nondesignated country* means a country other than the United States or a designated country

*Recovery Act designated country* means any of the following countries:

(1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Aruba, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, or United Kingdom);

(2) A Free Trade Agreement country (FTA)(Australia, Bahrain, Canada, Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Israel, Mexico, Morocco, Nicaragua, Oman, Peru, or Singapore); or

(3) A least developed country (Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, East Timor, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Laos, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Tanzania, Togo, Tuvalu, Uganda, Vanuatu, Yemen, or Zambia).

*Recovery Act designated country construction material* means a construction material that is a WTO GPA country construction material, an FTA country construction material, or a least developed country construction material.

*Steel* means an alloy that includes at least 50 percent iron, between .02 and 2 percent carbon, and may include other elements.

*United States* means the 50 States, the District of Columbia, and outlying areas.

*Unmanufactured construction material* means raw material brought to the construction site for incorporation into the building or work that has not been--

- (1) Processed into a specific form and shape; or
- (2) Combined with other raw material to create a material that has different properties than the properties of the individual raw materials.

*WTO GPA country construction material* means a construction material that--

- (1) Is wholly the growth, product, or manufacture of a WTO GPA country; or
- (2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country into a new and different construction material distinct from the materials from which it was transformed.

(b) *Construction materials.* (1) The restrictions of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) and the Buy American Act (41 U.S.C. 10a-10d) do not apply to Recovery Act designated country construction material. Consistent with U.S. obligations under international agreements, this clause implements--

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- (i) Section 1605 of the Recovery Act by requiring, unless an exception applies, that all manufactured construction material in the project is manufactured in the United States and, if the construction material consists wholly or predominantly of iron or steel, the iron or steel was produced in the United States (produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, except metallurgical processes involving refinement of steel additives); and
- (ii) The Buy American Act by providing a preference for unmanufactured domestic construction material mined or produced in the United States over unmanufactured construction material mined or produced in a nondesignated country.

(2) The Contractor shall use only domestic or Recovery Act designated country construction material in performing this contract, except as provided in paragraphs (b)(3) and (b)(4) of this clause.

(3) The requirement in paragraph (b)(2) of this clause does not apply to the construction materials or components listed by the Government as follows: None

*[Contracting Officer to list applicable excepted materials or indicate "none"]*

(4) The Contracting Officer may add other construction material to the list in paragraph (b)(3) of this clause if the Government determines that--

(i) The cost of domestic construction material would be unreasonable.

(A) The cost of domestic iron, steel, or other manufactured goods used as construction material is unreasonable when the cumulative cost of such material will increase the overall cost of the contract by more than 25 percent;

(B) The cost of unmanufactured construction material is unreasonable when the cost of such material exceeds the cost of foreign material by more than 6 percent;

(ii) The construction material is not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities of a satisfactory quality; or

(iii) The application of the restriction of section 1605 of the Recovery Act or the Buy American Act to a particular construction material would be inconsistent with the public interest.

(c) *Request for determination of inapplicability of section 1605 of the Recovery Act or the Buy American Act.*

(1)(i) Any Contractor request to use foreign construction material in accordance with paragraph (b)(4) of this clause shall include adequate information for Government evaluation of the request, including--

(A) A description of the foreign and domestic construction materials;

(B) Unit of measure;

(C) Quantity;

(D) Cost;

(E) Time of delivery or availability;

(F) Location of the construction project;

(G) Name and address of the proposed supplier; and  
 (H) A detailed justification of the reason for use of foreign construction materials cited in accordance with paragraph (b)(4) of this clause.

(ii) A request based on unreasonable cost shall include a reasonable survey of the market and a completed cost comparison table in the format in paragraph (d) of this clause.

(iii) The cost of construction material shall include all delivery costs to the construction site and any applicable duty.

(iv) Any Contractor request for a determination submitted after contract award shall explain why the Contractor could not reasonably foresee the need for such determination and could not have requested the determination before contract award. If the Contractor does not submit a satisfactory explanation, the Contracting Officer need not make a determination.

(2) If the Government determines after contract award that an exception to section 1605 of the Recovery Act or the Buy American Act applies and the Contracting Officer and the Contractor negotiate adequate consideration, the Contracting Officer will modify the contract to allow use of the foreign construction material. However, when the basis for the exception is the unreasonable cost of a domestic construction material, adequate consideration is not less than the differential established in paragraph (b)(4)(i) of this clause.

(3) Unless the Government determines that an exception to the section 1605 of the Recovery Act or the Buy American Act applies, use of foreign construction material other than that covered by trade agreements is noncompliant with the applicable Act.

(d) *Data*. To permit evaluation of requests under paragraph (c) of this clause based on unreasonable cost, the Contractor shall include the following information and any applicable supporting data based on the survey of supplier.

**FOREIGN AND DOMESTIC CONSTRUCTION MATERIALS COST COMPARISON**

<b>Construction material description</b>	<b>Unit of measure</b>	<b>Quantity</b>	<b>Cost (dollars)*</b>
Item 1:			
Foreign construction material			
Domestic construction material			
Item 2:			
Foreign construction material			
Domestic construction material			

*[ List name, address, telephone number, and contact for suppliers surveyed. Attach copy of response; if oral, attach summary.] [ Include other applicable supporting information.]*  
*[\* Include all delivery costs to the construction site.]*

(End of clause)

- c. Alternate I (March 2009) FAR Clause 52.225-23, Required Use of American Iron, Steel, and Other Manufactured Goods-Buy American Act-Construction Materials under Trade Agreements (March 2009)

As prescribed in 25.1102(e), add the following definition of "Bahrainian, Mexican, or Omani construction material" to paragraph (a) of the basic clause, and substitute the following paragraphs (b)(1) and (b)(2) for paragraphs (b)(1) and (b)(2) of the basic clause:

*Bahrainian, Mexican, or Omani construction material" means a construction material that --*

- (1) Is wholly the growth, product, or manufacture of Bahrain, Mexico, or Oman; or  
(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in Bahrain, Mexico, or Oman into a new and different construction material distinct from the materials from which it was transformed.

(b) *Construction materials.* (1) The restrictions of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) and the Buy American Act do not apply to Recovery Act designated country construction material. Consistent with U.S. obligations under international agreements, this clause implements-

- (i) Section 1605 of the Recovery Act, by requiring, unless an exception applies, that all iron, steel, and other manufactured goods used as construction material in the project are produced in the United States; and  
(ii) The Buy American Act providing a preference for unmanufactured domestic construction material.

(2) The Contractor shall use only domestic or Recovery Act designated country construction material other than Bahrainian, Mexican, or Omani construction material in performing this contract, except as provided in paragraphs (b)(3) and (b)(4) of this clause.

#### **ARTICLE I.5. SERVICE CONTRACT ACT**

This contract is subject to the Service Contract Act of 1965, as amended. The following clauses are hereby incorporated and made a part of this contract. All clauses incorporated by reference have the same force and effect as if they were given full text. Upon request, the Contracting Officer will make their full text available.

FAR Clause 52.222-41, SERVICE CONTRACT ACT OF 1965, as amended (NOVEMBER 2007).

FAR Clause 52.222-42, STATEMENT OF EQUIVALENT RATES FOR FEDERAL HIRES (JULY 2005)

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In compliance with the Service Contract Act of 1965, as amended, and the regulations of the Secretary of Labor (29 CFR Part 4), this clause identifies the classes of service employees expected to be employed under the contract and states the wages and fringe benefits payable to each if they were employed by the contracting agency subject to the provisions of 5 U.S.C. 5341 or 5332.

THIS STATEMENT IS FOR INFORMATION ONLY: IT IS NOT A WAGE DETERMINATION

<u>CLASS OF EMPLOYEE</u>	<u>HOURLY WAGE</u>
Accounting Clerk I	\$11.91
Accounting Clerk II	\$13.00
Accounting Clerk III	\$14.59
Accounting Clerk IV	\$16.33
Alarm Monitor	\$16.33
Animal Caretaker	\$18.16
Carpenter, Maintenance	\$30.69
Computer System Analyst I	\$27.74
Computer Operator I	\$14.59
Computer Operator II	\$16.33
Computer Operator III	\$20.22
Computer Programmer I	\$16.33
Computer Programmer II	\$20.22
Dishwasher	\$12.62
Document Preparation Clerk	\$13.00
Drafter I	\$13.00
Drafter II	\$14.59
Drafter III	\$16.33
Drafter IV	\$20.22
Driver, Messenger	\$14.47
Duplicating Machine Operator	\$13.00

<u>CLASS OF EMPLOYEE</u>	<u>HOURLY WAGE</u>
Elec. Tech., Maint. I	\$25.45
Elec. Tech., Maint. II	\$26.93
Elec. Tech., Maint. III	\$28.45
Electrician, Maintenance	\$28.45
Engineering Tech. I	\$13.00
Engineering Tech. II	\$14.59
Engineering Tech. III	\$16.33
Environmental Technician	\$20.22
Gardener	\$19.82
General Clerk I	\$11.44
General Clerk II	\$11.63
General Clerk III	\$12.69
General Clerk IV	\$14.25
General Maintenance Worker	\$23.05
Guard I	\$14.25
Guard II	\$15.94
Heat, Ref., Air Cond. Mechanic	\$25.77
Heavy Equipment Mechanic	\$25.77
Housekeeping Aid II	\$123.10
Illustrator I	\$15.94
Illustrator II	\$19.75
Illustrator III	\$24.96
Industrial Hygiene Tech.	\$14.25
Inspector	\$19.75
Instrument Mechanic	\$25.77
Insulator	\$25.77

<u>CLASS OF EMPLOYEE</u>	<u>HOURLY WAGE</u>
Janitor	\$13.10
Key Entry Operator I	\$11.63
Key Entry Operator II	\$12.69
Laboratory Technician	\$17.77
Laborer	\$13.10
Laborer, Grounds Maintenance	\$14.78
Locksmith	\$24.46
Machine Tool Operator	\$24.46
Machinery Maint. Mechanic	\$25.77
Machinist, Maintenance	\$25.77
Mail Clerk	\$12.69
Maintenance Trades Helper	\$18.14
Material Handling Laborer	\$13.10
Medical Assistant	\$14.25
Medical Laboratory Tech.	\$14.25
Millwright	\$25.77
Order Clerk I	\$11.63
Order Clerk II	\$12.69
Order Filler	\$14.25
Painter, Maintenance	\$24.46
Park Attendant	\$14.78
Payroll Clerk	\$14.25
Personnel Assistant I	\$12.69
Personnel Assistant II	\$14.25

<u>CLASS OF EMPLOYEE</u>	<u>HOURLY WAGE</u>
Personnel Assistant III	\$15.94
Personnel Assistant IV	\$17.77
Pest Controller	\$21.51
Photofinishing Worker	\$12.69
Photographer I	\$14.25
Photographer II	\$15.94
Photographer III	\$19.75
Pipefitter, Maintenance	\$25.77
Plumber	\$24.46
Secretary I	\$14.25
Secretary II	\$15.94
Secretary III	\$17.77
Secretary IV	\$19.75
Service Order Dispatcher	\$14.25
Sheetmetal Worker, Maintenance	\$25.77
Shipper/Packer	\$16.46
Shipping/Receiving Clerk	\$16.46
Shuttle Bus Driver	\$19.82
Stock Clerk	\$16.46
Supply Technician	\$19.75

<u>CLASS OF EMPLOYEE</u>	<u>HOURLY WAGE</u>
Switchboard Op-Receptionist	\$12.69
Technical Writer	\$29.22
Telecommunications Mechanic I	\$25.77
Telecommunications Mechanic II	\$27.15
Tool and Die Maker	\$29.74
Tools and Parts Attendant	\$18.14
Travel Clerk	\$14.25
Typist I	\$11.63
Typist II	\$12.69
Van Driver	\$19.82
Warehouse Specialist	\$18.14
Welder, Maintenance	\$25.77
Woodcraft Worker	\$25.77
Word Processor I	\$12.69
Word Processor II	\$14.25
Word Processor III	\$15.94

### PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

#### SECTION J - LIST OF ATTACHMENTS

1. Statement of Work
2. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, May, 2007.
3. Privacy Act System of Records
  - a. 09-25-0007 - NIH Safety Glasses Issuance Program, HHS/NIH/OR, 2 pages.
  - b. 09-25-0054 - Administration: Property Accounting, HHS/NIH/ORS, 2 pages.
  - c. 09-25-0200 - Clinical, Epidemiologic, and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD, 8 pages.
  - d. 09-25-0105 - Administration: Health Records of Employees, Visiting Scientists, Fellows, and Others Who Receive Medical Care Through the Employee Health Unit, HHS/NIH/ORS, 2 pages.
  - e. 09-25-0166 - Administration: Radiation and Occupational Safety and Health Management Information Systems, HHS/NIH/ORS, 3 pages.
  - f. 09-25-0168 - Invention, Patent, and Licensing Documents Submitted to the Public Health Service by its Employees, Grantees, Fellowship Recipients, and Contractors, HHS/PHS/FDA/NIH/OTT, 3 pages.
  - g. 09-90-0001 - Telephone Directory/Locator System, HHS/OS/ASMB/OMAS, 3 pages.
  - h. 09-90-0005 - Safety Management Information System (HHS Accident, Injury, and Illness Reporting System), HHS/OS/ASMB/Office of Safety and Occupational Health, 5 pages.
  - i. Reserved
4. HHSAR 352.223-70, Safety and Health (JANUARY 2006).
5. Parent Company Guarantee (Revision 1) dated November 5, 2007.
6. Leidos Biomedical Representations and Certifications dated April 13, 2015.
7. Subcontracting Plan, dated July 14, 2008, for the period September 26, 2008 through September 25, 2018.
8. FAR 52.227-13 (Deviation) Patent Rights-Acquisition by the Government (DEC 2007) [Patent Rights- OTS Prime Contractor].
9. FAR 52.227-11 (Deviation) Patent Rights--Ownership by the Contractor (DEC 2007) [Patent Rights-Use of Third-party Technology and Information by OTS Subcontractors].
10. FAR 52.227-11 (Deviation) Patent Rights--Ownership by the Contractor (DEC 2007) [Patent Rights-NCI Full-length cDNA Initiative].
11. FAR 52.227 11, (Deviation) Patent Rights --Ownership by the Contractor (DEC 2007) [Patent Rights--NCI Initiative for Chemical Genetics (ICG)] (formerly called the Molecular Targets Laboratories (MTL) Initiative).
12. FAR (Deviation) 52.227-14 Rights in Data-General (DEC 2007) [Rights in Data-NCI Full-length cDNA Initiative].
13. FAR 52.227-14 (Deviation) Rights in Data-General (DEC 2007) [Initiative for Chemical Genetics (ICG)] (formerly called the Molecular Targets Laboratories (MTL) Initiative).

**Contract Number: HHSN261200800001E**  
**NCI Control Number: N01-CO-2008-00001**

14. FAR 52.227-17 (Deviation) Rights in Data--Special Works (DEC 2007) [Rights in Data-Use of Third-party Technology and Information].
15. Management and Support Information and Information Systems Impact Levels (See Article H.32.a. and b.
16. Reserved
17. Wage Determination No. 2005-2104, Revision No. 8 revised May 29, 2008, covering the period, September 26, 2008-September 25, 2009.
18. Electronic Contract Reporting Requirements Summary
19. Listing of Building Responsibility
20. Reserved
21. Wage Determination No. 2005-2104, Revision No. 10 revised May 26, 2009, covering the period, September 26, 2009-September 25, 2010
22. Wage Determination No. 2005-2104, Revision No. 12 revised June 15, 2010, covering the period, September 25, 2010 - September 25, 2011
23. Wage Determination No. 80-0829, Revision No. 31 revised February 9, 2010.
24. Wage Determination No. 2005-2104, Revision No. 13 revised June 13, 2010, covering the period, September 24, 2011 - September 25, 2012
25. Goals and Objectives
26. Award Fee Deliverables
27. FAR 52.227-11 (Deviation) Patent Rights--Ownership by the Contractor (TBD) [OTS Contractor CRADAs]
28. FAR 52.227-13 (Deviation) Patent Rights--Ownership by the Government (TBD) [Patent Rights-OTS Prime Contractor] (As amended MAR 2012)
29. Disposition of Contractor CRADA Income and Royalties (see Article H.16.)
30. Wage Determination No. 2005-2104, Revision No. 14 revised June 13, 2012, covering the period, September 26, 2012 - September 20, 2013
31. Wage Determination No. 2005-2104, Revision No. 15 revised June 19, 2013, covering the period, September 21, 2013 - September 25, 2014
32. Wage Determination No. 05-2104 (Rev. 18), dated July 8, 2015, effective September 26, 2015 is added.

**Attachment 1- Statement of Work**

**OPERATIONS AND TECHNICAL SUPPORT**

The Operations and Technical Support (OTS) Contractor shall exert its best efforts to perform the Government requirements delineated in this Statement of Work. It is essential that the OTS Contractor maintains flexibility and is rapidly responsive in supporting the evolving on-going research, emerging technologies and new research initiatives of the Government. Moreover, it is vital that the requirements of the Government be addressed proactively and that creativity and innovation be used in the performance of all aspects of this Statement of Work. OTS Key Personnel shall have primary managerial responsibility. All OTS Contract requirements are determined by the Government; quality scientific and business management and performance, including efficiency, cost effectiveness, optimal resource utilization, and technological currency, shall be the areas of paramount importance to the OTS Contractor. The FNLCR Project and Contracting Officers are the points of interface between the OTS Contractor and Government and other NCI Campus at Frederick Contractor activities. Requirements are developed in concert with program areas; all requirements are formalized by their submission through the Project Office and their approval by the Contracting Office. Such efforts shall be directed toward accomplishment of the following:

**I. EXECUTIVE SCIENTIFIC AND BUSINESS LEADERSHIP**

**A. Scope of Services and Oversight**

1. There shall be a group of key personnel that will be responsible for the comprehensive management and oversight of all scientific, business and financial activities conducted under the OTS contract. All OTS contract requirements are defined by the Government. The key personnel and their staff shall manage the Government's resources to ensure that these requirements are met and shall be responsible for the establishment and management of new Government efforts requested by the Office of the Director (OD), NCI, or the NCI Center/Divisions and their laboratories, branches or programs, or other Government entities during the term of this contract.

2. The Contractor shall provide Scientific and Technical personnel and support to various NCI/NIH programs. The staff shall have professional and technical expertise to conduct hypothesis-driven research - independently or in collaboration with Government or Government-designated scientists - and to provide a variety of research support activities, including technology application and development.

This research or research support shall encompass a wide range of scientific disciplines that shall include, but shall not be limited to: (i) analytical and biomolecular chemistry; (ii) biochemistry; (iii) immunology, including clinical immunology and patient monitoring; (iv) molecular biology and related molecular technologies, including genotyping, gene expression and protein production; (v) genetics, including epidemiological studies; (vi) virology, including virus production and diagnostics; (vii) structural biology; (viii) biophysics; (ix) cell biology; (x) microscopy; (xi) laboratory animal sciences, including diagnostic microbiology, animal health diagnostics, pathology, and histotechnology; (xii) in vivo and in vitro cancer

and viral therapeutics; (xiii) advanced scientific computer services, including molecular modeling, drug design and bioinformatics; (xiv) molecular targets and assay development; (xv) nanotechnology; (xvi) small animal imaging; and (xvii) clinical trials management and regulatory affairs for clinical research efforts. Other areas of research support may include, but are not limited to: (i) cGMP production, including the Biopharmaceutical Development Program and Vaccine Research Facility; (ii) repositories; (iii) graphic arts, photography and illustration; and, (iv) conference and conference facility management, video conferencing and meeting support.

3. The Contractor shall provide Business and Financial Management and Administrative Support to NCI/NIH programs in support of research and research support areas. The Contractor shall be responsible for the comprehensive operation of the NCI Campus at Frederick and other NCI/NIH facilities or programs as set forth in the Statement of Work. The Contractor shall provide an appropriate number of professional staff to function as administrative liaison between Contractor staff(s) and Government administrators and scientists.

4. It is understood and agreed that all Other NCI/NIH-Sponsored Work shall be within the purpose and mission of the FNLCR, as a Federally Funded Research and Development Center (FFRDC, Section I, B), as described in this RFP. Other sponsored work may include but is not limited to strategic initiatives for the development of science such as an advanced technology partnerships initiative. This type of initiative could include activities to accelerate the transition of drug and biological candidates into effective interventions for cancer patients through the use of advanced technologies and partnerships between the public and private sectors, non-profit organizations, national laboratories, extramural grantees, and other academic organizations. The contractor shall manage this initiative as a multi-disciplinary operation, capable of bringing together a diverse portfolio of state-of-the-art technologies. These technologies are critical to the rapid movement of newly identified basic research discoveries into potential new interventions for cancer patients. Included in the portfolio of technologies are: (i) Genetics and Genomics: genotyping, array technology, DNA sequencing, gene expression, miRNA analysis; (ii) Proteins and Proteomics: protein expression, purification, and characterization, mass spectroscopy, protein chemistry; (iii) Imaging: nanoparticles, small animals, electron microscopy, confocal microscopy, 3D tomography; (iv) Viruses: virus detection and vector construction; (v) Information Technology: bioinformatics, high performance computing; in silico modeling; (vi) Mouse Models: xenografts, transgenic knock-outs and knock-ins; and (vii) Biopharmaceutical Development and Manufacturing: drugs, vaccine, and biologics made in accordance with FDA's current Good Manufacturing Practices.

5. Frederick Management Oversight process occurs as follows: the NCI Associate Director located at NCI Campus at Frederick will evaluate new or expanded Contractor efforts on behalf of the Government, as well as recommending the appropriate use of the FNLCR, as an FFRDC (Section I, B). The COR and Contract Officer will provide final approval.

6. Appropriate NCI/NIH personnel or review boards appointed by the Director, NCI, will provide additional oversight of all OTS Contractor research and research support activities.

At the discretion of the Director, NCI, certain Contractor scientists, conducting hypothesis-driven, investigator-initiated research programs, will be recognized as independent investigators; presently, approximately 13 OTS Contractor scientists have been recognized as principal investigators (PIs). The Government will inform the Contractor, in writing, whenever the status of a PI changes. The Government will provide each NCI-designated PI with the resources to conduct his/her research and each PI will be held accountable for his/her scientific program and resource utilization in quadrennial peer-reviews conducted under the auspices of the NCI Board of Scientific Counselors (BSC). The BSC will recommend to the NCI the continuation, expansion, or discontinuation of the resources provided to the reviewed PI.

The Advanced Technology Program (Section II.E. hereof) and other shared-research support services (Section II) will be evaluated by User Oversight Committees, review teams composed of experts in the field or other NCI-designated evaluation groups, as appropriate. All recommendations or requirements resulting from such evaluations will be transmitted to the Contractor through the Project and Contracting Officers.

The Program-Dedicated Research (Section III hereof) will be evaluated by the supported NCI/NIH programs. This evaluation will be direct in the case of NCI-designated PIs, as described above; other Program-Dedicated Research will be evaluated indirectly through the OD and Divisional budget processes and peer-review of the supported NCI independent investigators. All recommendations or requirements resulting from such evaluations will be transmitted to the Contractor through the Project and Contracting Officers.

7. Following Office of the Director, NCI, (OD), NCI Divisional or other NCI/NIH programmatic and financial approvals, all technical requirements shall be developed in accordance with the terms and conditions of the contract. When necessary, specific service protocols may be formulated by mutual agreement between requester(s) and Contractor staff performing the services(s). Final consent and authority for such shall be furnished, in writing, by the Contracting Officer. The COR, or his/her designee(s), will coordinate all technical/scientific requirements. The COR, or his/her designee(s) will determine specific tasks, protocols, delivery schedules, etc. in conjunction with the requesting program. The Contracting Officer shall grant final approval of all requests to, or requirements, of the Contractor.

## **B. Operation of FNLCR**

The FNLCR is a **Federally Funded Research and Development Center (FFRDC)** and is an operation in dynamic change as the scientific areas currently represented continue to evolve. The FFRDC Contractor shall maintain currency in the fields of expertise necessary to perform the Statement of Work, and provide quick response capability consistent with the needs of the sponsor. For these reasons, the Government may find it necessary to re-apportion or redirect the utilization of Government facilities and resources at the FNLCR as a means to accomplish critical Government objectives. Such changes could result from additional deployments of or changes in Government professional and technical staff or programs at the FNLCR or other designated sites that require modification of the quantity and type(s) of Contractor support.

Contractors operating FFRDCs are allowed access, beyond that which is common to the normal contractual relationship, to Government and supplier data, including sensitive and proprietary data, and to Government employees and facilities (FAR 35.017). Because of this special relationship, it is required that the FNLCR be operated in the public interest with objectivity and independence, be free from organizational conflicts of interest and have full disclosure of its affairs to the Government. Additionally, the Contractor shall not use its privileged information or access to facilities gained because of the FFRDC to compete with the private sector in contravention of FAR 35.017. Notwithstanding this special relationship, the Contractor is not an agent of the Government.

## **II. SHARED-RESEARCH SUPPORT SERVICES**

The Contractor shall be responsible for the management and conduct of a broad range of research, research support, and administrative support services in response to the requirements of NCI/NIH scientific directions and priorities, as well as of other Government organizational units. All requirements shall be developed in accordance with the terms and conditions of the contract and shall be approved by the COR, or his/her delegated representative(s), in conjunction with the requesting program, and with the final approval of the Contracting Officer. Such shared-research support services efforts shall include, but not be limited to:

### **A. Satellite Research Centers/Special Projects,** to include:

1. The Contractor shall support an Institute of Chemical Genomics (ICG) Program to mount an intensive program of ligand discovery including exploration of their potential importance for cancer-relevant targets. From these ligands, drug candidates, imaging probes, and perturbational probes and databases thereof for biology will be derived.

The ultimate product of the ICG will be repositories of chemicals, assays and information: a) Chemical libraries will constitute the principal sources of chemical diversity to be interrogated by the biological assays developed in the ICG; b) Cancer-relevant target assays, suitable for high-throughput screening of chemical libraries; these assays will not be claimed as intellectual property and will be made publicly available; c) Chemical probes for biological studies, ligands with important biochemical or phenotypic effects will be placed into a repository and made available to qualified research groups; d) Information, including the identification of biologically active small molecules and the relation of particular chemical structures to biochemical activity and cellular phenotype; this information may be used in construction of a publicly available database relating chemical structure to biological function.

2. The Contractor shall provide support to the Cancer Genome Anatomy Project (CGAP) and other efforts including The Cancer Genome Atlas (TCGA) and Cancer Genetic Markers of Susceptibility (cGEMs) directed toward elucidating the molecular events in normal, pre-cancer and cancer cells. The Contractor will assist in the identification of institutions having unique capabilities to conduct the analysis of the cellular genes and gene products, including DNA sequencing and the construction of expression libraries, and will access such institutions through its subcontracting program. The Contractor shall also provide research support to these efforts through its Advanced Technology Program.

3. The Contractor shall provide support to the pilot study for the NCI Community Cancer Centers Program (NCCCP). This pilot will study the feasibility for providing up-to-date cancer care to patients within their local medical community. This effort will be supported primarily by the Contractor's Clinical Monitoring Research Program, part of the Clinical Research Directorate via subcontracts. In addition, the Contractor shall also provide other support as necessary through its other support programs.

**B. An Applied and Developmental Program**

to provide both shared and dedicated research support for laboratory and clinical investigations to the NCI and other IC such as NIAID. These research support efforts include, but are not limited to: (i) immunological monitoring; (ii) virus isolation and serology; (iii) molecular cell biology; (iv) cell biology; (v) molecular retrovirology; (vi) neutrophil monitoring; (vii) human papilloma virus (HPV) monitoring; (viii) immunotherapy; (ix) preclinical research; (x) clinical and epidemiological support, including clinical and epidemiological trials and maintenance of a biospecimen processing laboratory; (xi) oversight of the repository subcontract; and (xii) administrative and data management. Details on the dedicated support can be found in Section III.

**C. A Clinical Research Directorate**

that includes a Clinical Monitoring Research Program to provide clinical research support to the NCI and the NIAID and other entities, as requested. These efforts include, but are not limited to: (i) clinical trial monitoring/management; (ii) regulatory compliance including medical monitoring and adverse event reporting; (iii) management of support subcontracts; (iv) clinical research nursing and associated clinical professionals and protocol support; (v) grant management; (vi) information technology management support; (vii) logistical and operational support to a variety of clinical projects; and (viii) project management support to a variety of domestic and international clinical studies and pilot projects.

**D. A Laboratory Animal Sciences Program (LASP) –**

to provide personnel and expertise for animal holding, technical and health diagnostic support to NCI/NIH PIs and programs at the NCI-FNLRCR, for the small animal/rodent facilities at NCI-Bethesda including those in Buildings 10, CRC Vivarium, 37, 41 and non-human primate facilities at NCI-Bethesda including Building 14D and other facilities as requested.

The Contractor shall ensure that all animal care and procedures are conducted in a humane manner in a controlled environment and that all animal housing and procedures shall conform to the most recent version of the NIH Guide for the Care and Use of Laboratory Animals (the Guide). The LASP shall work closely with the FNLRCR Animal Care and Use Committee (ACUC) and the NCI-Bethesda ACUCs, as required, in the development, implementation, and oversight of animal programs, procedures, and facilities in compliance with Public Health Service (PHS) Policy on The Care and Use of Laboratory Animals, the Animal Welfare Act regulations, and the Guide, as well as in maintaining accreditation by AAALAC International.

The LASP activities shall include, but not be limited to: animal health diagnostics and genetic monitoring; receiving and quarantine, including rederivation services; animal holding and technical support, including core and investigator/program-specific support; animal inventory system maintenance; support to ACUC(s); laboratory animal medicine; transgenic and gene targeted mice/rodents; cryopreservation; histotechnology; veterinary pathology; molecular pathology; mouse/rodent model repository; small animal imaging support; as follows:

1. **Animal Health Diagnostic (AHD) and Molecular Diagnostics & Genotyping (MDGL) Laboratories** shall ensure disease prevention, detection, and eradication for all designated areas that produce or house research animals or animal cells and tissues. The serological and molecular diagnostic systems that the AHD employ will be designed specifically to identify the viruses, bacteria, and parasites that infect rodents, guinea pigs, and other vertebrates.

The AHD shall develop and maintain, but not be limited to: (i) specimen collection, storage and processing; (ii) isolation and identification of protists and parasites in specimens, emphasizing those that may be detrimental to animal health, experimental results, or animal facility integrity; (iii) diagnosis of abnormal animal health conditions employing serological testing and other systems; (iv) reporting laboratory and related test results expeditiously to investigators/programs and the COR when results deviate from the norm; (v) interpretation of diagnostic tests and results; (vi) coordination of all diagnostic requests; (vii) evaluation of health status of source colonies; (viii) implement procedures for eradication of adventitious agents from cell cultures; and, (ix) develop and implement novel diagnostic procedures.

The MDGL shall provide serological and molecular testing, genetic monitoring, and verification of defined flora in FNLCR animals. Assurance shall be provided of pathogen status, defined flora status, and genetic integrity.

2. The **Receiving and Quarantine (R&Q)** shall include, but not be limited to: (i) receipt and quarantine of incoming animals and animal tissues; (ii) isolation of animals that may possess infectious hazards; (iii) the provision of on-site facilities and technical capabilities for embryo, sperm, and/or caesarian rederivation of mouse strains, as well as for the quarantine of “rederived” rodents until their health status is confirmed.

3. **Animal Holding Facilities** shall be operated for housing research animals in research studies at the sites designated above. Unless otherwise designated, all facilities shall be maintained as specific-pathogen-free and this status ensured by an animal health surveillance program.

The animal holding facilities shall provide the following capabilities, including but not limited to: (i) daily husbandry, animal identification, animal health surveillance; (ii) cage washing services, facility and equipment cleaning and disinfection; (iii) racks, cages, filter tops and other animal holding equipment, as necessary; (iv) order research animals and supplies, including animal food, bedding; (v) environmental monitoring; and, (vii) facility management and administration.

4. The **Animal Technical Support Program** shall provide technical support to the animal facilities designated above and for PIs/ programs holding animals in those facilities, and other facilities as requested.

The Contractor shall provide for **“Conventional” (non-specific-pathogen-free) Animal Holding** for rodents and ensure the facility provides technical support for experimental protocols. The facility shall conform to the Guide’s standards for animal care and housing and be AAALAC-accredited.

5. The Contractor shall implement an **Animal Inventory Reporting System**, including the weekly accounting of cages occupied, technical hours and other costs. This system will provide the basis for cost allocation to PIs/programs.
6. The Contractor shall be responsible for providing administrative support to the FNLCR Animal Care and Use Committee (ACUC) and the NCI-Bethesda ACUCs and to assist the principal investigators in preparing their Animal Study Proposals. The ACUCs report to and makes recommendations to the NCI-Frederick or NCI-Bethesda Institutional Official or his/her designee.
7. The Contractor shall employ **veterinarian(s)** with VMD/DVM degree(s), who shall provide clinical veterinary care, preventative medicine, training of personnel in the humane care and use of laboratory animals, as well as have primary responsibility for maintaining AAALAC accreditation and assuring compliance with the Guide and all PHS and Animal Welfare Act regulation. A Contractor veterinarian shall be designated as the FNLCR ACUC Institutional Veterinarian; a veterinarian shall be designated program director/institutional veterinarian for the NCI-Bethesda small animal/rodent program.
9. The Contractor shall operate core support facilities for the production of **Transgenic and Gene Targeted Rodents** and the **Cryopreservation** of rodent embryos, sperm or ovaries, and assisted rodent reproduction through in vitro fertilization. The Contractor shall provide technical and administrative support, as required, for these facilities, as well as necessary expertise to maintain technological currency for these efforts.
10. The Contractor shall provide to NCI/NIH investigators/programs comprehensive veterinary pathology, histotechnological and molecular pathology services.  
  
The **Pathology Laboratory**, headed by a Board Certified Pathologist with experience in rodent diagnostic pathology, toxicology, and laboratory animal science, shall provide, but not be limited to: (i) pathology evaluation of experimental studies with electronic reporting of results to investigators; (ii) pathology expertise; and (iii) protocol development.  
  
The **Histotechnology Laboratory** shall provide, but not be limited to: (i) necropsies; (ii) histological preparations/procedures; (iii) immunohistochemistry; (iv) technological currency; and, (v) maintenance of an animal tissue paraffin block library (~ 800,000 specimens).  
  
The **Molecular Pathology Laboratory** shall provide, but not be limited to: (i) in situ hybridization; and, (ii) technology development to meet the research needs of investigators.
11. The LASP shall operate a **Mouse Models Repository**, for the maintenance of live and cryopreserved mouse strains, in support of the NCI Mouse Models of Human Cancer Consortium.
12. The LASP shall operate a **Small Animal Imaging Facility/Program**, in the support of the NCI small animal imaging initiatives. This support will be provided to the following NCI entities: Office of Technology & Industrial Relations (OTIR), Center for Cancer Research (CCR), Division of Cancer Treatment and Diagnosis (DCTD) and Office of Scientific Operations, Office of the Director (OSO, OD). This facility/program shall provide state-of-the-art scientific, technical and instrument support including but

not limited to: optical, magnetic resonance (MR), computed tomography (CT), single photon emission computed tomography (SPECT), and positron emission tomography (PET) imaging modalities.

**E. Advanced Technology Program**

The Contractor shall establish and maintain an **Advanced Technology Program** and implement a fee-for-service system, as set forth in contract Article B.4. Advance Understandings, by which requesters are charged for their requested service(s). Maintenance of technological currency will be essential. These facilities include, but are not limited to:

1. **Laboratory of Molecular Technology**, an integrated molecular biology laboratory providing, but not limited to: (i) standard and high throughput DNA sequencing, processing and analysis of commercially available DNA microarrays, and associated technologies; (ii) development of customized microarrays primarily using commercially available platforms; (iii) synthesis of specialized oligonucleotides and peptides; (iv) genomics and genotyping technologies to enable clinical and research diagnostics, including mutation detection, single nucleotide polymorphism (SNP) analysis, and pathogen detection; (v) bioinformatics support; (vi) real-time quantitative PCR; (vii) RNA isolation strategies and (viii) primer design. To ensure technological currency and consistency for NCI/NIH scientists, the activities of this Laboratory shall be coordinated with similar efforts of other laboratories within the NCI, including, but not limited to, the Genetics Branch and its Molecular Profiling Core and the Core Genotyping Facility.
2. **Image Analysis Laboratory**, a laboratory providing, but not limited to: (i) ultrastructural analysis, using scanning electron, transmission electron, light, and confocal laser scanning microscopy; (ii) immunoelectron, immunofluorescence, and digital imaging technologies; (iii) time-lapse imaging of live cells; (iv) data analysis, including computational resources and algorithms for visualization and extraction of quantitative information from images.
3. **Protein Chemistry Laboratory**, a laboratory providing but not limited to: (i) high-sensitivity amino acid sequencing; (ii) characterization of proteins, protein complexes and protein-nucleic acid complexes and post-translational modifications, using mass spectrometry, HPLC, and other preparative, biophysical or analytical methods; (iii) macromolecular interactions, using the BIAcore Biosensor and other methodologies; and, (iv) experimental design, interpretation, mathematical modeling, and data analysis.
4. **Laboratory of Proteomics and Analytical Technology**, a laboratory providing, but not limited to: (i) nuclear magnetic resonance spectroscopy and related technologies; (ii) mass spectrometry; (iii) separation sciences, including capillary electrophoresis, chromatography and spectroscopy. The laboratory shall ensure that requesting investigators can gain access to sophisticated instruments and technologies for performing both structural and quantitative analytical measurements for proteomics, metabolomics, and small molecule studies. Services shall be provided for quantitative and structural analysis of bioactive lipids, glycans, small molecules, vitamins and nutrients, proteins, peptides, DNA and measurement of hormones and hormone metabolites.
5. **Protein Expression Laboratory**, a laboratory providing, but not limited to: (i) consultation on cloning, protein expression, and protein purification issues; (ii) acquisition and tailoring of genes for protein expression and purification; (iii) invention, construction, an adaptation of protein expression vectors; (iv) cloning of tailored genes into protein expression and other vectors, including mutagenesis; (v) purification of vectors and cloned

genes suitable for cloning, transformation, and transfection; (vi) testing of protein expression and purification alternatives, including cell-free expression and innovative cellular hosts; (vi) scale-up of protein expression in bacterial, yeast, insect, and mammalian hosts;(vii) purification of proteins from both native and recombinant sources, including fusion tag removal and endotoxin assay and reduction.

6. **Virus Technology Laboratory**, a laboratory providing, but not limited to: (i) the generation and production of adenoviral and lentiviral vectors for expression of genes and shRNAs in both animal and cell culture model systems; (ii) specialized viral vector design and constructions; (iii) viral plasmid preparations; (iv) bulk nucleic acid isolation; and (v) development and performance of molecular and serological testing for the detection of cancer-related viruses.

7. **Core Genotyping Facility**, a laboratory providing genotyping and DNA sequencing support to the NCI's Division of Cancer Epidemiology and Genetics (DCEG) and Center for Cancer Research (CCR).

8. The **Nanotechnology Characterization Laboratory (NCL)** a laboratory to perform and standardize the pre-clinical characterization of nanomaterials intended for cancer therapeutics and diagnostics developed by researchers from academia, government, and industry. The NCL shall provide nanotechnology characterization resources and expertise, including but not limited to an assay cascade consisting of: (i) physicochemical characterization such as measurement of nanoparticle size, topology, molecular weight, aggregation state, purity, chemical composition and surface chemistry; (ii) in vitro protocols developed specifically for the evaluation of nanoparticle sterility, blood contact properties, toxicity, and interaction with the immune system; and (iii) in vivo experiments tailored to evaluate the toxicity, immunotoxicity, and efficacy of nanoparticles intended as cancer therapeutics. The NCL also (iv) conducts independent and collaborative research programs directed at understanding the relationships between nanoparticle structure and biological activity.

9. The Contractor shall operate the **Information Systems Program (ISP)**, located primarily in FNLCR, Bldg, 430, as the main scientific computational resource for the NCI Campus at Frederick, the ISP shall provide state-of-the-art computing support and technology to NCI/NIH-supported scientists and other DHHS components.

- (a) The ISP staff shall employ computer and advanced discipline specialists to apply computing technology to problems in biomedical research, as required. These staff members shall address, but are not limited to: (i) planning, development, coordination and implementation of hardware, systems software, networks, data communication, user services, engineering and maintenance, facility planning, training, and operations or administration; and, (ii) development and maintenance of programs and systems in support of biomedical research, including proteomics, bioinformatics, imaging, structural and molecular biology data, genomics, and other emerging disciplines, such as nanotechnology as requested by the NCI.
- (b) The ISP shall provide technical support, including consultation, training, and educational services; collaboration on research and emergent technology; and complex algorithm programming. The ISP shall maintain technological currency to provide a cyber infrastructure to produce an environment for the solution of data intensive problems, and shall operate in accordance with policy and guidance established by the DHHS Information Resources Management Manual applicable public law, and Federal regulations.
- (c) The ISP shall provide services for computer utilization, code optimization, computer programs, database development, data management, data visualization. The ISP shall also provide a system capability to

support remote access for interactive processing, as well as capability for developing and processing large complex scientific problems. The ISP shall, as requested by the NCI, provide a computational environment for the support of special NCI initiatives and missions.

- (d) The ISP shall provide networking, video conferencing and local area network (LAN) support to the NCI Campus at Frederick, as required by the Government. The ISP shall define and submit to NCI for funding requirements and implementation plans for bandwidth adequate to support the Frederick and Bethesda research data management environment, maintain the Frederick network infrastructure, and cooperate with CIT for joint data sharing activities, and network security protocols.
- (e) The ISP shall, in collaboration with the NCI, establish a User Oversight Committee consisting of internal NCI ISP users and outside experts in various disciplines. This committee shall provide guidance and advice for the ISP on a yearly basis.

#### F. Repositories

The Contractor shall provide, through subcontracting arrangements, state-of-the-art technical expertise in the operation and cost control of **Repositories** at the FNLCR and off-site, as required. The repositories shall provide ambient, 4oC, -20oC, -80oC and liquid nitrogen storage capacity; and shall operate under Good Laboratory Practices (GLP) standards, with the capability of limited storage under current Good Manufacturing Practices (cGMP) standards, as needed. The existing repositories are located at FNLCR in Buildings 1066 and 434, and in off-site leased space (e.g., Wedgewood II); (Section III, C.6).

This effort shall include, but not be limited to: (i) maintenance of required specimen storage units and facilities, including routine temperature monitoring, alarm systems, and preventive maintenance; (ii) technical personnel for receipt, storage, retrieval, and distribution of specimens and monitoring of specimen storage units; (iii) maintenance of laboratory facilities for sample manipulation; (iv) maintenance and updates of computer inventory systems for sample storage and retrieval; (v) performance of specific protocols and requirements; (vi) preparation of inventory, monthly storage cost reports and other reports; (vii) maintenance of quality control (QC) and quality assurance (QA) programs, including standard operating procedures for routine and emergency operations and QA reporting; and, (viii) provision of adequate safeguards and emergency capabilities.

The Repository Quality Board, consisting of NCI/NIH and OTS Contractor representatives will provide general oversight of all repository operations. In addition, the Contractor shall support and conduct biorepository science research in support of the NCI biospecimen initiatives.

### III. PROGRAM-DEDICATED RESEARCH

The Contractor shall conduct independent investigator-initiated and collaborative research, as well as provide research support for NCI Divisions, their Laboratories and Programs, and other designated NIH entities.

#### A. Office of Scientific Operations (OSO)

An **AIDS and Cancer Virus Program** -- to conduct investigator-initiated research and provide research support including, but not limited to: (i) investigation of basic immunological and biochemical approaches for therapy and vaccine development, including the use of animal models; (ii) production and purification of viruses; (iii)

purification and characterization of viral products; (iv) production and manipulation of cultured cells and the isolation of products from cultured cells; (v) performance of assays for biological products; (vi) development and performance of biochemical, biological and immunological tests; (vii) development and improvement of technology; (viii) investigation of the role of viruses in cancer; and (ix) phylogenetic and molecular analysis of cancer-related pathogens. The investigator-initiated research conducted and resources utilized by the AIDS and Cancer Virus Program will be peer-reviewed quadrennially under the auspices of the NCI Board of Scientific Counselors (Section I, A).

**B. Center for Cancer Research (CCR)**

1. The Contractor shall provide, through a **Basic Research Program**, research, technical support, laboratory management, and administrative support, as required, to the Laboratories and Programs of the Center for Cancer Research (CCR) located at the NCI Campus at Frederick. Note that all CCR investigator-initiated research efforts, including those conducted by Contractor scientists designated as independent investigators (Section I, A), are peer-reviewed quadrennially under the auspices of the NCI Board of Scientific Counselors. Contractor support to the CCR will be required for:

(a) The **Center for Cancer Research Nanobiology Program** -- Support may include, but is not limited to: (i) analysis of membrane structure and function; (ii) evaluation of protein interactions; (iii) biomedical image and database analysis; (iv) structural bioinformatics; (v) structural glycobiology; (vi) molecular information theory; and, (vii) computational RNA structure.

(b) The **Cancer and Inflammation Program (CIP)** consists of the **Laboratories of Experimental Immunology (LEI) and Molecular Immunoregulation (LMI)** – Support may include, but is not limited to: (i) analysis of the cellular and molecular mechanisms of natural killer (NK) cell function; (ii) development of systems to study cytokine gene expression and induction; (iii) investigation of the effects and mechanism(s) of action of novel immunomodulators on the immune system and as antitumor therapies; (iv) identification of the mediators of leukocyte infiltration; (v) dissection of the molecular mechanisms regulating the transition from acute to chronic inflammation; (vi) cytokine function in T-cell development; (vii) molecular interactions of cytokine and nuclear receptor signal transduction pathways; and (viii) investigation of T-cell tolerance and autoimmunity.

The Contractor also shall staff and manage a **Flow Cytometry Core**, scientifically affiliated with the LEI. The Core shall provide support for a state-of-the-art flow cytometry and cell sorting (fluorescence-activated cell sorting, FACS) to analyze multiple-parameter cell surface markers in cells grown in tissue culture or in cells derived from patient samples and for comprehensive basic research studies.

(c) **The Laboratory of Protein Dynamics and Signaling (LPDS)** -- This support may include, but is not limited to the identification and characterization of enzymes involved in the ubiquitin pathway.

(d) **The Laboratory of Comparative Carcinogenesis (LCC)** -- Support may include, but is not limited to: (i) studies aimed at characterizing the potential activity of nitric oxide as both pro- and anti- carcinogen; and, (ii) elucidation of the mechanisms of k-ras-mediated carcinogenesis of the lung and preconceptional carcinogenesis mediated by chromium (iii) exposure.

(e) **The Laboratory of Genomic Diversity (LGD)** – Support may include, but is not limited to: (i) the study of genetics, molecular biology, molecular genetics and epidemiology underlying susceptibility and resistance in humans to infectious diseases and malignancies, particularly from HIV and hepatitis B, hepatitis C, breast and prostate cancer; (ii) isolation and molecular biology of retroviruses; (iii) development of animal models for retrovirus infections, infectious viral carcinogenesis and genetic analysis; (iv) identification of conserved chromosome regions, break points of rearranged chromosomes and evaluation of genomic changes during evolution; and, (v) comparative genomics particularly targeting the feline gene map; and, (vi) human disease gene discovery, focusing on polygenic and multifactorial diseases.

(f) **The Macromolecular Crystallography Laboratory (MCL)** – Support may include, but is not limited to: (i) structure-function studies of enzymes with anticancer, antimicrobial, or chemotactic activity, retroviral enzymes, proteases, RNA processing enzymes, cytokines, and cytokine receptors using x-ray diffraction, molecular biology, and biochemical techniques; and, (ii) support at the National Synchrotron Light Source at Brookhaven National Laboratory and, if required, other designated sites. The activities conducted at the(se) site(s) constitute an experimental resource for MCL and other NCI/NIH scientists.

(g) **The Structural Biophysics Laboratory (SBL)** – Support may include, but is not limited to: (i) electronics support and maintenance of NMR equipment; (ii) technical support for mechanistic, computational, synthetic chemistry, biochemistry, and biological studies aimed at developing new approaches to the design of drugs against cancer and viral diseases, especially AIDS; and, (iii) web page design and maintenance.

(h) **The HIV Drug Resistance Program (HIV DRP)** – Support may include, but is not limited to: (i) general scientific technical expertise; and, (ii) DNA sequencing and oligonucleotide synthesis support.

(i) **The Gene Regulation and Chromosome Biology Laboratory (GRCBL)** – Support may include, but is not limited to: staffing and managing a facility for the preparation of media for the growth and maintenance of both prokaryotic and eukaryotic cells in vitro, the latter including yeast as well as cells and cell lines derived from higher animals.

(j) **The Molecular Targets Development Program (MTDP)** -- Support may include, but is not limited to: (i) development, evaluation, and application of novel screening assays and technologies for lead molecule discovery and molecular target validation; and, (ii) chemistry and molecular biology support for isolation and characterization of protein, peptide, and non-protein lead compounds from libraries and other sources.

(k) **The Cancer and Developmental Biology Laboratory (CDBL)** -- Support may include, but is not limited to: (i) analysis of embryonic development and mechanisms of growth control via growth factors and cytokines; (ii) immunobiology of bone marrow transplantation; and, (iii) identification, purification, and characterization of murine and human hematopoietic stem cells and development of hematopoietic stem cell gene therapy techniques.

(l) **The Laboratory of Cancer Prevention (LCP)** -- Support may include, but is not limited to: (i) investigation of the molecular basis of cancer induction and progression following the perturbation of cellular processes; (ii) discovery and characterization of molecular targets for cancer prevention and intervention; and, (iii) the study of lymphoid-specific helicase (LSH) in lymphoid development and T cell receptor rearrangement.

(m) The Vaccine Branch (VB) – Support may include, but is not limited to: (i) analysis of HIV-1 expression, protein function, and the pathogenic mechanisms of AIDS, (ii) HIV RNA expression regulation, (iii) HIV-cytokine interactions and, (iv) protein localization and trafficking.

(n) The Urologic Oncology Branch (UOB) – Support may include, but is not limited to: (i) molecular genetic analysis of genetic events associated with initiation and progression of urologic malignancies and (ii) characterization of the VHL suppressor gene product.

(o) The Mouse Cancer Genetics Program (MCGP) – Support may include, but is not limited to: (i) stem cell regulation and animal aging in drosophila and mice (ii) drosophila JAK/STAT and JNK/JUN signal transduction pathways, and (ii) signalings that regulate male germline stem cell self-renewal or differentiation.

(p) The Laboratory of Metabolism (LM) – Support may include, but is not limited to: (i) the effect of phytochemicals and other chemopreventive agents on the carcinogen activation pathway mediated by the aryl hydrocarbon receptor and (ii) the effect of phytochemicals and other chemopreventive agents on novel biochemical mechanisms involved in the detoxification of aryl hydrocarbons.

(q) The Laboratory of Medicinal Chemistry (LMC) – Support may include, but is not limited to: (i) computer-aided drug design, (ii) enhanced NCI database browser; and (iii) HIV integrase studies.

2. The Contractor shall provide, through an Applied and Developmental Program, program-dedicated research for laboratory and/or clinical investigations to the laboratories and programs of the Center for Cancer Research (CCR) as required. The program must maintain the flexibility to adapt clinical monitoring programs, as required by CCR clinical research. Laboratories will maintain assay testing in accordance with Clinical Laboratory Improvement Amendments of 1988 (CLIA88), as modified when appropriate, and obtain/maintain relevant CLIA88 certification. Program laboratory services can be requested by other NCI divisions and NIH Institutes on a fee for service basis. Contractor support to the CCR will be required for:

(a) The Clinical Support Laboratory -- Contractor shall provide the capability to furnish services in clinical monitoring, phenotypic analysis of lymphoid tissues, lymphokine testing, biochemistry/molecular biology, and nucleic acid extraction at on-site and the NIH Clinical Center, Bethesda locations as needed. The work shall include, but not be limited to: A Clinical Monitoring Section responsible for clinical specimen processing, cryopreservation, DNA extraction, establishment of immortalized B cell lines from clinical material, and temporary storage of patient derived materials prior to transfer to the Central Repository or other locations as requested. A Lymphokine Testing Section with capabilities including, but not limited to: (i) assay of a diverse range of soluble molecules in serum, body fluids, and tissue culture fluids derived from normal donors and patients; (ii) bioassay services and current technology for lymphokine/ cytokine production; (iii) identification, and purification characterization of cytokines, cytokine receptors, and cytokine genes from human and animal blood tissues. A Flow Cytometry Section responsible for monitoring patient samples and testing of samples in support of clinical and basic research investigators as requested. A Clinical Pharmacology Program Support Group responsible for providing clinical specimen processing, assay development and validation, and pharmacokinetic and pharmacodynamic testing in support of the Clinical Pharmacology Program with support personnel located at the NIH Clinical Center, Bethesda.

(b) The Laboratory of Cell Mediated Immunity – The Contractor shall provide the analysis of the immunological function of normal donors and patients, including assays for cytotoxic T lymphocytes, ELISPOT, T-cell proliferation, cytokine induction, and other immune cell function conducted on peripheral blood leukocytes, bone marrow cells and cells from other lymphoid organs. The Contractor shall import or develop the necessary assays to carry out these functions, optimize the methodology, and validate the assays for clinical use. The Contractor shall maintain CLIA certification to allow results to be used for clinical decisions. The Contractor may also provide assays for pre-clinical animal models when needed.

(c) The Contractor shall maintain Data Management Group to perform programming, data management and infrastructure/networking support associated with collecting and maintaining data collected by labs in support of NCI clinical trials and researcher requested testing.

(d) The Contractor shall provide support to AIDS Clinical Trials including but not limited to: (i) analysis of the immune function of patients infected with HIV prior to, during, and following immunotherapy or other therapies; and, (ii) provide immunological support for experimental HIV vaccine trials. Assays will assess immune cellular function and will be performed on peripheral blood leukocytes, bone marrow cells, or cells from other lymphoid organs. The Contractor shall provide a comprehensive flow cytometry/hematology effort to define hematologic parameters in HIV patients.

(e) The Contractor shall provide a dedicated clinical courier system for transport of clinical samples and associated data between the NCI Campus at Frederick laboratories and the NIH Bethesda campus as well as other locations within the Washington, D.C. metro area in support of NCI clinical trials. Samples will be transported in accordance with governing policy and regulations.

3. The Contractor shall provide support to other CCR activities outside of the ADRSP including but not limited to:

(a) Core Chemistry Support to the CCR systemic radiation/ radioimmunotherapy program. This core group shall generate radionuclides to be linked to targeting moieties for the treatment and diagnosis of malignancies in animal model systems or humans, including but not limited to: (i) the generation of astatine-211 ( $^{211}\text{At}$ ) from internally and externally labeled bismuth targets; (ii) convert the targets to  $^{211}\text{At}$  gas by distillation; (iii) trap  $^{211}\text{At}$  on silver wire and isolate the  $^{211}\text{At}$ ; and, (iv) prepare and isolate Bismuth-212 and Lead-212 from thorium/radium generators. The Contractor personnel must be knowledgeable in: (i) the theory and techniques to link these radionuclides to monoclonal antibodies, antibody fragments, other specific immunoproteins and biotin; and, (ii) developing and producing chelating agents and their intermediates to link these radiolabeled materials to proteins and biotin.

(b) Technical and Administrative Support to the NCI Microarray Facility to conduct studies on gene expression employing “gene chip” technology. This effort shall be conducted primarily at the NCI Advanced Technology Center, Gaithersburg, Maryland or other sites, as required. (The Gaithersburg site can be the focus for budgeting purposes.)

4. The Contractor shall provide, through a Clinical Monitoring Research Program that is a component of a Clinical Research Directorate, dedicated clinical research support for clinical

investigations/clinical trials as required, to the Laboratories and Programs of the Center for Cancer Research (CCR) including, but not limited to: Medical Oncology Branch (MOB), Metabolism Branch (MB), Office of Protocol Administration, Experimental Transplantation and Immunology Branch (ETIB), Surgery Branch (SB), Urologic Oncology Branch (UOB), HIV/AIDS Malignancy Branch (HAMB), Office of the Clinical Director, and NCI Experimental Therapeutics Program. Contractor support to the CCR will be required for:

- (a) The Contractor shall provide clinical trials management and support for operations of intramural clinical research activities as requested, which may include: Phase 0, Phase I, Phase II and Phase III clinical trials sponsored by the CCR, NCI. Programmatic support including, but not limited to: medical officers/medical affairs scientists/physicians, nursing/study coordinators, nurse practitioners, case managers, pharmacy and laboratory technicians, regulatory/clinical trials staff, shuttle drivers, and clinical project managers. Other program and administrative positions will be requested as part of these clinical support efforts.
- (b) The Contractor shall provide clinical trial management of clinical research portfolios; direct expert nursing care and study coordination to assigned caseloads of patients on specific protocols; coordinating patient schedules to meet the requirements of protocol interventions and data collections; assisting in skilled procedures performed by medical affairs/physicians (e.g. phlebotomy and IV catheter placements); ordering diagnostic procedures per protocol; documenting patient care per protocol requirements; participating in clinical rounds; interpretation of data and clinical trials implementation; serving as a liaison with clinical, regulatory and laboratory personnel on assigned protocols; interacting with monitoring/auditing agencies; assistance in writing protocols and amendments; serving as associate investigators and participating in clinical trial protocol development; providing good clinical practices expertise and mentoring for other clinical staff; and, providing general programmatic support to the clinical research efforts (e.g., subcontracting, logistics and procurement).

5. Oversight by CCR Staff. The CCR, NCI will provide oversight as appropriate for these activities.

**C. Division of Cancer Epidemiology and Genetics (DCEG)**

The Contractor shall provide research, program-dedicated research including technical research, laboratory management, and administrative support, as required, to the laboratories and programs of the DCEG. All DCEG investigator-initiated research efforts, including those conducted by Contractor scientist(s) designated as PIs (Section I, A), are peer-reviewed quadrennially under the auspices of the NCI Board of Scientific Counselors. Support to DCEG includes, but is not limited to, the following:

1. The Contractor shall establish and operate a Bioprocessing Laboratory (Section II, B) for the processing of biological specimens prior to their storage in the Central Repository or dispersal to collaborators. In certain instances, the Contractor may be asked to procure and process biospecimens from healthy volunteers in support of DCEG studies. The processing laboratory shall provide, but not be limited to: (i) the processing and freezing of biological specimens, including whole blood, serum, plasma, urine, and feces; (ii) lyophilization of specimens; (iii) flash-freezing of tissue in liquid nitrogen; (iv) separation and viable cryopreservation of cell lines, including the routine assessment of viability; (v) cryopreservation of red blood cells to maintain enzymatic activity; (vi) establishment of cell lines; (vii) large scale propagation of cell lines; (viii) nucleic acid extraction; (ix) distribution of specimens; and, (x) support to field centers in collection procedures, equipment, materials and sample transportation, as requested.

2. The Contractor shall provide a DNA Extraction Laboratory that maintains technical expertise in DNA extraction from whole blood specimens, blood fractions, transformed lymphoblastoid lines, cultured fibroblasts, tumor specimens, buccal cells, paraffin-embedded tissue, Guthrie cards, cytology preparations, or other biological specimens. The laboratory will also provide sample handling expertise to support the Core Genotyping Facility or outside genotyping facilities through the creation of “run-ready” plates specific for requirements of various genotyping platforms.

3. The Contractor shall maintain a QC/QA program to monitor the performance of the Bioprocessing and DNA Extraction Laboratories, including the development of standard operating procedures (SOPs) for each protocol or process, optimized for maintaining the integrity of human biological material; for monitoring the quality of products; for the operation of the laboratories; and for tracking specimen influx, processing, and efflux.

4. The Contractor shall be responsible for Computer Support Services, including, but not limited to, data management, systems design and development, and statistical analysis and modeling, employing standard and specialized software.

5. The Contractor shall operate an Immunological Monitoring Laboratory to examine host immunological parameters potentially important in the pathogenesis or prevention of virus-related tumors. The laboratory’s capabilities shall include, but not be limited to: (i) receipt and processing of specimens, including whole blood and cervical specimens; (ii) cryopreservation, DNA extraction and Epstein-Barr virus transformation of peripheral blood mononuclear cells (PBMC); (iii) immunological testing, including a variety of in vitro PBMC functional assays; (iv) HLA and PBMC phenotyping by flow cytometry (fluorescence activated cell sorting – FACS); (v) temporary low temperature storage of biological specimens and transfer to the DCEG biorepository; (vi) electronic tracking of biospecimens and reporting of assay results to DCEG investigators; (vii) maintain quality control/quality assurance programs; and, (viii) apply state-of-the-art techniques, as they become available.

6. The Contractor shall provide, through subcontracting arrangements, state-of-the-art technical expertise to operate Repositories (see Section II, F) for the storage of biospecimens collected by and for DCEG investigators.

The DCEG requirements include, but are not limited to: (i) sample receipt and distribution; (ii) ambient and low temperature storage of environmental and biological specimens; (iii) computerized sample inventory maintenance and storage cost accounting, utilizing the DCEG Biospecimen Inventory System (BSI-II) as the sole alpha-numeric specimen identifier; (iv) maintain QC and QA programs; (v) development or identification of biospecimen collection and storage conditions to preserve specimen and target analyte integrity; and, (vi) support to field centers in collection procedures, equipment, materials, and sample transportation, as requested.

The transfer or disposal of any DCEG specimen or specimen collection into or out of the repository shall have the prior approval of a DCEG Assistant COR, designated COR for this purpose only. The DCEG APO shall be immediately informed of any specimens for which identity information is missing or incomplete.

7. The Contractor shall provide a Core Genotyping Facility (CGF), a laboratory providing, but not limited to: (i) technical, administrative, and bioinformatics support for a high-throughput genotyping core resource facility; (ii) production line genotyping; (iii) research and development; and (iv) analysis and bioinformatics data

management. The mission of the CGF is to meet the genotyping and DNA sequencing needs of the NCI's Division of Cancer Epidemiology and Genetics (DCEG) and Center for Cancer Research (CCR), which includes the assessment of human genetic variation, including Single Nucleotide Polymorphisms (SNPs) and other types of genetic variation (microsatellites, insertion/deletion mutations, etc.) in a large number of separate population and family studies initiated by NCI investigators. The CGF shall provide data and support for the SNP500Cancer website (<http://snp500cancer.nci.nih.gov>) and Genewindow (<http://genewindow.nci.nih.gov>), internationally used and recognized resources for molecular epidemiological studies in cancer and other diseases. This effort shall be conducted primarily at the NCI Advanced Technology Center, Gaithersburg, Maryland or other sites, as required.

8. Oversight of DCEG Activities. The Director, DCEG, will appoint one or more individuals as DCEG technical liaison(s) to Contractor Research Support Programs; the technical liaison(s) will serve as APO(s) for DCEG activities, subject to the approval of the COR; the Chairperson, DCEG Repository Committee will serve on the FNLCR Repository Quality Board.

The Contractor shall designate a doctoral-level, senior scientist as the primary point of contact with the DCEG APO(s). This individual must be knowledgeable in the operations and procedures of the central repository that stores DCEG biospecimens and other DCEG-supported activities, as well as be responsible for reporting on DCEG-supported projects. The reporting will be accomplished by biweekly electronic mail to and weekly meetings with the DCEG APO(s); these reports shall include, but not limited to: (i) progress report on DCEG repository and laboratory support efforts; (ii) summary of specimen receipts and shipments; (iii) summary of specimen processing activities; (iv) problems encountered in laboratory/repository specimen processing and storage; and, (v) results of all DCEG support-related QA reviews.

**D. Division of Cancer Treatment and Diagnosis (DCTD)/ Developmental Therapeutics Program (DTP)**

The Contractor shall provide program-dedicated research support, laboratory management, and administrative support, as required, to DCTD. Support to DCTD includes, but is not limited to, the following:

“The Contractor shall operate a Biopharmaceutical Development Program (BDP), a government-owned, contractor-operated facility established by the NCI to develop and produce clinical-grade biopharmaceuticals, including but not limited to: monoclonal antibodies, recombinant proteins, immunoconjugates, peptide and DNA plasmid vaccines, viruses, and other biologicals. The BDP also provides biopharmaceutical development expertise in the areas of cell culture, purification, characterization, analysis, vialing, and Food and Drug Administration (FDA) regulatory compliance. The mission of the BDP in support of the NCI and other entities, as requested through NCI, is to manufacture small to medium scale quantities of clinical-grade biopharmaceuticals under current Good Manufacturing Practices (cGMPs). The BDP complies with U.S. FDA regulations and guidelines as is appropriate to meet compliance level requirements for each product manufactured. Products intended for use in Exploratory IND clinical trials are manufactured and tested in accordance with the FDA's guideline, “Guidance for Industry, Investigators, and Reviewers – Exploratory IND Studies.” Products intended for Phase I clinical trials are manufactured in accordance with the guideline, “Guidance for Industry – cGMP for Phase I Investigational Drugs.” Products intended for Phase II and non-pivotal Phase III clinical trials are manufactured following those aspects of 21 CFR 211 that apply to investigational use products.

(a) All personnel conducting critical BDP activities, as described below, shall be dedicated solely to the BDP effort. Any deviation from this policy shall require the prior approval of the Contracting Officer, Project Officer and Director of the BDP.

(b) Occasionally, excess BDP capacity may be identified, resulting from fluctuations in demand for some components of BDP operations at the FNLCR, improved productivity, or other reasons. On a case-by-case basis, use of BDP resources for projects outside of the NCI pipeline may be approved by the Director, Division of Cancer Treatment and Diagnosis (DCTD), the Project Officer and Contracting Officer subject to the terms and conditions of the contract provided that these projects are compatible with the NCI mission and policies, that they do not interfere with the performance and priorities of NCI projects, and that appropriate accounting and payback are made for all financial impacts, both direct and indirect.

(c) In addition to BDP operations at FNLCR, the NCI expects that the Contractor will use subcontracts with outside vendors for performance of selected development, manufacturing or testing components, or even entire projects, when advantageous on the basis of cost, timeliness, quality, demands on available resources, or other considerations.

(d) The government-owned manufacturing facilities at FNLCR support many types of biopharmaceutical manufacture. Examples of the type of work the Contractor will be required to perform are as follows: (i) microbial fermentation using instrumented fermenters at 10L, 80L, 150L and 500L fermentation scales; (ii) small to medium scale production of monoclonal antibodies and other mammalian cell products using hollow fiber technology (3 Xcell and 2 Maximizer bioreactors); (iii) small to medium-scale production of monoclonal antibodies and other mammalian cell products using suspension culture bioreactors (150L to 1000L) technologies; (iv) development and optimization of methodology for fermentation and recovery; (v) development of purification methods; (vi) development and performance of protein refolding methods; (vii) development and performance of assays for process development, in-process monitoring and cGMP Quality Control (QC); (viii) clean room suite for cGMP purification and limited-scale vialing; (ix) BL2+/GMP suite for small scale production of infectious agents or other products requiring BL2+ containment (n.b. Depending on the agent being produced, recommended procedures may require vaccination of staff using approved or, in some cases, experimental vaccines); (x) development and production of viral therapeutics, such as oncolytic viruses, viral vectors, and vaccines; (xi) raw materials management and control; (xii) management and control of specimens, intermediate and final products; (xiii) stability analysis of produced drug substances and products; (xiv) staging and storage for quarantined, intermediate and final products; (xv) quality assurance (QA) services, including validation, auditing, cGMP documentation and preparation of CMC sections for IND submissions; (xvi) document storage and archives; and, (xvii) administrative support.

(e) The Contractor shall provide significant input at several stages of project selection, as well as milestones during project execution. Selection of projects for NCI funding is made by NCI designated procedures, depending on the source of the project (e.g., Intramural projects, extramural projects supported by special programs such as the NCI Experimental Therapeutics Program (NExT), extramural projects support by an NCI IND, etc.). Selection of projects from other Institutes or Agencies is made according to the procedures of those agencies. These selections are based on factors such as technical merit, scientific novelty, and appropriateness to the mission of the funding organization. These selections, which shall be in conformance with the contract terms and

conditions, shall be submitted in writing to the Contractor by the Contracting Officer prior to initiation. In each case, prior to actual initiation of projects, staff members of the BDP review the projects to assess feasibility, timeliness, cost estimates, safety, cGMP compliance capability, appropriateness of existing space, staff, equipment, and impact on existing project priorities and resources. The results of these assessments are communicated by NCI to the funding organization to be used in cost-effectiveness determinations during their review process. Staff members of the BDP may attend project reviews as well. In addition, following selection of candidate projects for BDP, and prior to beginning a new project, the portfolio of new projects is again reviewed by an NCI procedure, which prioritizes all projects based on the most appropriate use of the BDP resources. Projects determined to be inappropriate for BDP are referred for performance to vendors other than the BDP Contractor and the BDP may be required by NCI to manage these vendors through subcontract agreements. In addition, the NCI reviews the ongoing performance of projects in the BDP portfolio, and has the power to re-prioritize or drop projects, depending on new information, technical or feasibility problems that develop during performance of the project, or other factors.

(f) The Contractor shall, through its own operations, or by partnering or subcontracting with other business entities, provide the following services: (i) Operate the BDP at the FNLCR campus, including the training, supervision, monitoring, auditing of staff and the management of staff in a manner consistent with cGMP requirements for ongoing and planned projects; (ii) Operate the BDP facilities, including space, environment, equipment, utilities, inventory, and records, in a manner that meets cGMP requirements; (iii) Provide building maintenance and housekeeping to meet cGMP requirements, including appropriate maintenance, monitoring, calibration, validation, and SOP documentation of utilities, space, environment, information systems, and equipment in order to maintain compliance with cGMP, safety, and technical requirements for ongoing and planned production projects; (iv) For each production project, together with process development and testing, provide project planning, management and scheduling, according to a formalized and documented process that is consistent with cGMP requirements for that project; (v) For each project, the Contractor shall provide to the NCI its best estimates of project-specific costs, resource requirements, and timelines, after initial review of a proposed project. The Contractor shall provide reports and updates for these estimates when major project milestones are achieved, and monthly. The Contractor shall identify issues arising from one project that may impact on other projects or otherwise require a review of project prioritization or resource allocation by the NCI; (vi) Provide an integrated approach to QA Services for staff, facilities, equipment, utilities, space, environment, documentation, inventory, projects, and procedures to meet cGMP requirements; (vii) Provide an integrated approach to supervision and management of Technical Operations to meet project production goals in a manner consistent with cGMP requirements. Within the Contractor organization, the head of BDP QA Services shall not report to the head of BDP Production; nor shall the head of BDP QA Services report to any lower level in the Contractor organization than does the head of

Production; (viii) Provide an integrated approach to the provision of BDP Administrative Services to support production, QC and QA requirements, prepare cost estimates and resource tracking, and make appropriate arrangements for facilities, maintenance, and engineering support, subcontracting, human resources, and other activities not directly performed by BDP staff; (ix) Provide mammalian cell culture services; (x) Provide fermentation development services; (xi) Provide cGMP microbial fermentation services to 500L scale; (xii) Provide protein purification development services; (xiii) Provide cGMP QC testing services; (xiv) Provide assay services in

support of process development, in-process testing and product release; and, (xv) provide clean room services for biopharmaceutical clinical trial-stage activities.

(g) In order to provide appropriate oversight of BDP quality concerns, the FNLCR maintains a Quality Board with membership from senior management of the NCI as well as senior Contractor management. The BDP shall make regular reports to the Quality Board, describing results of internal audits, incident reports and failure investigations, and other matters as required by the Quality Board. The Quality Board reviews topics for auditing by outside commercial vendors. The Quality Board reviews all internal and external audit reports and communications from regulatory agencies, as well as proposed and ongoing remedies.”

2. The Contractor shall provide a Lymphokine Testing Laboratory in support of BRB. Laboratory responsibilities include, but are not limited to: (i) maintaining a repository of cytokines and other biological materials as requested by BRB with production of aliquots and distribution, including shipping, of materials to BRB approved recipients; (ii) perform cytokine bioassays and other forms of bioassays to evaluate activity of products produced by the BDP; (iii) transfer and validate bioassay methods used to support recertification testing of clinical grade cytokines as directed by BRB with testing requests submitted through the BDP.

3. The Contractor shall provide a Natural Products Support Laboratory (NPSL), responsible for the preparation of crude extracts from raw natural products collected by outside contractors and shall have the capability of processing raw materials at a rate directed by the Government. These materials may be of marine (sponges, mollusks, etc.), terrestrial (bark, needles, leaves and twigs, etc.), or microbial/fungal origin and be in either whole or partial forms. The extraction process involves the grinding, solvent extraction (organic and inorganic), lyophilization, weighing, aliquoting and delivery of crude biological samples back to the Natural Products Repository (NPR) for recall by the drug preparation staff for screening in the in vitro human tumor cell line panel, or delivery to grantees or other investigators designated by the DTP; support bioassay-guided fractionation and structure elucidation of natural products in support of various DTP screening efforts; and prepare 96-well microtiter plates from extracts for shipment to the biorepository while maintaining the full screening library plate set to allow for rapid access to these samples. Additional requirements include the ability to assay compounds for purity, prepare purified compounds by chromatography or other methods, and perform large scale (gram quantity) isolation of compounds as requested by DTP.

The Contractor shall provide a non-cGMP drug preparation capability within the NPSL that shall provide weighed and solubilized materials on demand, for testing by the anti-cancer drug screens, hollow fiber assays, and in vivo xenograft testing, as well as pharmacokinetic and metabolism assays. The drug preparation staff shall communicate with the screening laboratories to determine their weekly testing capacity, and to maintain a sufficient backlog of solubilized compounds to meet this capacity, but not to exceed it. Dry samples shall be shipped to the drug preparation staff, logged in, stored until the appropriate time, solubilized in the appropriate manner, and distributed immediately prior to testing. The various DTP drug screens shall test different agents and have different requirements for preparation.

4. The Contractor shall maintain and operate Cancer and Specialized Molecular Targeting Screens, as directed by the NCI. These efforts will include molecularly targeted assays, gene expression studies and other appropriate capabilities. The results of these screens shall be maintained utilizing a highly organized tracking and

record keeping system for inclusion in DTP's website. The laboratory shall perform the testing requirements of DTP investigators. Specialized personnel shall be provided to support DTP research efforts, as directed by the Government.

5. The Contractor shall develop, establish, and operate an In Vitro Cell Line Screen, an in vitro disease-oriented antitumor drug screening program utilizing a panel of 60 human tumor cell lines organized into subpanels representing leukemia, lung, melanoma, renal, central nervous system, ovarian, mammary, prostate, and colon cells. Contractor support shall include, but not be limited to:

(a) Testing of large numbers of unknown compounds against the well-characterized human tumor cell lines in a single dose screen using a sulphurhodamine B colorimetric methodology. Data shall be analyzed using microcomputer and AlphaServer systems. The screening libraries shall include synthetic compounds, natural product extracts, and natural product fractions. Compounds that pass the 1-dose screen are tested in a 5-dose screening assay.

(b) Development and conduct of assays for detailed follow-up studies of samples that show interesting differential activity in the primary screening protocol, as directed by the Government. These assays shall include but not necessarily be limited to time-duration, pulse-treatment, cell-recovery, colony-forming studies, and gene expression studies.

(c) Efforts to improve the screening panel by characterization of new cell lines acquired by the program. This will include both development of new cell lines suitable for replacement of some present cell lines from tumor types now included in the tumor panel and characterization of cell lines of tumor types not presently in the screening panel (i.e., breast, prostate).

(d) Respond to extramural investigators' requests for cell lines, non-viable cell pellets, and related materials such as DNA and RNA as directed by the DTP Molecular Targets Committee.

(e) The 60-Cell Line Screening Laboratory shall receive oversight from a committee organized through the DTP Office of the Director.

The Contractor shall provide support for the development of clinical pharmacodynamic markers of efficacy, and indicators of patient susceptibility for phase 0, or novel preclinical agents using in vitro or in vivo models, as directed by the government. These assays may include microarray analysis, specific gene or protein expression studies, transfections to augmentation or suppress gene expression, microscopy, biochemical modulation and cell cycle analysis.

The Contractor shall support DCTD-directed efforts to measure large-scale drug induced gene expression changes in the 60 cell lines of the NCI screen, using the most high-throughput assays available at NCI-FNLCR.

6. The Contractor shall provide support for the Analytical Chemistry and Pharmacokinetics Laboratory. This Biological Testing Branch (BTB), DTP-related laboratory develops analytical chemical methodology for newly discovered novel test agents identified by DTP. These methodologies are applied to selected studies of pharmacokinetics and metabolism (both preclinical and clinical), and optimization of formulations of new active agents. Support shall be provided for in vivo models of the absorption, distribution, metabolism, excretion and

pharmacokinetics of these novel compounds. The sophisticated techniques employed require extensive use of HPLC and gas chromatography (GC).

7. The Contractor shall support the In Vivo Model Development and Testing Laboratory responsible for all BTB-related in vivo studies conducted at NCI Campus at Frederick. This laboratory supports the animal research portions of the hollow fiber assay, as well as other in vivo model development studies, such as evaluating new tumor cell lines for tumorigenicity, in vivo efficacy studies, in vivo pharmacodynamic endpoint studies and, evaluating transgenic mouse tumor models submitted. The Contractor shall develop protocols that are required for these efforts and which can be used by screening laboratories; protocols must include parameters for evaluating tumor treatment efficacy.

The Contractor shall provide support for in vivo screening, including: (i) in vivo testing of all standard chemotherapeutic drugs as experimental references; (ii) preparation of test compounds for administration to animals; (iii) maintenance of a small repository for test compounds; (iv) tumor implantation and drug treatment of animals (for the hollow fiber assay, this shall include intraperitoneal or intravenous daily treatments against intraperitoneal and subcutaneous hollow fiber implants); (v) animal holding and evaluation of therapeutic effects; and, (vi) reporting of results via telecommunication to the appropriate NIH computer facility.

8. The Contractor shall operate a Fungal Laboratory responsible for expanding the approximately 75,000 samples currently stored in the Natural Products Repository for testing in the anti-cancer cell line screens. As samples show activity, fungal samples shall be scaled up for production of material suitable for further in vivo studies.

The Contractor shall provide additional support for acquisition of materials, taxonomy of unidentified fungal samples and in-house isolations and identification programs. The Contractor shall provide services in support of this work including fungal taxonomy, use and maintenance of 10-liter stir jars, fungal cell culture, etc.

9. The Contractor shall perform in vitro studies which directly support the BTB-related in vivo studies conducted at the NCI Campus at Frederick. The In Vitro/In Vivo Support Laboratory shall support the cell culture, fiber production and endpoint assay for the hollow fiber assay. In addition, the laboratory shall provide cell culture expertise for any cell lines which need to be expanded prior to implantation into experimental animals.

10. The Contractor shall operate the DTP Computer Center, providing computer support to the DTP drug discovery and development program. The Contractor shall be responsible for the operation, including system management and data base administration, of a totally integrated computer facility located in Bldg. 378 which is the main computational resource for the various laboratories supporting the DTP drug discovery program. The Contractor shall provide networking, database and systems software. The Contractor shall maintain the DTP web site and provide programming support for its continued development. In addition, the Contractor shall provide the necessary software engineering and development support to meet DTP needs. The Contractor shall provide technical support to the entire community of users including consultation, education services, and techniques for effective use of the computation services, subject to the approval of the COR and Contracting Officer. The Contractor shall support collaborative efforts to provide services for structure-based drug design to identify lead compounds as candidate therapeutics against various agents. These services may include, but are not limited to, using state-of-the-art methodologies in bioinformatics, chemoinformatics and molecular modeling.

11. The Contractor shall support the Specialized Assays Laboratory responsible for BTB-related testing of agents utilizing time course, ex vivo and soft agar clonogenic assays this laboratory evaluates test compounds for their in vitro sensitivity to selected cell lines over a period of time and aids in determining potential dosing schedules. The Contractor may be required to modify existing protocols specific to either cell lines or test compounds.
12. The Contractor shall provide the necessary support of collaborative efforts to evaluate potential radiation modifiers identified in connection with the DCTD RAMEN Program.
13. The Contractor shall provide dedicated support for the Translational Research Fund in the management of correlative studies performed during the conduct of sponsored clinical trials of the DCTD CTEP IND agents. These studies will require extensive subcontracting arrangements.
14. The Contractor shall provide, upon request, dedicated support for the RAID, R\*A\*N\*D, IIP and future peer-reviewed programs initiated by or in collaboration with the DCTD. Support shall be customized according to the requirements of the individual approved project, utilizing the expertise of many of the DTP-supported laboratories or through subcontracting arrangements.
15. The Contractor shall also provide support to the in vivo program of the BTB by performing in vitro studies to identify differences between molecular targets identified in lysates prepared from cells in culture, cells harvested from implanted hollow fibers, tumor tissue, or normal tissue. The goal from these studies is to derive both in vivo and in vitro assays that better predict the activity and eventual success of a drug/compound before it goes to the clinic.
16. The Contractor shall provide support for the Drug Mechanism Group responsible for elucidating the mechanism of action and identifying potential surrogate markers of drug activity for compounds identified as preclinical development candidates by the BTB, DTP. This laboratory utilizes transcriptomic (microarray, QPCR) and proteomic (quantitative, subcellular, chemical, and 2D PAGE) technologies to derive mechanistic information. Subsequent validation is performed using technologies such as cell-based assays, ELISA, flow cytometry, western blotting, immunohistochemistry and molecular biological approaches including cDNA/siRNA transfections.
17. The Contractor shall operate the Laboratory of Human Toxicology and Pharmacology (LHTP) to facilitate the entry of new chemical entities (NCEs) for the treatment of cancer into Phase 0/I clinical trials. This comprehensive laboratory will support a preclinical program based on pharmacokinetics and pharmacodynamics and the evaluation of human sensitivity in new in vitro toxicity assays for both traditional cytotoxic as well as newer molecular target-based small molecules. To meet this end, the Contractor shall establish and operate the following laboratories within the LHTP:
  - (a) Pharmacodynamic (PD) Assay Development and Implementation Section (PADIS) -- shall develop and validate sensitive methodologies to determine the impact of drug treatment on target(s) in tumors and selected normal tissues, that is, target status, downstream consequence, biomarker and toxicity marker; evaluate these pharmacodynamic changes in various species, starting with the animal tumor model to correlate doses and/or plasma drug levels with impact on target in tumor and normal tissues; determine whether peak plasma levels, AUC or time above a threshold is required for target modulation; develop an appropriate surrogate for tumor, if

possible, e.g., PBMCs, skin biopsy, saliva, buccal mucosa cell, etc.; oversee translation of these PD assays to the clinical setting and support assay of samples obtained in clinical trials, as necessary; develop procedures for biopsy of tumor and normal tissues using clinical instruments; formalize biopsy, specimen handling and analytical assays as SOP; transfer SOP to the National Clinical Target Validation Laboratory (NCTVL) or other laboratories as necessary.

(b) Predictive Toxicology Section (PTS) – shall maintain a laboratory whose primary focus will be the toxicity produced by small molecule cancer agents with the primary aim of predicting human versus animal sensitivity in CFU-GM testing and in new organ system tests such as fresh human liver and lung slices and human hepatocytes; the development of prediction models for organ system toxicity and markers; the discovery of markers for organ system toxicity; humanizing treatment arms for in vivo trials; humanizing test concentrations for discovery screening sets; the evaluation of starting dose safety, relative to predicted MTD form CFU-GM and other validated organ system assays; and the correlation of clinical data with animal data and in vitro safety data for validation. PTS shall also integrate molecular studies to identify candidate molecular toxicology markers in drug-exposed human tissues and their counterparts in other species. Candidate molecular toxicology markers shall be submitted to the PADIS for consideration for development and preclinical validation as PD markers of drug action.

(c) Viral Vector Toxicology Section (VVTS) -- As part of the in vitro toxicity evaluation effort described above for small molecules, a special virus laboratory shall be maintained to evaluate the toxicity of various viral vectors such as adenovirus, polio and measles in human tissues like liver, lung and nervous tissue that cannot be readily evaluated in animals. A dedicated laboratory shall be established for characterization of toxicity of novel anti-cancer viruses, and vectors with etiological significance for cancer. Because of the potential risks associated with new viral vectors, it will be important to operate this function with strict adherence to the relevant biosafety rules and to maintain appropriate approvals from the Institutional Biosafety Committee. Another function of this laboratory will be to transfect different tumor cell lines with luciferase using various viral vectors such as lenti- and retroviruses for use in the BTB in efficacy studies such that efficacy can be more readily quantitated using imaging. To accomplish this goal, coordination with the DTP in vivo effort will be necessary, both for selection and validation of the various cell lines being transfected.

(d) Formulation Development Section (FDS) – a laboratory shall be maintained that serves the needs of DTP for early pre-formulation development of potential drug candidates emerging both from the intramural (Joint Development Committee of DCTD-CCR) and the extramural community (DDG, RAID, etc.). In addition, this laboratory will quickly screens compounds for solubility, stability, and identification of potential formulations suitable for testing in animal models for efficacy studies, PK/PD evaluations, and initial assessment of toxicity. This laboratory will also be useful in formulation optimization, novel dosage form development, and preparation of custom formulations for specialized efficacy evaluations.

(e) Preclinical-Clinical Discrepancies Section (PCDS) -- Not all Phase 0 clinical trials will confirm PK/PD findings made in the preclinical models. Discrepancies between preclinical and clinical results point to opportunities to improve the predictive accuracy of the preclinical models. Investigating the explanation for the discrepancy will involve unanticipated “bed-to-bench” translational research and close interaction between PADIS and the Phase 0 program. Therefore, a laboratory shall be maintained whose activity will create a research effort that moves

against the normal directional flow of DTP activities in “bench-to-bedside” development, for which professional project management techniques are planned and time lines considered and adhered to. To avoid disrupting these scheduled development activities, yet still capitalize on opportunities to investigate preclinical-clinical discrepancies and improve discovery tools, it will be necessary to establish a dedicated research laboratory for these investigations.

18. The Contractor shall operate the National Clinical Target Validation Laboratory, which will serve as a national resource. The focus of this laboratory will be as follows:

(a) To perform and/or advise on validated procedures on tumor or surrogate tissues for the evaluation of molecularly targeted therapies. Ensure the origination and development of quality control methodologies for correlative clinical investigations essential to the evaluation of drug efficacy that utilize small, and difficult to obtain, patient specimens. Validation procedures developed, designed, and delivered by the laboratory will result in accelerating the completion of translational clinical investigations nationwide.

Provide scientific expertise in the development, testing, and further refinement of novel methodologies for use in target tissues specifically applicable to human cancer clinical trials. Such methodologies can demonstrate the therapeutic effects of small molecular anticancer agents on specific signal transduction pathways of interest.

(b) Provide scientific expertise and support to extramural investigators. Will assist investigators in acquiring the necessary skills and expertise to develop the correlative laboratory procedures for their own investigations ongoing at other, NCI-designated clinical research venues that are not part of the current NCI-funded phase I and II program (Cancer Centers, Cooperative Groups, and SPORES).

(c) Provide a central laboratory function to perform target validation assays for patients treated within the CCR. Will provide for the delivery of target validation assays for patient samples from NCI-funded extramural investigators lacking the expertise and/or facilities to perform such assays.

(d) Provide validation procedures to the extramural cancer clinical research community as part of NCI’s current early therapeutics development program and to the NCI’s intramural program.

(e) Provide for extramural investigators with NCI peer-reviewed clinical trials to access laboratory and/or clinical resources for the evaluation of molecular targets of interest critical to the completion of their studies with the approval of DCTD management.

19. The Contractor shall operate the Laboratory of Synthetic Chemistry Laboratory to provide support to a DCTD-CCR synthetic chemistry initiative. The laboratory will provide expertise including, but not limited to the development of novel synthetic methods, particularly those required for the production of research materials for projects approved by the Joint Development Committee of DCTD-CCR. Additional support may be provided to aid in the decision process for further testing of agents that pass the initial NCI 60 Cell Line Screen.

20. The Contractor shall provide technical and material support of laboratory correlate studies (PK/PD) in its Phase I and II clinical trials conducted in the oncology treatment areas at the NIH Clinical Center. Technical support will include staffing and materials required to interact closely with clinical staff to coordinate receipt of clinical samples, process samples for cryopreservation, prepare materials and packages for shipment of samples

to designated testing laboratories or long-term storage sites (e.g., repositories), and maintain a database of samples received, processed and distributed to analysis sites. This effort shall be located at the NIH Clinical Center.

21. The Contractor shall operate the DCTD Program Management Office (PMO) which is tasked with the following:

- (a) Provide and facilitate communication and coordination among all Phase 0/I and NCI RAID drug development project teams, including dissemination of information to NCI internal stakeholders and other interested parties.
- (b) Manage the flow of information, direction, planning, etc. for projects as they migrate between the various DTP and OTS Contractor laboratories, other DTP contractors or the various other NCI laboratories and clinics involved.
- (c) Act as a liaison between the various OTS Contractor and NCI entities.
- (d) Provide support for the preparation of clinical protocols and amendments and make certain that all appropriate responses to PRC, PRMC and the IRB are performed in a timely manner meeting established timelines; for the preparation of manuscripts as determined by the NCI; for the preparation of scientific presentations; and for the preparation of meeting minutes for various meetings as assigned.
- (e) Work with DCTD management to establish appropriate project tracking systems.

**E. Division of Cancer Control and Population Sciences (DCCPS)**

The Contractor shall provide, through a Clinical Monitoring Research Program, a component of the Clinical Research Directorate, program-dedicated research support to the programs of Division of Cancer Control and Population Sciences (DCCPS). Programmatic support to include, but not be limited to: behavior scientists, special project administrators, and program coordinators. The Contractor shall provide support for assisting in the coordination and dissemination of research activities including surveillance, epidemiology, health services, behavioral science, and cancer survivorship as they relate to cancer control and prevention in the U.S.

**F. Support for the National Institute of Allergy and Infectious Diseases (NIAID)**

The Contractor shall provide effective rapid responses to urgent and compelling public health concerns (e.g., HIV, SARS, influenza, malaria, etc) through program-dedicated research support to NIAID activities at the NCI Campus at Frederick. The Contractor shall provide laboratory management & support, clinical support services, project and program management and administration, biostatistical support, regulatory compliance and clinical trials management, and international collaborations support services. This support includes, but is not limited to:

- 1. Clinical Monitoring Research Program (CMRP) services as a component of a Clinical Research Directorate, including but not limited to Regulatory and Human Subjects Protection Programs, Clinical Consulting Services and Support to NIAID Clinical Teams. Contractor's CMRP services shall be comprehensive and shall enable the NIAID Division of Clinical Research to provide, guidance, policies, procedures, and services that facilitate investigators in the Intramural community and those sponsored by the NIAID Intramural programs to conduct clinical research of the highest quality in accordance with applicable regulations, standards and appropriate guidelines.

2. Regulatory/clinical trials management services shall support NIAID's clinical trials in areas that include, but are not limited to: HIV, malaria, avian flu, SARS, and other emerging infectious diseases; laboratory support to Mali, India and Nigeria and other international locations as well as infrastructure building through comprehensive project and program coordination and management. The augmentation and expansion of the clinical support being requested by NIAID provides maximum effectiveness, efficiency and synergism with existing supported clinical research efforts.
3. Programmatic support shall include, but not be limited to: Medical Officers/Medical Affairs Scientists/Physicians, nursing/study coordinators, case managers, pharmacy and laboratory technicians, regulatory/clinical trials staff, clinical project managers, biostatisticians. Other program and administrative positions will be requested as part of these clinical support efforts. These types of positions may be requested to support both domestic and international clinical research initiatives. Additional consultants and subcontracting efforts may also be requested as the NIAID clinical research efforts expand to meet the respective health challenges threatening the global community. These support services may also be requested in support of other NIAID divisions including but not limited to: the Division of Intramural Research, Division of AIDS and Division of Microbiology and Infectious Diseases.
4. Scientific oversight of clinical research portfolios; direct expert nursing care and study coordination to assigned caseloads of patients on specific protocols; coordinating patient schedules to meet the requirements of protocol interventions and data collections; assisting in skilled procedures performed by medical affairs/physicians (e.g., phlebotomy and IV catheter placements); ordering diagnostic procedures per protocol; documenting patient care per protocol requirements; participating in clinical rounds; interpretation of data and clinical trials implementation; serving as a liaison with clinical, regulatory and laboratory personnel on assigned protocols; interacting with monitoring/auditing agencies; assisting the PI in writing protocols and amendments; serving as Associate Investigators and participating in clinical trials protocol development; providing good clinical practices expertise and mentoring for other clinical staff, and, providing general programmatic support to the clinical research efforts (e.g., subcontracting, logistics, and procurement).
5. Contractor shall provide support to the NIAID International Centers for Excellence in Research (ICER) programs in Uganda, India, Mali and other international sites as requested. Support to the ICER Research Initiatives includes but is not limited to: provision of dedicated off-site personnel to coordinate activities to establish state-of-the-art laboratories, managing administrative concerns, tracking and monitoring dedicated budgets, project procurement, facility concerns, professional consulting and subcontracting agreements, quality assurance and associated clinical research support and overall coordination of administrative program level functions. In addition, the Contractor may be requested to provide technical training support to include laboratory equipment repair and laboratory technician personnel.
6. Specifically, the Contractor shall provide support and logistical services for the operations of intramural clinical research for Phase I, Phase II and Phase III clinical trials sponsored by the NIAID, NIH. The Contractor shall be responsible for data and document collection and compilation for regulatory filing (pre-IND, IND) with the US Food and Drug Administration; technical review and report preparation; clinical site monitoring activities; final container packaging, purchase, labeling, storage, distribution and tracking of investigational products; storage of biological samples; implementing and maintaining computer information systems; providing administrative

coordination and general logistical support for regulatory activities; training; and other services as required. The required tasks will include, but not be limited to:

(a) Informatics support for regulatory affairs activities, including (i) general administrative support; (ii) the writing and maintenance of procedure manuals; (iii) assistance in the preparation of responses on NIAID clinical trial activities; (iv) provision of protocol/data logistical support services; (v) assistance in the development and preparation of case report and data collection forms; (vi) maintenance of regulatory documents, complete source documentation and case report forms; (vii) assistance in the preparation of IRB, RAC, and RSC submissions; (viii) maintenance of updated protocol information in the NIAID computerized databases; (ix) dissemination of protocol information to NIAID staff, clinical investigators at non-NIH sites, and IRB members; (x) auditing of protocol files to ensure concordance between computer and physical records; (xi) correspondence; (xii) provision for translation of foreign language documents to and from English; (xiii) provision of general support for IND activities; (xiv) provision of audit support for FDA and OHRP inspections; (xv) training of investigators and study coordinators on records management and FDA Good Clinical Practice (GCP) guidelines; (xvi) development of automated management tracking tools for pre-IND filing and follow-up; (xvii) assistance in communications with sponsors, the FDA, the IRB, et al.; (xviii) provision of document courier services, as required; (xviii) assistance with investigators and study coordinators in the development of study SOPs; (xix) coordination of patient recruitment and screening; (xx) monitoring of project plans, timelines, budgets and provide progress reports; (xxi) management of cross-functional project teams; (xxii) development of automated management tracking tools for assurance negotiation; (xxiii) coordination of site visits and conference support; (xxiv) provision of necessary technical assistance for the assembly and review of documentation for IND submissions to the FDA, as described in 21 CFR 312.23; (xxv) provision of logistical support and technical assistance for project assurance(s) filings; (xxvi) maintenance of NIAID IRB Web Page and required links; (xxvii) provision of IRB meeting support, including electronic protocol filing and related support; (xxviii) provision of electronic information systems and software; (xxix) provision of electronic information systems and software; and, (xxx) provision of "user friendly" MIS reporting capability for reports.

(b) Provide quality assurance and quality control oversight, including, but not limited to: (i) Good Clinical Practice (GCP) monitoring of non-IND protocols; (ii) IND clinical trial monitoring; (iii) study monitor support by personnel with appropriate training and educational credentials; (iv) formulate and manage data safety monitoring boards; (v) provide general QA for data acquisition; (vi) formulate and manage ad hoc reviews; (vii) formulate and manage scientific pre-reviews of protocols prior to IRB submission; (viii) provide logistic and secretarial support for IRB submissions; (ix) provide interface between biostatistics staff and investigators; and. (x) develop and maintain a database to track and tabulate adverse events.

(c) Ensure the provision of training for, but not limited to, investigators to reinforce and enhance a GCP culture.

(d) Provide repository and pharmacy management, including, but not limited to: (i) receipt, storage, labeling and final packaging; (ii) inventory, distribution, as well as processing and disposal of returned investigational agents; (iii) tracking of these activities; and, (iv) provide expertise and guidance to NIAID-supported clinical trial sites in the handling and shipping of investigational products.

(e) Conduct related activities, as required, including, but not limited to: (i) maintenance of back-up support personnel system; (ii) provide log of task assignments; (iii) interact with other NIAID contracts for data exchange and movement of sample and investigational products; and, (iv) develop a transition plan in the event aspects of this project are transferred to another Contractor.

7. A Neutrophil Monitoring Laboratory, shall be maintained that conducts assays on blood, urine, and blister fluids and capable of performing a large number of functional assays on neutrophils from patients with chronic granulomatous disease or other related conditions. This effort includes assays on human white blood cells (WBC), as well as immunological assays for human cytokines in sera and plasma. Neutrophils and monocytes will be separated and purified from whole blood and their function assessed by reduction of nitroblue tetrazolium dye, production of superoxide, chemotactic activity, bactericidal activity, phagocytic activity, spreading potential, and hydrogen peroxide production. Plasma and sera shall be evaluated by ELISAs and RIAs for lactoferrin content production and cytokine levels.

8. An Immunological Monitoring Laboratory shall characterize immunologic function in Patients with Acute or Chronic Inflammatory Disorders. The Contractor shall perform detailed single or serial cellular immunological assessments on representative populations of patients with inflammatory or immunodeficiency states, viral or immune-based, and on appropriate controls (healthy and with relevant diseases).

The Contractor shall provide a general immunological service in support of ongoing clinical research studies being conducted by investigators within the Laboratory of Clinical Investigation, National Institutes of Allergy and Infectious Diseases. The Contractor shall arrange to receive or ship research specimens from the NIH-Bethesda or other sites collaborating with NIH investigators in accordance with governing policy and regulations. The Contractor shall access the specimens as needed, maintain a specimen repository and perform immunological studies of the specimens, including assays for cytokines or chemokines or other inflammatory markers in serum or plasma or other relevant bodyfluids. Also, when peripheral blood cells are collected from patients and controls, the cells shall be separated, counted, and cryopreserved for future analysis. Functional analysis of these purified cells shall be determined by stimulation with appropriate antigens, mitogens, or cytokines, followed by analysis of the cytokine or chemokines released by the stimulated cell.

The Contractor shall maintain state-of-the-art facilities to support these studies; maintain rigorous quality assurance and quality control standards; organize and help analyze data generated from its studies, and help prepare these data for presentation and publication. The Contractor shall be available for routine and special meetings by telephone or in person to plan, discuss and review the work.

9. The Contractor shall provide freezer repository services, as required, for the NIAID Intramural Program investigators. Responsibilities will include, but not be limited to: (i) Picking up specimens to be held frozen at the NCI Campus at Frederick and delivering sorted frozen specimens to NIAID scientists at NIH-Bethesda, as requested; (ii) maintaining an on-line, data-based inventory of all specimens, some at the vial level, some at the box level, as requested; and, (iii) assuring that specimens are maintained at temperatures specified, during holding and transportation.

10. The Contractor shall provide personnel to support clinical trial work conducted by or on behalf of the NIAID either on site or off site, especially for support that is time sensitive such as blood processing or pharmacokinetics.

11. The Contractor shall furnish services to establish immunologic profiles of patient specimens in support of the NIAID intramural program commitment to AIDS Clinical Research. When appropriate, testing procedures are to be performed under the auspices of CLIA88, as modified, and laboratories performing the testing will maintain CLIA88 certification. Procedures to be performed include, but are not limited to: (i) enumeration of lymphocyte subsets; (ii) cell sorting; (iii) cloning; (iv) proliferative responses of lymphocytes to mitogens and antigens; (v) spontaneous plaque-forming cell assays; (vi) natural killer cell assays; (vii) lymphokine activated killer cell assays; (viii) antibody-dependent, cell-mediated cytotoxicity (ADCC); (ix) measurement of various cytokines in body fluids and tissue culture; (x) establishment of EBV transformed cell lines; (xi) p-24 analysis; (xii) hematologic evaluation of patient's PBLs; (xiii) GC mass spectrometer analysis; and, (xiv) preservation of cells, plasma and serum.

The Contractor shall perform specific assays for HIV with confirmatory tests; the detection of live HIV utilizing co-cultivation techniques and reverse transcriptase assays; isolation and/or synthesis of HIV viral proteins; and the maintenance of cell lines in continuous culture. The Contractor shall provide, but not limited to, the following support:

(a) Specific assays for HIV utilizing the following: (i) Enzyme-linked immunosorbent assays (ELISA).  
(ii) Confirmatory analysis of positive ELISA tests with immunoblotting (Western blot) analysis.

(b) Other tests for the detection of HIV and for the evaluation of HIV immune responses include: (i) Polymerase chain reaction to detect HIV in peripheral blood mononuclear cells; (ii) ELISA assays utilizing purified viral antigens and antibodies; (iii) Isotype-specific assays; (iv) Radioimmunoprecipitation assays; (v) In situ hybridization; (vi) Branched DNA; (vii) Amplicor RTPCR; (viii) NASBA; (ix) Quantitation of HIV by both RNA and DNA; and, (x) Gene expression arrays using Affymetrix genechip technology.

(c) Specific assays for the detection of live HIV from clinical specimens include: (i) Cell co-cultivation; (ii) Assay of culture fluids for reverse transcriptase activity; and, (iii) Assay for plasma viremia, utilizing endpoint-dilution cultures.

(d) Development of monoclonal antibodies to viral proteins and cell surface antigens associated with HIV and the maintenance of up to 25 various cell lines in continuous culture, for basic studies on virus-host cell interactions and studies on the prevention of infection and/or disease.

(e) Services to be provided include arrangement of courier services to and from the NIH campus or other locations as specified. The facilities must have the capability for work with biohazardous materials (HIV) under BL-2\* laboratory conditions. The laboratory data shall be forwarded via computer to the NIH database in the manner specified by the NIAID. Additionally, the Contractor will provide programming and LAN support to the NIAID Network system.

(f) Bead separation of lymphocyte subsets;

(g) HIV genotyping with sequence analysis;

- (h) Measurement of levels of T cell receptor excision circles (TREC) in T cell subsets;
- (i) Quantitation of levels of exogenously administered genes and their products;
- (j) DNA sequencing;
- (k) Quantitation of telomere and telomerase activity; and
- (l) Assays for quantitation of hepatitis B and C.
- (m) Drug Resistance studies
- (n) Development and implementation of any new state of the art assays useful in the monitoring of patients with HIV or emerging and re-emerging infectious diseases.

**G. Support to the NIAID Vaccine Research Center (VRC)**

The VRC cGMP pilot plant shall be leased and operated by the Contractor. The Contractor's major responsibilities for this program-dedicated research support include, but are not limited to:

1. Support all aspects of cGMP development, including warehousing, QA, maintenance, QC, and preparation of manufacturing documents for IND and related submissions;
2. Establish and manage the production, testing, release, filling/packaging, and regulatory filing preparation of Phase I/II vaccine products, as requested;
3. Establish and manage the development of manufacturing processes that are suitable for eventual manufacture by VRC partners of material for Phase III and licensed vaccine production, including Process qualification, Assay Development, and Process Validation, as requested;
4. The VCMP complies with U.S. Food and Drug Administration regulations as is appropriate to meet compliance-level requirements for each product manufactured. Projects intended for Phase I clinical trials are manufactured in accordance with the guideline, "Guidance for Industry – cGMP for Phase I Investigational Drugs (July 2008)". Products intended for Phase II and non-pivotal Phase III clinical trials are manufactured following those aspects of 21 CFR Part 211 that apply to investigational use products.
5. Manufacture Phase I/II clinical lots of candidate vaccines utilizing appropriate cGMP standards;
6. Support the development of manufacturing processes through staffing in the various VRC developmental laboratories, including those on the NIH-Bethesda campus;
7. Establish Quality Systems to support manufacturing of candidate vaccines by other VRC Contractors;
8. Participate in the conceptual design of vaccine manufacturing processes as projects are transferred from basic research laboratories to VRC developmental laboratories; and

9. Facilitate the transfer of technology to VRC partners.

#### **IV. BUSINESS EXECUTION AND OPERATIONAL SUPPORT ACTIVITIES**

##### **A. Business Management**

1. The **Contracts and Administration Directorate (C&A)** is responsible for the overall business management of the OTS contract relating to the operation of the NCI Campus at Frederick. The C&A component shall provide administrative, logistical, procurement, and business support to all operating entities at the NCI Campus at Frederick. The specific operating components of C&A are Human Resources, Financial and Administrative Systems, and Acquisitions and Logistical Systems.

2. **Human Resources Department** shall be responsible for OTS contract personnel, providing direct oversight and responsibility for recruitment, employee relations, employee benefit programs, development and delivery of training programs to all levels of staff, affirmative action programs, employee counseling, administration of Wage and Salary Program, and administration of the Service Contract Act compliance requirements, if applicable. Human Resource services are extended to other NCI Campus at Frederick contractors in support of their specific contract areas through interfaces established by the NCI Contracting Officer with the primary objective of minimizing duplication of effort and expense.

3. The **Financial and Administrative Systems Department** shall be the central point of responsibility for all OTS Contractor fiscal and budget functions. Responsibilities include preparation and administration of budgets, coordination of all budgetary and funding issues with NCI, fiscal maintenance of the Advanced Technology Program and other "fee-for-service" programs, accounting and cost control, payroll, travel, and management information systems. Responsibilities of each of these components shall include but not be limited to:

(a) Finance shall have the primary responsibility for annual budget preparation, cost control monitoring, and reporting of cost status to the NCI Project and Contracting Officers. Additionally, this function serves as the central interface point on all "fee-for-service" issues as they relate to the Advanced Technology Program and other "fee-for-service" programs.

(b) Accounting shall be responsible for the review and approval of all disbursements of funds from the FNLCR Special Bank Account (SBA) and provides administration of the SBA and audits of funds disbursements to ensure compliance with contract provisions and the prompt payment requirements.

(c) Payroll shall be responsible for all payroll functions, including the collection and review of time cards, employee wages and deductions, and employer withholdings and payments. Compliance shall be maintained with regulatory requirements, i.e., year-end W-2s, quarterly 941s, and FICA remittances.

(d) Travel shall be responsible for the coordination of all NCI Campus at Frederick Contractor travel.

4. **Contracts and Acquisition (C&A) Department** shall be responsible for general purchasing, warehousing and inventory control, transportation, property accountability, contracts, management of the government fleet program and other tasks, as required.

The Contractor shall provide and be responsible for such services to include but not be limited to:

(a) Purchasing shall provide centralized procurement for all operating entities at the NCI Campus at Frederick for general procurement of capitalized equipment, administrative and laboratory supplies, and industrial supplies.

(b) Warehouse and Inventory Control shall be responsible for the receipt, inspection, and delivery of all incoming items as well as operation of the Central Supply Warehouse and the Maintenance Supply Warehouse. These services extend to all operating components housed at the NCI Campus at Frederick.

(c) Transportation shall be responsible for all courier and mail services at the NCI Campus at Frederick. This includes incoming and outgoing mail to and from the NCI Campus at Frederick via the U.S. and international mail services, the daily exchange of interoffice correspondence, incoming and outgoing air and ground shipments, courier services by internal personnel and commercial companies, and relocation of household goods for new employees.

(d) Property Accountability shall manage all Government-owned personal property at the NCI Campus at Frederick, as directed by the Contracting Officer. This includes maintenance of property inventories, transfers of property and accountability within the NCI Campus at Frederick, trade-ins, transfers to various agencies, and GSA sales.

(e) The Contractor shall obtain mainframe computer systems, research support services, logistical services, equipment, vehicles, consulting services, off-site facilities and support, A&E services, construction/renovation projects, and interim facilities needed for contract requirements. In carrying out these responsibilities, the contractor shall ensure that all materials and services are directly provided or as necessary acquired from other sources at the lowest possible cost consistent with the mission requirements of the FNLCR. In making recommendation to the Government on whether to make or buy services and/or supplies, the OTS Contractor will continually review the methods used for work accomplishment and suggest ways to adjust the mix (in-house/out-of-house) as appropriate to meet changing mission requirements while carefully balancing cost and quality.

**B. Research Support Miscellaneous Services**

1. Publications and Graphic Arts, The Contractor shall furnish a service that provides resources and expertise for the publication and presentation of scientific and other information including, but not limited to: (i) illustration and graphic arts, including computer graphics; (ii) photography; (iii) reproduction; and, (iv) audio-visual and poster presentations.
2. Conferences/Seminars/Meeting Services. The Contractor shall furnish services for the timely accommodation of conferences, seminars, and meetings at NCI Campus at Frederick and off-site. The Contractor shall maintain the conference and meeting facilities located in NCI Campus at Frederick Bldg. 549 and provide oversight and assistance with video conferencing between NCI Campus at Frederick and other approved locations.
3. Logistical Support for Transportation The Contractor shall coordinate requests for driver(s) and appropriate vehicle(s) during normal business hours to transport personnel, animals, biological specimens, and other materials within the NCI Campus at Frederick and between the NCI Campus at Frederick and other local Government facilities.

4. Glassware Services The Contractor shall provide to NCI Campus at Frederick programs suitable quantities of common, reusable, heavy-duty glassware items using existing washing and storage facilities. Appropriate procedures shall be instituted for the daily pick up, washing, wrapping, sterilizing, and restocking the laboratories with glassware from an inventory of 85 different standard items. Special processing services (i.e., siliconizing, specialized glassware cleaning and assembly) shall be provided, as required.

**C. Environment, Health and Safety Support**

1. The Contractor shall design and conduct Environment and Safety Support to provide a safe and healthful environment, including a biological control program and a Radiation Safety Program compliant with the site-specific radioactive material use license(s) issued by the regulatory authority having jurisdiction for all NCI Campus at Frederick employees and visitors. The program also shall be designed to protect the surrounding community from any adverse effect resulting from activities conducted at the NCI Campus at Frederick. The program shall arrange for safety coverage, outside of normal working hours and on holidays, to ensure personnel safety and to respond in the event of improper operation of scientific equipment, building mechanical systems, and alarm-monitored systems, as required.

In the design and conduct of the safety program, the Contractor shall utilize applicable Government regulations, Executive Orders, standards, or guidelines. In the absence of regulations, Executive Orders, standards, or guidelines, the Contractor shall exercise professional judgment in application of "state-of-the-art" technology. The Contracting Officer and COR will clearly delineate the Contractor's role in implementing agency responsibilities under Executive Orders.

Some of the more established elements of the EHS program include but are not limited to:

- (a) Accident Reports -- Investigate causality of work-related incidents and make appropriate recommendations for corrective action. Provide reports as necessary and conduct trend analysis.
- (b) Blueprint Review -- Review blueprints and advise FME regarding EPA, OSHA, and NFPA compliance issues associated with renovation or new construction.
- (c) Emergency Response -- Respond to fire alarms, heat/smoke detector alarms, medical emergencies, and other applicable emergencies. Assess safe working conditions during chemical spills, gas leaks, oxygen deficiencies, and chemical/biological contamination of employees.
- (d) Ergonomics -- Conduct risk assessment, product evaluations, provide resources for affected individuals and other related ergonomic activities.
- (e) Exposure Monitoring/Control -- Conduct worksite employee exposure surveys to evaluate employee exposures in accordance with OSHA, and prepare reports to document findings and recommend additional control measures.

- (f) Fire Extinguisher Maintenance -- Coordinate the testing and maintenance in accordance with NFPA guidelines for approximately 800 fire extinguishers placed throughout the facility.
  - (g) Fire Safety Activities -- Provide comprehensive fire safety services: conduct emergency evacuation drills and training; maintain fire safety inspection program; ensure compliance with standards governing inspection, testing, and maintenance of fire detection/suppression systems; provide training/outreach program.
  - (h) IACUC Liaison -- Review all Animal Study Proposals for potential employee health and safety risks. Recommend supplementary control efforts, safety registrations, etc. Represent EHS interests at monthly meetings of Institutional Animal Care and Use Committee (IACUC).
  - (i) Indoor Air Quality Evaluation -- Investigate indoor air quality complaints to assess deficiencies in local or general exhaust ventilation, including conducting walk-through survey, interview of employees, subsequent environmental monitoring when applicable.
  - (j) Inspections - Labs/Animal Facilities/Offices, Sanitation & Shops -- Regularly evaluate compliance with OSHA and EPA regulations, with FNLCR policies, and with EHS program elements delineated in the Safety Manuals and internal program SOPs.
  - (k) Institutional Biosafety Committee (IBC) Program Registration – Assess safety and compliance of research using pathogenic and recombinant materials. Assign biosafety level and coordinate review by IBC. Maintain relevant database. Assist PI with registration forms.
  - (l) Respiratory Protection – Provide comprehensive respiratory protection services to employees, including training, fit-testing, and related programmatic elements. Maintain database documenting OSHA compliance.
  - (m) Risk Assessment -- Industrial, Chemical, and Biological – Evaluate potential hazards associated with work practices. Review the Mandatory Medical Surveillance form for all new employees, transfers, and annually for current employees, and enroll in surveillances as needed. Develop toxicity reviews as necessary.
  - (n) Select Agents Program – Monitor laboratories using Select Agents, approve transfers of Select Agents, and notify the CDC of any change in the registration of the FNLCR.
  - (o) Training – Provide mandated and supplemental OSH training to employees. Provide customized health and safety training sessions and workshops as requested. Implement computer based training modules. Assist supervisors with program-specific safety training.
2. The Contractor shall provide the personnel and management to conduct a comprehensive program of Occupational Health Care, including operation of Occupational Health Services (OHS), for NCI Campus at Frederick employees. The program shall include, but not be limited to, emergency treatment, annual training in emergency care (cardiopulmonary resuscitation and first-aid), treatment for work-related injuries and illnesses, health screening and preventive programs, fitness-

for-duty evaluations, work termination physical examinations, clinical and hematological screening tests, maintenance of health records, and preparation of an Operating Manual for Employee Health Care to cover NCI Campus at Frederick Contractor and Government personnel. Only authorized, qualified medical personnel shall conduct medical surveillance or medical procedures at the OHS.

Responsibilities of the OHS will include but are not limited to:

- (a) In laboratories or areas where specific disease or occupational health exposure potential may exist or has been identified, periodic health screening programs shall be executed for those employees potentially at risk. These screening programs shall include, but not be limited to: (i) physical examinations, including hematological profile and urinalysis; (ii) tuberculin skin testing and chest x-ray, in accordance with NIH and CDC guidelines; (iii) hepatitis screening;; and, (iv) visual acuity and audiometric screening. Statistical summaries of frequency and severity of occupational illness and disabilities shall be prepared for identified individual departments or areas so that trends can be identified. A voluntary wellness program will be available to all contractor and government employees and may include services including, but not limited to, serum cholesterol testing, triglycerides and blood pressure screening.
- (b) Employees with work-related injuries and illnesses shall receive emergency treatment and follow-up care either by the OHS or referral to qualified medical facilities or physicians.
- (c) Employees experiencing non-occupational illness during working hours may receive preliminary diagnosis and treatment at OHS with subsequent referral to the patient's physician. This care is limited to short-term, urgent care for non-complex medical conditions that can be treated within 1-2 visits. Preliminary or palliative treatment may be given for conditions for which the attention of a personal physician would not be sought. OHS shall identify qualified physicians to whom the employee may be referred for additional medical care, if required. Physician consultation reports may be requested to evaluate whether the condition may be job-related.
- (d) OHS shall offer immunizations, including tetanus and diphtheria, those required for foreign travel, influenza vaccine, and others consistent with potential or actual work exposures.
- (e) OHS shall receive copies of pre-employment examinations for NCI Campus at Frederick Government employees.
- (f) OHS shall review applications for special handicapped parking permits. In general, recommendations will be made following the review; however, a physician's interview or examination may be required.
- (g) The OHS medical consultant/nurse practitioner and/or attending physician shall order special diagnostic tests, as required
- (h) Health records shall be maintained and retired in accordance with OSHA regulations, and for Government employees in accordance with Federal Personnel Manual and NIH requirements.

Occupational accident and illness forms and reports for Government and Contractor employees shall be prepared in accordance with Office of Workers' Compensation Program, Department of Labor.

(i) The Contractor's OHS shall conduct a Research Donor Program for the provision of anonymous human blood samples for solely research purposes. The Program shall adhere to the rules established by the NCI/NIH Institutional Review Board with the involvement of the Project Office, as appropriate. The OHS shall retain a separate, confidential database of donors.

(j) The Contractor shall establish and operate an Employee Assistance Program that will provide a comprehensive and confidential work life, counseling, and referral program for NCI Campus at Frederick government and contractor employees and their dependents.

3. The Contractor shall provide **Protection and Security** for the real estate, personnel, equipment and materials within the NCI-FNLCR without regard to occupancy, Contractor or Government. The Contractor shall provide NCI Campus at Frederick scientific alarm surveillance and physical security checks twenty-four hours a day, 365 days a year. The Contractor shall maintain a twenty-four hour communications center in order to allow immediate response, alarm monitoring, and communications with Fort Detrick, state, and local support agencies. The Contractor shall administer and maintain the NCI Campus at Frederick interchangeable core lock, key control system, and the Cardkey electronic access control system. Fingerprinting will be available upon request.

In cooperation with the NIH Police, the Contractor shall investigate reports of missing property, vehicle accidents, and other incidents reported to Protective Services.

The Contractor shall provide crime prevention services, personal protection seminars, , emergency preparedness plans, an emergency notification system, employee identification cards, lost and found, notification to the appropriate personnel for receipt of shipments after hours, administer the parking plan, provide services to maximize the use of parking facilities, and the operation of a passenger Shuttle Service on a scheduled basis during normal business hours between the NCI Campus at Frederick and the NIH campus in Bethesda, Maryland and other Government or contractor utilized space as required. Special shuttles outside of normal business hours or to locations not described above may be authorized by the EHS Director or their designee on a case-by-case basis.

The Contractor shall assist NCI with implementation of Homeland Security Presidential Directive 12 (HSPD-12) and may provide enrollment and badging services as directed by the Contracting Officer.

**D. Facilities Maintenance and Engineering**

1. The Contractor shall ensure the proper Maintenance, Operation, Renovation, Repair, Improvement, and Alteration of facilities at the NCI Campus at Frederick. The Contractor, based on guidance provided by the Government, shall provide a program for the continued maintenance and upgrading of facilities and accomplishment of major construction projects in support of NCI/NIH programs at the NCI Campus at Frederick. The format, content, and delivery instructions for such programs shall be as directed by the Contracting Officer. All such work shall be accomplished in accordance with applicable local, state and federal laws and regulations.

2. Maintenance Responsibilities shall be compatible with the current Interagency Agreement including any revisions thereto, between the U.S. Army Garrison (USAG), Fort Detrick, and the NCI Campus at Frederick with the Contractor performing those functions designated as being the responsibility of the NCI Campus at Frederick. Services to be provided include, but are not limited to: (i) start up, maintenance, repair, and operation of all buildings and their utilities systems; (ii) modifying or rearranging laboratory or administrative spaces to make them functional as the NCI or occupants require; (iii) modification, repair, calibration, and installation of special research equipment; (iv) general housekeeping; and, (v) telephone installation and repairs. The Contractor shall arrange maintenance coverage, outside of normal working hours and on holidays, to ensure proper operation of scientific equipment, all building mechanical systems, and alarm-monitored systems. Unscheduled utility outages, equipment failures, etc., shall be reported immediately to Government personnel. The Contractor shall coordinate scheduled utility outages in close communication with responsible Program personnel.
3. Requirements for the NCI Campus at Frederick construction, alteration and renovation projects are developed through discussions with NCI program personnel and administrative staff, and approved by the COR and Contracting Officer. At the start of the contract, the proposed NCI Campus at Frederick construction program is again reviewed for relevance, need and priority by the Government. The program is also reviewed periodically throughout the life of the contract and changes made based on new program directions, changing priorities and the availability of funds.
  - a. Upon receipt of a requirement for a renovation, the Contractor shall assess immediately whether this requirement can best be met, in a cost effective and timely fashion, through the employment of available in-house resources or through outsourcing. The Contractor's recommendation shall be conveyed to the Government, through the approval process delineated in the contract Article B.4. Advanced Understanding.
  - b. Coordination of construction, alteration and renovation projects with the USAG will be the responsibility of the Contracting Office.
  - c. Any subcontracts or purchase orders awarded by the Contractor, whether for construction, alteration, renovation, equipment installation, leases, rentals or any other type of items or services, shall include all required representations, certifications, and Federal, Departmental and other applicable clauses.
  - d. It is understood and agreed by the parties that the projects described above require formal acceptance by the Government prior to final payment.
4. The Contractor shall provide Engineering Services, design criteria work, material flow studies, drawings and specifications for major alterations and maintenance projects and for specified items of equipment.
5. The Contractor shall solicit Bids and Proposals for the accomplishment of the work delineated in Section IV.D. utilizing competitive arrangement to the fullest practicable degree, and small business set-aside arrangements, whenever feasible.
6. The Contractor shall maintain a computerized database of all usable **Space** at the NCI Campus at Frederick, utilizing database(s) and metric standards that conform with NIH-Bethesda. The database shall include room locations, Center/Division and Laboratory/Program allocations, square footage, designated usage, special features, and occupancy levels (square footage per occupant). Since numerous areas are occupied by primarily Government or other Contractor employees, occupancy level assessment must be

accomplished with the input of representatives of the affected groups. The nature and timing of space report(s) shall be as requested and approved by the COR and Contracting Officer.

**E. Personnel Support Services**

The Contractor shall provide a variety of Personnel Support Services for NCI, NIH and Contractor Programs located at the NCI Campus at Frederick. These Personnel Support Services shall include, but not be limited to:

1. The operation of passenger **Shuttle Services and Personnel Transport** on a scheduled basis during normal business hours between the NCI Campus at Frederick and the NIH campus in Bethesda, Maryland.
2. The Contractor shall also be responsible for the operation of an NCI Campus at Frederick **Cafeteria**. This service shall be provided to all Contractors and the Government at the NCI Campus at Frederick. The Contractor shall strictly comply with the sanitation standards in the most current Food Code Manual, Public Health Service, Publication (FDA) and the most recent local Health Department codes. The Contractor shall also comply with all other federal, state, and local laws applicable to provision of these food services. The Contractor shall maintain all necessary permits, licenses, and food handlers' cards and will post such permits where required.
3. Reserved

End of Attachment 1