PROPOSED ADVANCE UNDERSTANDINGS

a. Costs

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

1. Forward Pricing Rates (FPR) – Indirect rates

   i. Provisional Forward Pricing Rates dated TBD provide interim indirect rates which the Contractor is authorized to utilize for Task Order proposals and billing purposes. The FPR shall be managed in accordance with FAR 15.407-3 and Subpart 42.17.

   ii. Provisional rates included in the FPR are subject to change. Changes or updates to the rates shall be provided annually by the Contractor, or more frequently as required by FAR 42.704, and shall be submitted as notifications.

   iii. Under this contract, FPRs shall be approved by the NIH Division of Financial and Advisory Services (DFAS), or alternative Government Agency. Approved FPR agreements will be negotiated within 12 months from the date of contract award or annual updates.

2. Travel Costs

   i. Total direct cost expenditures for domestic/foreign travel (transportation, lodging, subsistence, and incidental expenses) are based upon the amounts specified in each individual task order.

   ii. Allowable travel costs shall be in accordance with the current Federal Travel Regulations (FTR), the current General Services Administration (GSA) per diem rates, current Department of State foreign per diem rates, and FAR 31.205-46.

3. Advisory and Assistance Services

   The Contractor shall not provide any advisory and assistance services during contract performance that violate the conditions established under FAR 37.203(c).

4. 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.

5. Overtime Premium Expenses
   Pursuant to the provisions of FAR 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 amounts specified in each individual task order.

b. On-site Corporate Authority
   The following listed full-time positions shall have the authority to represent and commit the Contractor in dealing with the Government and other Contractors on the NCI Campus at Frederick site on all matters. One of these employees shall be available on any given working day of the contract period to perform this function, e.g. to sign contract modifications.

Name of Individual	**Position**

c. Parent Company Guarantee
The revised "Parent Company Guarantee", dated _____, as submitted in the Contractor's Business Proposal under Section____, Financial Capacity, is incorporated herein as Attachment #.

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

e. Work Requirement Resolution
In those situations where the Contractor cannot meet the terms of a request(s) 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.

f. Contractor Recommended Within Scope Changes
The Contractor may recommend changes in the direction/emphasis of the work within the scope of the Statement of Work. These recommended changes shall be submitted to the Contracting Officer for consideration. The Contractor shall take no action in these recommendations without the specific written direction of the Contracting Officer.

g. Discretionary Leave
The Contractor shall be held accountable to comply with the Discretionary Leave Policy approved under this contract.

h. Environmental Health and Safety/Regulations at the NCI Frederick

1. The 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 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 Contractor's Safety Officer or his/her designated representative has the authority to enter all areas/facilities at the NCI-Frederick to make periodic, routine or unannounced inspections. The Contractor shall attempt to resolve all deviations in safety and environmental regulations through the appropriate lines of authority.

   Upon inspection, deviations or discrepancies shall be reported to the Laboratory Chief/Manager/Program Head for corrective action with 30-45 days. The results of the re-inspection shall be reported to the Contractor Principal Investigator/Project Manager/Key Person or Government authority shall provide assistance to the Safety Officer to resolve the problem, upon request.

   The Contractor shall immediately or within 48 hours 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 those that the Contractor is unable to resolve after re-inspection.

   The Contractor shall also submit a quarterly report to the Contracting Officer summarizing all deviations and discrepancies with Safety and Environmental Regulations on or before 10/1, 01/01, 04/01, and 07/01. In some cases where the 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 take corrective action. If the Contractor fails or refuses to comply promptly, the Contracting Officer may issue and 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 claims(s) for extension of time or for costs or damages by the Contractor.

i. Cancer Research Technology Program (CRTP)
All requests for CRTP core services shall 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 shall be routed electronically (via e-mail notification) to the appropriate laboratory to review and provide a cost estimate. The response and estimate shall be routed electronically to the requestor for consideration. For projects originating from non-NCI customers, or if a request exceeds $10,000, the NCI Office of Scientific Operations shall 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 shall be notified electronically to review for funds availability. Projects shall not commence until all necessary approvals for scientific content and funds availability have been received.

j. Facility Work Orders
The Contractor shall work closely with the customer to determine needs and priorities associated with customer requirements. Customer requirements and priorities shall be reduced to writing by the Contractor and formally approved by the customer.

Work order requests for renovation or alteration of facilities, Architect-Engineer (A&E) design, and repair of facilities shall be reviewed and approved by the FME COR. All approved work order requests with total value/amount is estimated to exceed $50,000 in Materials and Supplies (M&S), labor, or a combination of M&S and labor shall require submission of a single Project Approval (PA) package for CO approval. The PA package shall include at a minimum 35% design information and enough detail to adequately address the requestor's needs to allow project execution upon approval of the package. Should subcontracting be required to develop a PA package, the Contractor shall submit an advanced notification as required by FAR 52.244-2. The CO's approval of the PA package shall direct the Contractor to either: 1) Proceed to submission of a Design Completion (DC) package or 2) Proceed to Project Completion. A DC package shall consist of at minimum 95% design information. Design Completion packages may be approved by the CO to: 1) proceed to project completion or 2) initiate a Task Order Request for Proposal. The submission of a Project Approval or Design Completion package, as required by this article, satisfies the advanced notification requirement of FAR 52.244-2.

Projects estimated to cost less than $50,000 shall require CO determination of funding source. Approval of the cost estimate summary shall 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 $50K 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 shall be released to Contractor and the requestor, unless additional funds are required. Thus changes within the approved project amount do not require additional CO and FME 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 FME COR shall be notified of the impact. If additional funding is necessitated by the requirements of the approved impact plan, CO approval is required.

Weekly meetings between the Contractor and NCI designated representatives shall be held for: 1) Reviewing new work order requests and 2) Reviewing the status of all new work orders, work orders in development, and approved work orders.

The Contractor and NCI designated representatives, shall hold quarterly Facility Projects Status Report Meeting in January, April, July, and October, at which the status of all facilities projects shall be reviewed.

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

k. 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.

l. Personal Services and Inherently Governmental Functions
Pursuant to FAR 37.1, no personal services shall be performed under this contract. See Informational Attachment 25, FFRDC Policy 101, Government and Contractor Interactions at the Frederick National Laboratory for Cancer Research (FNLCR). 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.

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.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently governmental functions under this contract. No Contractor employee shall represent themselves as a Government employee, agent, or representative. In all communications under the contract, Contractor employees shall identify themselves as such and specify the name of the company for which they work.

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.

1. Product Liability Insurance and Licensing

    i. cGMP 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 Determination of Exceptional Circumstance (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 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 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 contract shall 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 (iii) below shall be the general rule unless there is a compelling reason, such as the public health, to change it. The NCI-FFRDC contractor shall be notified of any changes to the language in paragraph (iii) "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 shall 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 shall be only in the circumstances described below:

- Technology is invented by Contractor in the performance of the contract;

- An NIH Employee Invention Report (EIR) is submitted in which a Contractor 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.

ii. 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 shall 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 the Contractor, 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 shall 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 shall 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 shall include an option to purchase extended reporting coverage, which shall 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 contract.

iii. 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.

2. Electronic Commerce
The Contractor shall utilize electronic commerce tools to the maximum extent practicable.

3. Cost Efficiencies of Contractor
   The Contractor shall have the same buying power as that of its parent (Corporate). Other than the normal application of approved overheads and adders, there shall be no "mark up" of any costs transferred from its parent (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 the parent (Corporate) approved under Article B.#TBD of this contract.

4. Hazardous Materials
   In the event it is alleged that the 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 shall apply.

   i. If the Contractor incurs costs, expenses, damages, or liabilities to third parties (Athird-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 FAR 52.228-7 shall be relied upon.

   ii. 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 shall be allowable and allocable to the contract, and NCI shall reimburse the Contractor for these costs, subject to the limits set forth in FAR 52.232-20 -- Limitation of Cost. If such actions result in loss or damage to government property, such costs shall 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.

   iii. 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 shall be allowable and allocable to the contract per FAR 31.205-15, and NCI shall reimburse the Contractor for these costs, subject to the limits set forth in FAR 52.232-20 -- Limitation of Cost.

5. 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 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, rather than as a result of its own acts or omissions or those of subcontractors, the resulting costs shall be allowable and allocable to the contract in accordance with FAR 31.205-15, and NCI shall reimburse the Contractor for these costs, subject to the limits set forth in FAR 52.232-20 -- Limitation of Cost. The Contractor shall 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.

6. Management of Hazardous Waste

    i. The existing Hazardous Waste Generator Permit EPA ID Number **TBD** issued to the FNLCR shall continue to be used for the FNLCR hazardous waste program.

    ii. NCI shall be identified as the owner of the FNLCR.

    iii. The Contractor shall be identified as the point of contact for matters relating to the hazardous waste program and shall 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.

7. 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 shall be flowed down to the repository subcontractor and the cost of this insurance shall 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.

8. Technical Requirements and 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. 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 under a task order is appropriate and its funding is identified. No work shall begin until the funded task order is executed.

   Upon preliminary agreement between the Contractor and customer, the Contractor shall 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 COR, shall have final approval as to whether the work will be performed under this contract.

9. 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 shall 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.

10. 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.

11. Insurance
    In accordance with FAR 52.228-7, 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.

    i. 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

12. Approval of Press Releases
    All press releases or other dealings with the press shall first be approved by the Contracting Officer's Representative.

13. 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.

14. Defrayment of Idle Facilities and 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 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.

15. Vaccine Clinical Materials Program (VCMP)
    The Contractor shall comply with U.S. Food and Drug Administration regulations as is appropriate to meet compliance-level requirements for each product manufactured under VCMP. 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.

16. Contract Retirement Programs Modification

The Contractor shall utilize the following Retirement Programs:

i. Two Retirement Programs sponsored by the Contractor exclusively for the Contractor employees of the Frederick National Laboratory for Cancer Research (FNLCR) exist.

ii. 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 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. (Note: As a practical application of these statutes, NCI and the Contractor, 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.)

iii. 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.

iv. Retirement Program B is a 401(k) Defined Contribution Plan (New 401(k)). It is the sole retirement program available to Contract employees who accepted an offer of employment on or after July 1, 2006.

v. 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 Contract employees of the FNLCR and will continue to do so during the term of the Contract. However, the parties agree that after the term of the Contract, the Contractor shall 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, the Contractor 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).

vi. The cost of the Retirement Programs A and B is allocable. Thus, the Contractor's 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 Contract term, when these costs are measured, assigned and allocated in accordance with the Cost Accounting Standards ("CAS"). The Government and the Contractor intend under the terms of the 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.

vii. Annual Reporting: the Contractor 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.