PROPOSED SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.#. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in SECTION I of this contract, 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. TBD. 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. TBD

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), Contractor Name, 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 current “Guide for Care and Use of Laboratory Animals”(National Research Council).

ARTICLE H.#. PROPERTY ADMINISTRATOR

a. 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.

b. Coordinates property issues with the COR and Contracting Officer.

c. Reviews and approves the property control system and notifies the contractor when the property control system does not meet DHHS requirements.

ARTICLE H.#. 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.

    4. 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:

i. In the event there is a successor Contractor: The successor Contractor shall adopt, as plan sponsor and employer, the Contract Employee Savings Plan and the defined benefit Retirement Plan and the Contractor's 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

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 full force and effect.

ii. 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 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 contract and meets the conditions or Article B.# TBD, Product Liability Insurance and Licensing.

- The successor contractor shall assume responsibility for bringing acquisitions initiated by the predecessor Contractor to an orderly conclusion. All subcontracts having anticipated completion dates beyond the expiration date of the Contract shall be novated/transferred to the successor contractor.

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 Contractor 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.#. OBSERVANCE OF FORT DETRICK REGULATIONS

Because the NCI Campus at Frederick 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.

ARTICLE H.#. 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, acting within the limits of their authority as set forth in ARTICLE G.#TBD of this contract

ARTICLE H.#. 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.

NOTE for all references to Contractor CRADA (cCRADA) herein: Applicability of cCRADA authority is dependent upon receiving an approved Determination of Exceptional Circumstance (DEC).

a. Technology Transfer

1. Definitions

i. GOCO Laboratory means the entire GOCO (FFRDC) laboratory research effort of the Contractor at the FNLCR. Contractor may be substituted herein for GOCO Laboratory

ii. 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.#TBD.

iii. 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.

iv. Intellectual Property means patents, trademarks, copyrights, mask works, and other forms of comparable property rights protected by Federal law.

v. 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.

vi. 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.

vii. 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.

viii. 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.

ix. 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

x. 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

i. 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.

ii. Removed.

iii. 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.)

    i. 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.

ii. 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 TBD herein.

9. Reporting of CRADA and Licensing Activities

i. 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.

ii. 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 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) [Contractor CRADAs] and in Attachment TBD.

11. Technology Transfer Export

i. 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.

ii. 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 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.

i. Inbound Materials-Sole GOCO Laboratory Use: After consultation with a COR 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.

ii. 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.

iii. 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 COR for Intellectual Property.

iv. To the extent that the Contractor produces research materials under an 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.

i. 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.

ii. 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.

iii. 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.

i. 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.

ii. 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:

i. 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 contract DEC and FAR 52.227-13 (Deviation) Patent Rights--Ownership by the Government (DEC 2007) [Patent Rights- Prime Contractor] as amended.

ii. 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) [Contractor CRADAs] and the procedures found in Attachment TBD. 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 TBD). Contractor CRADAs may not directly support or involve an NIH program.

iii. Contractor Process for Government CRADAs

A. 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.

B. 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.

C. 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.

iv. 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.

A. 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.

B. 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).

C. 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.

v. 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:

A. Give special consideration to small business firms, and consortia involving small business firms;

B. Comply with the Conflicts of Interest requirements;

C. Provide Fairness of Opportunity;

D. Grant U.S. preference in accordance with the licensing and assignment requirements.

vi. Withholding of Data

A. 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.

B. 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.#. DISPOSITION OF ANIMALS

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.#. 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.#. SAFETY STANDARDS

All work with hazardous biological materials will be conducted in compliance with the publication, Biosafety in Microbiological and Biomedical Laboratories.

ARTICLE H.#. 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.#. COMMITTEE RESPONSIBILITIES

a. The Contractor shall maintain and operate various committees in support of government and contractor programs at the FFRDC, including but not limited to:

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

    2. Animal Care and Use Committee for review and approval of animal protocols.

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

ARTICLE H.#. 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 is a wholly owned subsidiary of its parent (Corporate). As a result, this prohibition does not apply to the parent organization or other subsidiary of the parent organization in its non-FFRDC operations.

1. <u>Use of Contractor's Work Product</u>

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—

ii. use such information for any private purpose unless the information has been released or otherwise made available to the public;

iii. 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;

iv. 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

v. release such information unless such information has previously been released or otherwise made available to the public by the Government.

3. 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.

4. 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.#. 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 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.#, 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 are provided: TBD

ARTICLE H.#. 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:

a. 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.

b. 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).

c. Represent the NCI Campus at Frederick's information-security (InfoSec) interests to NCI.

    1. Stay informed about NCI Campus at Frederick's InfoSec needs.

    2. 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
        - NIH - http://www.cit.nih.gov/security-policies.asp
        - NIST - http://csrc.nist.gov/publications/nistpubs/index.html

    3. Implement federal InfoSec directives and policies.

d. Keep up-to-date on policy changes.

e. Educate staff on policies and directives. Inform staff when there are changes.

f. Oversee development, implementation, and promulgation of objectives, goals, policies, standards, guidelines, and other InfoSec requirements.

g. Recommend improvements and updates to policies and procedures.

h. Inform management about the development of InfoSec system and application policies, guidelines, standards, requirements, and procedures.

i. Request exceptions to HHS, NIH, or NCI policies and procedures, if exclusion from the standard requirements is warranted.

ARTICLE H.#. 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 the contract Information Security provisions. 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. #. 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.

<u>Third-party Materials Provided to NIH</u>

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.