

FAR 52.227-13 (Deviation) Patent Rights--Ownership by the Government (DEC 2007) [Patent Rights-OTS Prime Contractor]

This clause is to be applied to all work done by the NCI-Frederick FFRDC Operations and Technical Support (OTS) prime contractor except when (i) the OTS contractor is operating according to Bayh-Dole doing work for other organizations or in support of STTR/SBIR awardees or (ii) appropriate to meet Government mission, goals and outcomes as directed by the Government. When the OTS contractor is operating according to Bayh-Dole doing work for other organizations or in support of STTR/SBIR awardees or directed by the Government, the Contractor will be governed by the standard patent rights clause at FAR 52.227-11, Patent Rights – Ownership by the Contractor (DEC 2007)

a) Definitions.

As used in this clause—

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means—

(1) When used in relation to any invention other than a plant variety, means the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, means that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Practical application means to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Subject invention means any invention of the Contractor made in the performance of work under this contract.

Cooperative Research and Development Agreement (CRADA)," as used in this clause, means any agreement pursuant to 15 U.S.C. 3710a entered into between one or more Federal Government Owned-Contractor Operated (GOCO) laboratories and one or more non-Federal parties under which the Government, through its GOCO laboratories, provides personnel, services, facilities, equipment, and other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the contract; 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.

FFRDC means Federally Funded Research and Development Center as authorized under FAR 35.017.

SBIR means Small Business Innovation Research program (15 U.S.C. 638)

STTR means Small Business Technology Transfer program (15 U.S.C. 638)

(b) Ownership.

(1) Assignment to the Government. The Contractor shall assign to the Government title throughout the world to each subject invention, except to the extent that rights are retained under paragraphs (b)(4) and (d) of this clause. The provisions of subparagraph (b)(4) and paragraph (d) below shall not apply when the subject invention has been developed under a CRADA or in cases where the Contractor uses third-party proprietary information or technology provided to NIH in performance of the contract. The foregoing notwithstanding, in the circumstances stated in subparagraph (b)(2) below, the disposition of rights shall be as directed in subparagraph (b)(2) for those particular circumstances.

(2) Retention by the Contractor. The Contractor shall be governed by the standard FAR 52.227-11 Patent Rights-Ownership by the Contractor (DEC 2007) and retain the entire right, title, and interest throughout the world in and to each subject invention except to the extent that rights are retained by the Government in this clause or in the standard FAR 52.227-11. This subparagraph (b)(2) applies when:

(i) Directed by the Government to meet Government mission, goals and outcomes; or

(ii) Conducting work under specific FFRDC authorities listed elsewhere in this contract (e.g., work for other organizations and Collaboration with SBIR/STTR awardees on research projects independent of the sponsoring Government agency).

(3) With respect to any subject invention in which the Contractor retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(4) Greater rights determinations.

(i) The Contractor, or an employee-inventor after consultation with the Contractor, may request greater rights than the nonexclusive license provided in paragraph (d) of this clause. The request for a greater rights must be submitted to the Contracting Officer at the time of the first disclosure of the subject invention pursuant to paragraph (e)(2) of this clause, or not later than 8 months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. Each determination of greater rights under this contract normally shall be subject to paragraph (c) of this clause, and to the reservations and conditions deemed to be appropriate by the agency.

(ii) Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if

filed in a language other than English), and patent number and issue date for any subject invention in any country for which the Contractor has retained title.

(iii) Upon request, the Contractor shall furnish the agency an irrevocable power to inspect and make copies of the patent application file.

(c) Minimum rights acquired by the Government.

(1) Regarding each subject invention to which the Contractor retains ownership, the Contractor agrees as follows:

(i) The Government will have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(ii) The agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c) and in accordance with the procedures set forth in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of the contract award.

(iii) Upon request, the Contractor shall submit periodic reports no more frequently than annually on the utilization, or efforts to obtain utilization, of a subject invention by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and any other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceedings undertaken by the agency in accordance with paragraph (c)(1)(ii) of this clause. To the extent data or information supplied under this section is considered by the Contractor, or its licensees, or assignees to be privileged and confidential and is so marked, the agency, to the extent permitted by law, will not disclose such information to persons outside the Government.

(iv) When licensing a subject invention, the Contractor shall—

(A) Ensure that no royalties are charged on acquisitions involving Government funds, including funds derived through a Military Assistance Program of the Government or otherwise derived through the Government;

(B) Refund any amounts received as royalty charges on a subject invention in acquisitions for, or on behalf of, the Government;

(C) Provide for this refund in any instrument transferring rights in the subject invention to any party.

(v) When transferring rights in a subject invention, the Contractor shall provide for the Government's rights set forth in paragraphs (c)(1)(i) through (c)(1)(iv) of this clause.

(2) Nothing contained in paragraph (c) of this clause shall be deemed to grant to the Government rights in any invention other than a subject invention.

(d) Minimum rights to the Contractor.

(1) The Contractor is hereby granted a revocable, nonexclusive, paid-up license in each patent application filed in any country on a subject invention and any resulting patent in which the Government obtains title, unless the Contractor fails to disclose the subject invention within the times specified in paragraph (e)(2) of this clause. The Contractor's license extends to any of its domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency except when transferred to the successor of that part of the Contractor's business to which the subject invention pertains.

(2) The Contractor's license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304-1(f).

(3) When the Government elects not to apply for a patent in any foreign country, the Contractor retains rights in that foreign country to apply for a patent, subject to the Government's rights in paragraph (c)(1) of this clause.

(e) Invention identification, disclosures, and reports.

(1) The Contractor shall establish and maintain active and effective procedures to educate its employees in order to assure that subject inventions are promptly identified and disclosed to Contractor personnel responsible for patent matters. The procedures shall include the maintenance of laboratory notebooks or equivalent records and other records as are reasonably necessary to document the conception and/or the first actual reduction to practice of subject inventions, and records that show the procedures for identifying and disclosing subject inventions are followed. Upon request, the Contractor shall furnish the Contracting Officer a description of these procedures for evaluation and for a determination as to their effectiveness.

(2) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters or, if earlier, within 6 months after the Contractor becomes aware that a subject invention has been made, but in any event before any on sale (i.e., sale or offer for sale), public use, or publication of the subject invention known to the Contractor. The disclosure shall identify the contract under which the subject invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale, or public use of the subject invention and whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(3) The Contractor shall furnish the Contracting Officer the following:

(i) Interim reports every 12 months (or a longer period as may be specified by the Contracting Officer) from the date of the contract, listing subject inventions during that period, and stating that all subject inventions have been disclosed (or

that there are none) and that the procedures required by paragraph (e)(1) of this clause have been followed.

(ii) A final report, within 3 months after completion of the contracted work, listing all subject inventions or stating that there were none, and listing all subcontracts at any tier containing a patent rights clause or stating that there were none.

(4) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by paragraph (e)(2) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(5) Subject to FAR 27.302(i), the Contractor agrees that the Government may duplicate and disclose subject invention disclosures and all other reports and papers furnished or required to be furnished pursuant to this clause.

(f) Examination of records relating to inventions.

(1) The Contracting Officer or any authorized representative shall, until 3 years after final payment under this contract, have the right to examine any books (including laboratory notebooks), records, and documents of the Contractor relating to the conception or first actual reduction to practice of inventions in the same field of technology as the work under this contract to determine whether—

(i) Any inventions are subject inventions;

(ii) The Contractor has established and maintains the procedures required by paragraphs (e)(1) and (e)(4) of this clause; and

(iii) The Contractor and its inventors have complied with the procedures.

(2) The Contractor shall disclose to the Contracting Officer, for the determination of ownership rights, any unreported invention that the Contracting Officer believes may be a subject invention.

(3) Any examination of records under paragraph (f) of this clause will be subject to appropriate conditions to protect the confidentiality of the information involved.

(g) Withholding of payment. (This paragraph does not apply to subcontracts.)

(1) Any time before final payment under this contract, the Contracting Officer may, in the Government's interest, withhold payment until a reserve not exceeding \$50,000 or 5 percent of the amount of this contract, whichever is less, shall have been set aside if, in the Contracting Officer's opinion, the Contractor fails to—

(i) Establish, maintain, and follow effective procedures for identifying and disclosing subject inventions pursuant to paragraph (e)(1) of this clause;

(ii) Disclose any subject invention pursuant to paragraph (e)(2) of this clause;

(iii) Deliver acceptable interim reports pursuant to paragraph (e)(3)(i) of this clause; or

(iv) Provide the information regarding subcontracts pursuant to paragraph (i)(4) of this clause.

(2) The Contracting Officer will withhold the reserve or balance until the Contracting Officer has determined that the Contractor has rectified whatever deficiencies exist and has delivered all reports, disclosures, and other information required by this clause.

(3) The Contracting Officer will not make final payment under this contract before the Contractor delivers to the Contracting Officer, as required by this clause, all disclosures of subject inventions, an acceptable final report, and all due confirmatory instruments.

(4) The Contracting Officer may decrease or increase the sums withheld up to the maximum authorized. The Contracting Officer will not withhold any amount under this paragraph while the amount specified by this paragraph is being withheld under other provisions of the contract. The withholding of any amount or the subsequent payment shall not be construed as a waiver of any Government rights.

(h) Preference for United States industry.

Unless provided otherwise, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement may be waived by the agency upon a showing by the Contractor or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

(i) Subcontracts.

(1) The Contractor shall incorporate the standard FAR Clause 52.227-11 Patent Rights-Ownership by the Contractor (DEC 2007) in all subcontracts regardless of tier, for experimental, developmental, or research work. The foregoing notwithstanding, if one or more of the circumstances at subparagraph (i)(2)(i-iv) of this Clause applies then the Contractor shall incorporate the appropriate FAR clause(s) into said subcontracts as directed in subparagraph (i)(2)(i-iv) below for those particular circumstances. The prescribed patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) Subcontracts at all tiers shall operate as directed in this subparagraph (i)(2)(i-iv) for these particular circumstances:

(i) Use of Third-party Technology or Information: The Contractor shall incorporate the clause, FAR 52.227-11(Deviation) Patent Rights- [Patent Rights- Ownership by the Contractor (DEC 2007) [Use of Third-party Technology and Information by Subcontractors] into subcontracts at all tiers, when the subcontractor will be working with third party proprietary technology or information provided to NIH by a third-party unless subparagraph (i)(2)(iv) applies.

(ii) NCI Full-length cDNA Initiative: The Contractor shall incorporate the clause, FAR 52.227-11(Deviation) Patent Rights - Ownership by the Contractor (DEC 2007) [Patent Rights NCI Full-length cDNA Initiative, into all subcontracts, at all tiers, when the subcontractor will be working under the NCI Full-length cDNA Initiative unless subparagraph (i)(2)(iv) applies.

(iii) Initiative for Chemical Genetics: The Contractor shall incorporate the clause, FAR 52.227-11(Deviation) Patent Rights - Ownership by the Contractor (DEC 2007) [Patent Rights-Initiative for Chemical Genetics (ICG) (formerly called the Molecular Targets Laboratories (MTL) Initiative], into all subcontracts, at all tiers, when the subcontractor will be working under the NCI ICG Initiative unless subparagraph (i)(2)(iv) applies.

(iv) When directed by the Government to meet Government mission, goals and outcomes, the Contractor shall substitute FAR Clause 52.227-11 Patent Rights - Ownership by the Contractor (DEC 2007) into subcontracts instead of the FAR Clauses required under subparagraph (i)(2)(i-iii).

(3) In the event of a refusal by a prospective subcontractor to accept the clause, the Contractor—

(i) Shall promptly submit a written notice to the Contracting Officer setting forth the subcontractor's reasons for such refusal and other pertinent information that may expedite disposition of the matter; and

(ii) Shall not proceed with such subcontract without the written authorization of the Contracting Officer.

(4) In subcontracts at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by the patent rights clause constitute a contract between the subcontractor and the agency with respect to those matters covered by this clause.

(5) The Contractor shall promptly notify the Contracting Officer in writing upon the award of any subcontract at any tier containing a patent rights clause by identifying the subcontractor, the applicable patent rights clause, the work to be performed under the subcontract, and the dates of award and estimated completion. Upon request of the Contracting Officer, the Contractor shall furnish a copy of such subcontract, and, no more frequently than annually, a listing of the subcontracts that have been awarded.

(End of clause)

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]

This clause deviation applies to inventions resulting from activities performed by subcontractors of the OTS prime Contractor at all tiers involving the use of proprietary technology or information provided to NIH by a third-party except when appropriate to meet Government mission, goals and outcomes as directed by the Government. Inventions developed by OTS subcontractors without the use of third-party proprietary technology or information or when directed by the Government will be governed by the standard patent rights clause at FAR 52.227-11, Patent Rights – Ownership by the Contractor (DEC 2007)

(a) As used in this clause—

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means--

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

Practical application means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is

being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Subject invention means any invention of the Contractor made in the performance of work under this contract.

(b) Allocation of principal rights.

(1) Assignment by the Contractor. The Contractor shall assign to the Government the entire right, title and interest throughout the world in each and to each subject invention except to the extent that rights are retained by the Contractor under subparagraph (b)(3) of this clause. The foregoing notwithstanding, in the circumstances noted in subparagraph (b)(2), the disposition of rights shall be as directed in subparagraph (b)(2) for those particular circumstances.

(2) Retention by the Contractor. When directed by the Government to meet Government mission, goals and outcomes, the Contractor shall be governed by the standard FAR 52.227-11 Patent Rights-Ownership by the Contractor (DEC 2007) and retain the entire right, title, and interest throughout the world in and to each subject invention except to the extent that rights are retained by the Government in this clause or in the standard FAR 52.227-11. With respect to any subject invention in which the Contractor retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(3) Greater Rights Determinations.

(i) The Contractor (or an employee-inventor of the contractor after consultation with the Contractor) may request greater rights to an identified invention in accordance with the procedures in paragraph 27.304-1 (b) (and paragraph 27.304-1 (c) in the case of an employee--inventor) of the Federal Acquisition Regulations (FAR). In addition to the considerations set forth in paragraph 27.304-1 (b), the NCI will also consider whether granting the requested greater rights will interfere with the rights of the Government or any Collaborating Party or otherwise impede the ability of the Government to develop and

commercialize new compounds, technologies or other approaches to improved treatment, diagnosis or prevention of cancer, AIDS or other diseases in a rapid, efficient, and cost effective manner. A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the NCI Contracting Officer at the time of first disclosure of the invention pursuant to subparagraph (c)(1) below, or not later than 8 months thereafter, unless a longer period is authorized by the Contracting Officer for good cause shown in writing, by the Contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227--13 (DEC 2007) and to the reservations and conditions deemed to be appropriate by NCI. A determination by NCI denying a request by the Contractor for greater rights in a subject invention may be appealed, within 30 days of the date the Contractor is notified of the determination, to an agency official at a level above the individual who made the determination.

(ii) Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any subject invention in any country for which the Contractor has retained title.

(iii) Upon request, the Contractor shall furnish the agency an irrevocable power to inspect and make copies of the patent application file.

(c) Contractor's obligations.

(1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(d) Contractor action to protect the Government's interest.

(1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to—

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions pursuant to (b)(1); and

(ii) Assign title to the Government when requested under paragraph (b)(1) of this clause and to enable the Government or third-party designated by the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions in which it has been granted greater rights and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall include, within the specification of any United States patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, in which it has been granted greater rights the following statement, "This invention was made with Government support under (identify the contract) awarded by the National Cancer Institute of the National Institutes of Health.. The Government has certain rights in the invention."

(4) The Contractor agrees to provide a final invention statement and certification prior to the close-out of the contract listing all subject inventions or stating that there were none.

(e) Reporting on utilization of subject inventions.

In Subject Inventions in which the Contractor has been granted greater rights, the Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(f) Preference for United States industry.

Notwithstanding any other provision of this clause, in Subject Inventions in which the Contractor has been granted greater rights neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(g) March-in rights.

The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(h) Special provisions for contracts with nonprofit organizations.

If the Contractor is a nonprofit organization and has been granted greater rights in a Subject Invention, it shall—

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education;

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor; and

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(i) Communications. [Complete according to agency instructions.]

(1) All invention disclosures and requests for greater rights shall be sent to the NCI Contracting Officer pursuant to the contact information found elsewhere in this contract. Additionally, a copy of all disclosures, confirmatory licenses to the government, face page of the patent applications, waivers and other routine communications should be sent to the Director, Office of Extramural Research Administration, Division of Extramural Inventions and Technology Resources, National Institutes of Health, by mail or through an approved electronic system for this purpose (e.g., iEdison).

(j) Subcontracts.

(1) (i) The Contractor shall include the substance of this clause, including this paragraph (j), in all subcontracts at all tiers for experimental, developmental, or research work except when appropriate to meet Government mission, goals and outcomes as directed by the Government pursuant to subparagraph (b)(2).

(ii) When directed by the Government to meet Government mission, goals and outcomes pursuant to subparagraph (b)(2), the Contractor will include the standard FAR 52.227-11 Patent Rights – Ownership by the Contractor (DEC 2007) into subcontracts.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all

rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (g) of this clause.

(End of clause)

FAR 52.227-11 (Deviation) Patent Rights--Ownership by the Contractor (DEC 2007)[Patent Rights-NCI Full-length cDNA Initiative]

This clause deviation applies to inventions resulting from activities performed by subcontractors of the prime NCI Operations and Technical Support contractor at all tiers working as part of the NCI Full-length cDNA initiative except when appropriate to meet Government mission, goals and outcomes as directed by the Government. Inventions developed by subcontractors not part of the NCI Full-length cDNA initiative or when directed by the Government will be governed by the standard patent rights clause at FAR 52.227-11, Patent Rights - Ownership by the Contractor (DEC 2007).

(a) As used in this clause—

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means--

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

Practical application means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and

that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Subject invention means any invention of the Contractor made in the performance of work under this contract.

(b) Allocation of principal rights.

(1) Assignment to the Government. The Contractor shall assign to the Government, the entire right, title and interest throughout the world in each and to each subject invention except to the extent that rights are retained by the Contractor under subparagraph (b)(3) of this clause. The foregoing notwithstanding,

in the circumstances noted in subparagraph (b)(2), the disposition of rights shall be as directed in (b)(2) for those particular circumstances.

(2) Retention by the Contractor. When directed by the Government to meet Government mission, goals and outcomes, the Contractor shall be governed by the standard FAR 52.227-11 Patent Rights-Ownership by the Contractor (DEC 2007) and retain the entire right, title, and interest throughout the world in and to each subject invention except to the extent that rights are retained by the Government in this clause or in the standard FAR 52.227-11. With respect to any subject invention in which the Contractor retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(3) Greater Rights Determinations.

(i) The Contractor (or an employee-inventor of the contractor after consultation with the Contractor) may request greater rights to an identified invention in accordance with the procedures in paragraph 27.304-1 (b) (and paragraph 27.304-1 (c) in the case of an employee--inventor) of the Federal Acquisition Regulations (FAR). In addition to the considerations set forth in paragraph 27.304-1 (b), NCI will also consider whether granting the requested greater rights will interfere with the programmatic objectives of the Government to

maintain sufficient rights in Federally supported inventions to meet the needs of the Government and to protect the public against nonuse or unreasonable use of such inventions by making the libraries, arrays, clones, sequences and databases generated from the NCI Full-Length cDNA Initiative freely and rapidly accessible to the public. A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the NCI Contracting Officer at the time of first disclosure of the invention pursuant to subparagraph (c)(1) below, or not later than 8 months thereafter, unless a longer period is authorized by the Contracting Officer for good cause shown in writing, by the Contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227--13 (DEC 2007) and to the reservations and conditions deemed to be appropriate by NCI. A determination by NCI denying a request by the Contractor for greater rights in a subject invention may be appealed, within 30 days of the date the Contractor is notified of the determination, to an agency official at a level above the individual who made the determination. If greater rights are not granted, the Contractor may elect to request a statutory invention registration (SIR) in accordance with 35 U.S.C. 157.

(ii) Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English language version if filed in a language other than English), and patent number and issue date for any subject invention in which the Contractor has retained title.

(iii) Upon request, the Contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(c) Contractor's obligations.

(1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been

submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(d) Contractor action to protect the Government's interest.

(1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to—

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions pursuant to (b)(1); and

(ii) Assign title to the Government when requested under paragraph (b)(1) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall include, within the specification of any United States patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, in which it has been granted greater rights the following statement, "This invention was made with Government support under (identify the contract) awarded by the National Cancer Institute of the National Institutes of Health. The Government has certain rights in the invention."

(4) The Contractor agrees to provide a final invention statement and certification prior to the close-out of the contract listing all subject inventions or stating that there were none.

(e) Reporting on utilization of subject inventions.

In Subject Inventions in which the Contractor has been granted greater rights, the Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(f) Preference for United States industry.

Notwithstanding any other provision of this clause, in Subject Inventions in which the Contractor has been granted greater rights neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(g) March-in rights.

The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and

210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(h) Special provisions for contracts with nonprofit organizations.

If the Contractor is a nonprofit organization and has been granted greater rights in a Subject Invention, it shall—

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education;

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor; and

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing

policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(i) Communications. [Complete according to agency instructions.]

(1) All invention disclosures and requests for greater rights shall be sent to the NCI Contracting Officer pursuant to the contact information found elsewhere in this contract. Additionally, a copy of all disclosures, confirmatory licenses to the government, face page of the patent applications, waivers and other routine communications should be sent to the Director, Office of Extramural Research Administration, Division of Extramural Inventions and Technology Resources, National Institutes of Health, by mail or through an approved electronic system for this purpose (e.g., iEdison).

(j) Subcontracts.

(1) (i) The Contractor shall include the substance of this clause, including this paragraph (j), in all subcontracts at all tiers when working as part of the NCI Full-length cDNA initiative except when appropriate to meet Government mission, goals and outcomes as directed by the Government pursuant to subparagraph (b)(2).

(ii) When directed by the Government to meet Government mission, goals and outcomes pursuant to subparagraph (b)(2), the Contractor will include the standard FAR 52.227-11 Patent Rights – Ownership by the Contractor (DEC 2007) into subcontracts.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of

the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (g) of this clause.

(End of clause)

FAR 52.227-11 (Deviation) Patent Rights--Ownership by the Contractor (DEC 2007) [Patent Rights-Initiative for Chemical Genetics (ICG) (formerly called the Molecular Targets Laboratories (MTL) Initiative]

This Clause applies to work done by OTS subcontractors at all tiers when working under the NCI Initiative for Chemical Genetics. Note that Molecular Targets Laboratory initiative (MTL) is now called the Initiative for Chemical Genetics (ICG).

(a) Definitions

As used in this clause—

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means--

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

Practical application means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and

that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Subject invention means any invention of the Contractor made in the performance of work under this contract.

IP means intellectual property including patents, copyrights, trademarks and SIRs

NCI means the National Cancer Institute of the National Institutes of Health

SIR means a Statutory Invention Registration as provided for by the United States Patent and Trademark Office

IP Committee means the NCI sponsored committee responsible for reviewing the ICG Contractor's patenting, licensing and other IP activities and for reviewing and approving the Contractor's IP management strategy and execution of said IP management strategy.

ICG means Initiative for Chemical Genetics

(b) Allocation of principal rights.

(1) The Contractor shall assign to the Government, the entire right, title and interest throughout the world in each and to each subject invention except to the extent that rights are retained by the Contractor under subparagraph (b)(2) of this clause. The Government retains additional rights when Contractor is a nonprofit organization pursuant to (h) of this clause.

(2) Contractor Greater Rights

(i) Paragraph (b)(1) notwithstanding, the Government hereby grants the Contractor blanket greater rights to Subject Inventions developed under the ICG subject to the terms contained herein at (b)(2). It is the intent of the Government that there be broad dissemination of research tools developed under this contract. Accordingly it is anticipated that the Contractor will

dedicate the majority of Subject Inventions developed under the contract to the public domain so that these resources will help advance scientific knowledge for the public good. Therefore, the Contractor agrees to dedicate those inventions (e.g. research tools) that do not require patent protection to promote further development of the invention to the public domain through publication or other appropriate means as agreed to by the Contractor and the Government. The Contractor may seek an SIR to such inventions as appropriate. The Government also recognizes the benefit of patent protection for those inventions that require further development and the participation of commercial entities to have a valid impact on the public. As part of the blanket greater rights granted, Contractor may elect title to Subject Inventions that require patent protection to advance the technology subject to the terms of (b)(3).

(3) IP Management by Contractor and Government's Rights

(i) Contractor shall submit an IP management strategy to the Contracting Officer for approval that details how the Contractor intends to administer IP to meet the intent of broad dissemination set forth in (b)(2) within forty-five (45) days of award of this contract. Contractor's IP strategy shall include patenting and licensing of inventions, strategic use of SIRs, identification and distribution of research materials, and organization and dissemination of data. Any changes to Contractor's IP management strategy during the course of the contract will be implemented only after consultation with and approval of NCI.

(ii) Contractor's IP management strategy and the implementation of said Strategy will be reviewed initially and up to twice per year as necessary by the IP committee. NCI, through the IP committee, will determine if Contractor's patenting and licensing activities, dissemination of research materials and overall IP management meets the goals set forth for the ICG.

(iii) During the term of the contract, should the NCI find that Contractor's IP management is inconsistent with the intent for the ICG as set forth in (b)(2) of this clause, the Government at its sole discretion may prospectively revoke Contractor's blanket greater rights granted under (b)(2) thus claiming right and title to all future Subject Inventions made under the contract and/or terminate the contract. Upon termination of blanket greater rights granted under (b)(2),

the Contractor must request future greater rights to any subsequent Subject Inventions on a case-by-case basis.

(iv) The Contractor shall submit a written report to the Contracting Officer forty-five (45) days prior to each review under (b)(3)(2) by the IP Committee. The report will contain:

(A) An update on all patent or other IP applications, licenses, invention administration agreements, sponsored research agreements or other IP issues. This update should include prosecution status of IP applications, technology development milestones achieved by licensees and any other appropriate reporting relating to IP.

(B) A summary of non-patented technology created and the effectiveness of the Contractor's dissemination of the technology to the scientific community.

(C) The effectiveness of Contractor's data release, data management and availability of data to the scientific community.

(v) Contractor will be granted 90 days to correct deficiencies in its IP management prior to NCI exercising its rights in (b)(3)(3).

(c) Contractor's obligations.

(1) If greater rights have been granted, the Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall

promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) If greater rights have been granted, the Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within 2 years of disclosure to the agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) If greater rights have been granted, the Contractor shall file either a provisional or a non-provisional patent application or a Plant Variety Protection Application on an elected subject invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either 10 months of the first filed patent application (whether provisional or non-provisional) or 6 months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(5) Contractor shall provide copies of all patent or other IP applications, licenses, invention administration agreements, sponsored research agreements or other documents relating to the administration of IP to the Contracting Officer within thirty (30) days after filing or execution. A copy of all disclosures, confirmatory licenses to the Government, face pages of patent applications, waivers, and other routine communication shall be sent to the Director, Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH pursuant to paragraph (j).

(d) Government's rights—

(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention--

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within 60 days after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government's interest.

(1) The Contractor agrees-

(i) To manage IP in accordance with the IP strategy approved by the NCI per (b)(3), and

(ii) To report all IP in accordance with (c), and

(iii) To establish or confirm the rights the Government has throughout the world in Subject Inventions pursuant to paragraph (b)(1), and

(iv) To assist the Government in obtaining patent protection throughout the world to Subject Inventions which the Government has the right to title under paragraph (b)(3)(3) of this clause.

(2) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to—

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions pursuant to (b)(1); and

(ii) Assign title to the Government when requested under paragraph (b)(1) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(3) The Contractor shall require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(4) The Contractor shall notify the Contracting Officer of any decisions not to file a non-provisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response or filing period required by the relevant patent office.

(5) The Contractor shall include, within the specification of any United States patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, in which it has been granted greater rights

the following statement, "This invention was made with Government support under (identify the contract) awarded by the National Cancer Institute of the National Institutes of Health. The Government has certain rights in the invention."

(6) The Contractor agrees to provide a final invention statement and certification prior to the close-out of the contract listing all subject inventions or stating that there were none.

(f) Reporting on utilization of subject inventions.

The Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(g) Preference for United States industry.

Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights.

The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations.

If the Contractor is a nonprofit organization, it shall—

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education;

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor; and

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications. [Complete according to agency instructions.]

(1) All invention disclosures and requests for greater rights shall be sent to the NCI Contracting Officer pursuant to the contact information found elsewhere in this contract. Additionally, a copy of all disclosures, confirmatory licenses to the government, face page of the patent applications, waivers and other routine communications should be sent to the Director, Office of Extramural Research Administration, Division of Extramural Inventions and Technology Resources, National Institutes of Health, by mail or through an approved electronic system for this purpose (e.g., iEdison).

(k) Subcontracts.

(1) The Contractor shall include the substance of this clause, including this paragraph (k), in all subcontracts at all tiers for experimental, developmental, or research work.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the

clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (h) of this clause.

(End of clause)

FAR 52.227-14 (Deviation) Rights in Data—General (DEC 2007) [Rights in Data-NCI Full Length cDNA Initiative]

This clause deviation applies to activities performed under the NCI Full-length cDNA Initiative by the OTS prime Contractor and its subcontractors at all tiers.

(a) Definitions. As used in this clause—

Computer database or database means a collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

FAR 52.227-14 (Deviation) Rights in Data—General (DEC 2007) [Initiative for Chemical Genetics (ICG)] (formerly called the Molecular Targets Laboratories (MTL) Initiative)

This Clause applies to work done by OTS subcontractors at all tiers when working under the NCI Initiative for Chemical Genetics. Note that Molecular Targets Laboratory initiative (MTL) is now called the Initiative for Chemical Genetics (ICG).

(a) Definitions. As used in this clause—

Computer database or database means a collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

FAR 52.227-17 (Deviation) Rights in Data--Special Works (DEC 2007). [Rights in Data-Use of Third-party Technology and Information]

This clause deviation applies to activities performed by the OTS Contractor and its subcontractors at all tiers involving the use of proprietary technology or information supplied to NIH by a third-party except when appropriate to meet Government mission, goals and outcomes as directed by the Government. Data resulting from activities using non-proprietary technology or information or when directed by the Government to meet Government mission, goals and outcomes will be covered by the standard rights in data clause at FAR 52.227-14, Rights in Data-General (Dec 2007).

For any institution operating under a state constitution or other organization as specifically negotiated, delete the current paragraph (g) in this clause FAR 52.227-17, (Deviation) Rights in Data-Special Works (DEC 2007).

(a) Definitions.

As used in this clause--

Data means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Unlimited rights means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

(b) Allocation of Rights.

(1) The Government shall have—

(i) Unlimited rights in all data delivered under this contract, and in all data first produced in the performance of this contract, except as provided in paragraph (c) of this clause.

(ii) The right to limit assertion of copyright in data first produced in the performance of this contract, and to obtain assignment of copyright in that data, in accordance with paragraph (c)(1) of this clause.

(iii) The right to limit the release and use of certain data in accordance with paragraph (d) of this clause.

(2) The Contractor shall have, to the extent permission is granted in accordance with paragraph (c)(1) of this clause, the right to assert claim to copyright subsisting in data first produced in the performance of this contract.

(3) The foregoing notwithstanding, unless provided for otherwise elsewhere in this contract and to the extent that other terms agreed to by the Contractor and the Government elsewhere in this contract are met, the Contractor may establish, without prior approval of the Contracting Officer, claim to copyright subsisting in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings or similar works but only after allowing the Government a minimum of thirty (30) days to review such publications for confidential or proprietary information belonging to the Government or a third-party prior to submission for publication. The Contractor agrees to remove such confidential or proprietary information belonging to the Government or a third-party.

(c) Copyright—

(1) Data first produced in the performance of this contract.

(i) The Contractor shall not assert or authorize others to assert any claim to copyright subsisting in any data first produced in the performance of this contract without prior written permission of the Contracting Officer. When copyright is asserted, the Contractor shall affix the appropriate copyright notice

of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship (including contract number) to the data when delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. The Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all delivered data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government.

(ii) If the Government desires to obtain copyright in data first produced in the performance of this contract and permission has not been granted as set forth in paragraph (c)(1)(i) of this clause, the Contracting Officer shall direct the Contractor to assign (with or without registration), or obtain the assignment of, the copyright to the Government or its designated assignee.

(2) Data not first produced in the performance of this contract.

The Contractor shall not, without prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract and that contain the copyright notice of 17 U.S.C. 401 or 402, unless the Contractor identifies such data and grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause.

(d) Release and use restrictions.

Except as otherwise specifically provided for in this contract, the Contractor shall not use, release, reproduce, distribute, or publish any data first produced in the performance of this contract, nor authorize others to do so, without written permission of the Contracting Officer.

(e) Restrictive markings

The Contractor agrees that to the extent it receives or is given access to information necessary for the performance of this contract which is proprietary to a third-party, which is associated with Government –owned Therapeutics, Vaccines and Diagnostics or which contains restrictive

markings, the contractor shall treat the information in accordance with such markings unless otherwise specifically authorized in writing by the Contracting Officer.

(f) Subcontracts

The Contractor agrees to include this FAR 52.227-17 (Deviation) Rights in Data- Special Works (DEC 2007) [Rights in Data- Use of Third-party Technology and Information] into all subcontracts at all tiers when said subcontractor receives or is given access to information necessary for the performance of this contract which is proprietary to a third-party and which contain restrictive markings. The Contractor shall treat the information in accordance with such markings unless otherwise specifically authorized in writing by the Contracting Officer. Notwithstanding the foregoing, when appropriate to meet Government mission, goals and outcomes as directed by the Government, the Contractor may substitute an alternative FAR Rights in Data clause or alternative contract terms or both.

(g) Indemnity.

The Contractor shall indemnify the Government and its officers, agents, and employees acting for the Government against any liability, including costs and expenses, incurred as the result of the violation of trade secrets, copyrights, or right of privacy or publicity, arising out of the creation, delivery, publication, or use of any data furnished under this contract; or any libelous or other unlawful matter contained in such data. The provisions of this paragraph do not apply unless the Government provides notice to the Contractor as soon as practicable of any claim or suit, affords the Contractor an opportunity under applicable laws, rules, or regulations to participate in the defense of the claim or suit, and obtains the Contractor's consent to the settlement of any claim or suit other than as required by final decree of a court of competent jurisdiction; and these provisions do not apply to material furnished to the Contractor by the Government and incorporated in data to which this clause applies.

(End of clause)

FAR 52.227-11 (Deviation) Patent Rights--Ownership by the Contractor (DEC 2007) [OTS Contractor CRADAs

The clause applies to all work done by the OTS prime contractor when conducting approved OTS Contractor CRADAs.

(a) As used in this clause-

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means--

- (1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or
- (2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

Practical application means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent

permitted by law or Government regulations, available to the public on reasonable terms.

Subject invention means any invention of the Contractor made in the performance of work under this contract.

NIH means the National Institutes of Health which is part of the United States Department of Health and Human Services

Cooperative Research and Development Agreement (CRADA)," as used in this clause, means any agreement pursuant to 15 U.S.C. 3710a entered into between one or more Federal Government Owned- Contractor Operated (GOCO) laboratories and one or more non-Federal parties under which the Government, through its GOCO laboratories, provides personnel, services, facilities, equipment, and other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the contract; 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.

NIH CRADA means any CRADA executed by the NIH and in direct support of NIH programs.

OTS Contractor CRADA Subject Invention means a Subject Invention specifically made under an OTS Contractor CRADA.

OTS Contractor means the Operations and Technical Support (OTS) contractor at the FNLCR FFRDC OTS Contractor CRADA means any approved CRADA executed by the Contractor which supports the FFRDC mission but does not directly support or involve an NIH program.

(b) Contractor's rights.

- (1) Ownership(A} the Contractor shall conditionally own OTS Contractor CRADA Subject Inventions produced by the contractor under approved OTS Contractor CRADAs subject to the terms herein.
- (A) The Contractor shall manage such OTS Contractor CRADA Subject Inventions as follows:
- (i) In accordance with the CRADA statute found at 15 U.S.C. 3710a;
 - (ii) Consistent with the terms found elsewhere in this contract;
 - (iii) In the event of a successor OTS Contractor at the FFRDC, the present OTS Contractor shall relinquish ownership of its OTS Contractor CRADA Subject Inventions to the successor OTS Contractor or the Government if otherwise instructed by the Contracting Officer; and
 - (iv) In the event that the OTS Contract is not renewed, ownership of the OTS Contractor CRADA Subject Inventions shall be transferred to the Government; and
 - (v) In the event that the OTS Contractor CRADA program is otherwise terminated during the term of the OTS contract, ownership and management of OTS Contractor CRADA Subject Inventions shall be handled as directed elsewhere in this contract.
- (B) The Contractor shall abide by all other terms and conditions elsewhere in this contract related to the OTS Contractor CRADA program.
- (C) This clause shall not apply to inventions made by the OTS Contractor when working in support of NIH CRADAs.
- (D) Inventions made by the Contractor which are not OTS Contractor CRADA

Subject Inventions shall be owned by the Government pursuant to FAR Clause 52.227-13 (Deviation) Patent Rights-Ownership by the Government (Dec. 2007) [Patent Rights-OTS Prime Contractor].

(2) Contractor License when the Government Obtains Ownership of Subject Inventions. In the event that the Government obtains title to a subject invention, the license rights of the Contractor in that subject invention are the minimum rights to the Contractor described in FAR Clause 52.227-13 (Deviation) Patent Rights-Ownership by the Government (Dec. 2007) [Patent Rights-OTS Prime Contractor].

(c) Contractor's obligations.

(1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within 2 years of disclosure to the agency.

However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The Contractor shall file either a provisional or a nonprovisional patent

application or a Plant Variety Protection Application on an elected subject invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either 10 months of the first filed patent application (whether provisional or nonprovisional) or 6 months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(5) The Contractor shall further manage inventions which are OTS Contractor CRADA Subject Inventions and provide any additional reporting related to the OTS Contractor CRADA Program as required elsewhere in this contract.

(d) Government's rights-

(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention--

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within 60 days after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to

its receipt of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government's interest.

(1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to-

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions in which the Contractor elects to retain ownership; and

(ii) Assign title to the agency when requested under paragraph (d) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through

employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall notify the Contracting Officer of any decisions not to file a nonprovisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response or filing period required by the relevant patent office.

(4) The Contractor shall include, within the specification of any United States nonprovisional patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, the following statement, "This invention was made with Government support under (identify the contract) awarded by (identify the agency). The Government has certain rights in the invention."

(f) Reporting on utilization of subject inventions.

The Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause.

The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(g) Preference for United States industry.

Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights.

The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions. The Contractor shall-

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education and for OTS Contractor CRADA

Subject Inventions in a manner consistent with (b) (1); and

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor.

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

j) Communications. [Complete according to agency instructions.]

(k) Subcontracts.

(1) The Contractor shall include the standard FAR Clause 52.227-11 Patent Rights-Ownership by the Contractor (Dec. 2007) in all subcontracts for work under an OTS Contractor CRADA for experimental, developmental, or research work.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the

subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (h) of this clause.

(End of clause)

FAR 52.227-13 (Deviation) Patent Rights--Ownership by the Government (DEC 2007) [Patent Rights-OTS Prime Contractor] (As amended MAR 2012)

This clause is to be applied to all work done by the FNLCR FFRDC Operations and Technical Support (OTS) prime contractor except when conducting OTS Contractor CRADAs.

a) Definitions.

As used in this clause—

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means—

(1) When used in relation to any invention other than a plant variety, means the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, means that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Practical application means to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

NIH means the National Institutes of Health which is part of the United States Department of Health and Human Services

NCI means the National Cancer Institute, an institute within NIH

Subject invention means any invention of the Contractor made in the performance of work under this contract.

OTS Contractor CRADA Subject Invention means a Subject Invention specifically made under an OTS Contractor CRADA.

OTS Contractor means the Operations and Technical Support (OTS) contractor at the FNLCR FFRDC

Cooperative Research and Development Agreement (CRADA)," as used in this clause, means any agreement pursuant to 15 U.S.C. 3710a entered into between one or more Federal Government Owned-Contractor Operated (GOCO) laboratories and one or more non-Federal parties under which the Government, through its GOCO laboratories, provides personnel, services, facilities, equipment, and other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the contract; 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.

NIH CRADA means any CRADA executed by the NIH and in direct support of NIH programs.

OTS Contractor CRADA means any approved CRADA executed by the Contractor which supports the FFRDC mission but does not directly support or involve an NIH program.

FFRDC means Federally Funded Research and Development Center as authorized under FAR 35.017.

(b) Ownership.

(1) Assignment to the Government. The Contractor shall assign to the Government title throughout the world to each subject invention, except to the extent that rights are retained under paragraphs (b)(4) and (d) of this clause. The provisions of subparagraph

(b)(4) and paragraph (d) below shall not apply when the subject invention has been developed under an NIH CRADA or in cases where the Contractor uses third-party proprietary information or technology provided to NIH in performance of the contract. The foregoing notwithstanding, in the circumstances stated in subparagraph (b)(2) below, the disposition of rights shall be as directed in subparagraph (b)(2) for OTS Contractor CRADA Subject Inventions made under approved OTS Contractor CRADAs.

(2) OTS Contractor CRADAs.

OTS Contractor CRADAs and the disposition of OTS Contractor CRADA Subject Inventions made under approved OTS Contractor CRADAs shall be governed by FAR 52.227-11 (Deviation) Patent Rights-Ownership by the Contractor (Dec. 2007) [OTS Contractor CRADAs]

(3) With respect to any subject invention in which the Contractor retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(4) Greater rights determinations.

(i) For other than OTS Contractor CRADA Subject Inventions and as noted in (b)(1), the Contractor, or an employee-inventor after consultation with the Contractor, may request greater rights than the nonexclusive license provided in paragraph (d) of this clause. The request for a greater rights must be submitted to the Contracting Officer at the time of the first disclosure of the subject invention pursuant to paragraph (e)(2) of this clause, or not later than 8 months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. Each determination of greater rights under this contract normally shall be subject to paragraph (c) of this clause, and to the reservations and conditions deemed to be appropriate by the agency.

(ii) Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if

filed in a language other than English), and patent number and issue date for any subject invention in any country for which the Contractor has retained title.

(iii) Upon request, the Contractor shall furnish the agency an irrevocable power to inspect and make copies of the patent application file.

(c) Minimum rights acquired by the Government.

(1) Regarding each subject invention to which the Contractor retains ownership, the Contractor agrees as follows:

(i) The Government will have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(ii) The agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c) and in accordance with the procedures set forth in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of the contract award.

(iii) Upon request, the Contractor shall submit periodic reports no more frequently than annually on the utilization, or efforts to obtain utilization, of a subject invention by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and any other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceedings undertaken by the agency in accordance with paragraph (c)(1)(ii) of this clause. To the extent data or information supplied under this section is considered by the Contractor, or its licensees, or assignees to be privileged and confidential and is so marked, the agency, to the extent permitted by law, will not disclose such information to persons outside the Government.

(iv) When licensing a subject invention, the Contractor shall—

(A) Ensure that no royalties are charged on acquisitions involving Government funds, including funds derived through a Military Assistance Program of the Government or otherwise derived through the Government;

(B) Refund any amounts received as royalty charges on a subject invention in acquisitions for, or on behalf of, the Government;

(C) Provide for this refund in any instrument transferring rights in the subject invention to any party.

(v) When transferring rights in a subject invention, the Contractor shall provide for the Government's rights set forth in paragraphs (c)(1)(i) through (c)(1)(iv) of this clause.

(2) Nothing contained in paragraph (c) of this clause shall be deemed to grant to the Government rights in any invention other than a subject invention.

(d) Minimum rights to the Contractor.

(1) The Contractor is hereby granted a revocable, nonexclusive, paid-up license in each patent application filed in any country on a subject invention and any resulting patent in which the Government obtains title, unless the Contractor fails to disclose the subject invention within the times specified in paragraph (e)(2) of this clause. The Contractor's license extends to any of its domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency except when transferred to the successor of that part of the Contractor's business to which the subject invention pertains.

(2) The Contractor's license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304-1(f).

(3) When the Government elects not to apply for a patent in any foreign country, the Contractor retains rights in that foreign country to apply for a patent, subject to the Government's rights in paragraph (c)(1) of this clause.

(e) Invention identification, disclosures, and reports.

(1) The Contractor shall establish and maintain active and effective procedures to educate its employees in order to assure that subject inventions are promptly identified and disclosed to Contractor personnel responsible for patent matters. The procedures shall include the maintenance of laboratory notebooks or equivalent records and other records as are reasonably necessary to document the conception and/or the first actual reduction to practice of subject inventions, and records that show the procedures for identifying and disclosing subject inventions are followed. Upon request, the Contractor shall furnish the Contracting Officer a description of these procedures for evaluation and for a determination as to their effectiveness.

(2) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters or, if earlier, within 6 months after the Contractor becomes aware that a subject invention has been made, but in any event before any on sale (i.e., sale or offer for sale), public use, or publication of the subject invention known to the Contractor. The disclosure shall identify the contract under which the subject invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale, or public use of the subject invention and whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the

Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(3) The Contractor shall furnish the Contracting Officer the following:

(i) Interim reports every 12 months (or a longer period as may be specified by the Contracting Officer) from the date of the contract, listing subject inventions during that period, and stating that all subject inventions have been disclosed (or that there are none) and that the procedures required by paragraph (e)(1) of this clause have been followed.

(ii) A final report, within 3 months after completion of the contracted work, listing all subject inventions or stating that there were none, and listing all subcontracts at any tier containing a patent rights clause or stating that there were none.

(4) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by paragraph (e)(2) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(5) Subject to FAR 27.302(i), the Contractor agrees that the Government may duplicate and disclose subject invention disclosures and all other reports and papers furnished or required to be furnished pursuant to this clause.

(f) Examination of records relating to inventions.

(1) The Contracting Officer or any authorized representative shall, until 3 years after final payment under this contract, have the right to examine any books (including laboratory notebooks), records, and documents of the Contractor relating to the conception or first actual reduction to practice of inventions in the same field of technology as the work under this contract to determine whether—

(i) Any inventions are subject inventions;

(ii) The Contractor has established and maintains the procedures required by paragraphs (e)(1) and (e)(4) of this clause; and

(iii) The Contractor and its inventors have complied with the procedures.

(2) The Contractor shall disclose to the Contracting Officer, for the determination of ownership rights, any unreported invention that the Contracting Officer believes may be a subject invention.

(3) Any examination of records under paragraph (f) of this clause will be subject to appropriate conditions to protect the confidentiality of the information involved.

(g) Withholding of payment. (This paragraph does not apply to subcontracts.)

(1) Any time before final payment under this contract, the Contracting Officer may, in the Government's interest, withhold payment until a reserve not exceeding \$50,000 or 5 percent of the amount of this contract, whichever is less, shall have been set aside if, in the Contracting Officer's opinion, the Contractor fails to—

(i) Establish, maintain, and follow effective procedures for identifying and disclosing subject inventions pursuant to paragraph (e)(1) of this clause;

(ii) Disclose any subject invention pursuant to paragraph (e)(2) of this clause;

(iii) Deliver acceptable interim reports pursuant to paragraph (e)(3)(i) of this clause; or

(iv) Provide the information regarding subcontracts pursuant to paragraph (i)(4) of this clause.

(2) The Contracting Officer will withhold the reserve or balance until the Contracting Officer has determined that the Contractor has rectified whatever deficiencies exist and has delivered all reports, disclosures, and other information required by this clause.

(3) The Contracting Officer will not make final payment under this contract before the Contractor delivers to the Contracting Officer, as required by this clause, all disclosures of subject inventions, an acceptable final report, and all due confirmatory instruments.

(4) The Contracting Officer may decrease or increase the sums withheld up to the maximum authorized. The Contracting Officer will not withhold any amount under this paragraph while the amount specified by this paragraph is being withheld under other provisions of the contract. The withholding of any amount or the subsequent payment shall not be construed as a waiver of any Government rights.

(h) Preference for United States industry.

Unless provided otherwise, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement may be waived by the agency upon a showing by the Contractor or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

(i) Subcontracts.

(1) The Contractor shall incorporate the standard FAR Clause 52.227-11 Patent Rights-Ownership by the Contractor (DEC 2007) in all subcontracts regardless of tier, for experimental, developmental, or research work. The foregoing notwithstanding, if one or more of the circumstances at subparagraph (i)(2)(i-iv) of this Clause applies then the Contractor shall incorporate the appropriate FAR clause(s) into said subcontracts as directed in subparagraph (i)(2)(i-iv) below for those particular circumstances. The prescribed patent rights clause must be modified to identify the parties as follows:

references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) Subcontracts at all tiers shall operate as directed in this subparagraph (i)(2)(i-iv) for these particular circumstances:

(i) Use of Third-party Technology or Information: The Contractor shall incorporate the clause, FAR 52.227-11(Deviation) Patent Rights- [Patent Rights- Ownership by the Contractor (DEC 2007) [Use of Third-party Technology and Information by Subcontractors] into subcontracts at all tiers, when the subcontractor will be working with third party proprietary technology or information provided to NIH by a third-party unless subparagraph (i)(2)(iv) applies.

(ii) NCI Full-length cDNA Initiative: The Contractor shall incorporate the clause, FAR 52.227-11(Deviation) Patent Rights - Ownership by the Contractor (DEC 2007) [Patent Rights NCI Full-length cDNA Initiative, into all subcontracts, at all tiers, when the subcontractor will be working under the NCI Full-length cDNA Initiative unless subparagraph (i)(2)(iv) applies.

(iii) Initiative for Chemical Genetics: The Contractor shall incorporate the clause, FAR 52.227-11(Deviation) Patent Rights - Ownership by the Contractor (DEC 2007) [Patent Rights-Initiative for Chemical Genetics (ICG) (formerly called the Molecular Targets Laboratories (MTL) Initiative], into all subcontracts, at all tiers, when the subcontractor will be working under the NCI ICG Initiative unless subparagraph (i)(2)(iv) applies.

(3) In the event of a refusal by a prospective subcontractor to accept the clause, the Contractor—

(i) Shall promptly submit a written notice to the Contracting Officer setting forth the subcontractor's reasons for such refusal and other pertinent information that may expedite disposition of the matter; and

(ii) Shall not proceed with such subcontract without the written authorization of the Contracting Officer.

(4) In subcontracts at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by the patent rights clause constitute a contract between the subcontractor and the agency with respect to those matters covered by this clause.

(5) The Contractor shall promptly notify the Contracting Officer in writing upon the award of any subcontract at any tier containing a patent rights clause by identifying the subcontractor, the applicable patent rights clause, the work to be performed under the subcontract, and the dates of award and estimated completion. Upon request of the Contracting Officer, the Contractor shall furnish a copy of such subcontract, and, no more frequently than annually, a listing of the subcontracts that have been awarded.

(End of clause)