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

FORM 8-K/A
(Amendment No. 2)

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 5, 2011

GENESIS BIOPHARMA, INC.
(Name of small business issuer specified in its charter)

Nevada	**000-53127**	**75-3254381**
(State or other jurisdiction of incorporation)	(Commission File No.)	(I.R.S. Employer Identification No.)

11500 Olympic Blvd., Suite 400
Los Angeles, CA 90064
(Address of principal executive offices)

Not Applicable.
(former name or former address, if changed since last report)

(866) 963-2220
(Registrant's telephone number)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Explanatory Note

This Amendment No. 2 amends the Current Reports on Form 8-K and Form 8-K/A of Genesis Biopharma, Inc. filed with the Securities and Exchange Commission on August 11, 2011 and October 13, 2011, respectively (the "Reports"). The Form 8-K/A of Genesis Biopharma, Inc. included the Cooperative Research and Development Agreement referred to in the initial Form 8-K filed on August 11, 2011, but did not include Annex A thereto. Annex A was omitted based upon a request for confidential treatment filed with the Securities and Exchange Commission. The request for confidential treatment has been withdrawn, and the enclosed Cooperative Research and Development Agreement includes Annex A. The information reported in the Reports is incorporated by reference into this amendment.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits. The following exhibit is included as part of this report.

10.1 Cooperative Research and Development Agreement for Intramural-PHS Clinical Research, dated August 5, 2011, between the U.S. Department of Health and Human Services, as represented by the National Cancer Institute, and Genesis Biopharma, Inc.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

GENESIS BIOPHARMA, INC.

Date: November 28, 2011

By: /s/ ANTHONY CATALDO
Anthony Cataldo, Chief Executive Officer

PUBLIC HEALTH SERVICE

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT FOR INTRAMURAL-PHS CLINICAL RESEARCH

This Agreement is based on the model Cooperative Research and Development Agreement ("CRADA") adopted by the U.S. Public Health Service ("PHS") Technology Transfer Policy Board for use by components of the National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), and the Food and Drug Administration ("FDA"), which are agencies of the PHS within the Department of Health and Human Services ("HHS").

This Cover Page identifies the Parties to this CRADA:

The U.S. Department of Health and Human Services, as represented by the
National Cancer Institute
an Institute, Center, or Division (hereinafter referred to as the "**ICD**") of the
National Institutes of Health

and

Genesis Biopharma, Inc.
hereinafter referred to as the "**Collaborator**",
having offices at **10880 Wilshire Boulevard, Suite 950, Los Angeles, CA 90024**,
created and operating under the laws of Nevada.

Article 1. Introduction

This CRADA between ICD and Collaborator will be effective when signed by the Parties, which are identified on both the Cover Page and the Signature Page (page 21). The official contacts for the Parties are identified on the Contacts Information Page (page 22). Publicly available information regarding this CRADA appears on the Summary Page (page 23). The research and development activities that will be undertaken by ICD and Collaborator in the course of this CRADA are detailed in the Research Plan, attached as Appendix A. The staffing, funding, and materials contributions of the Parties are set forth in Appendix B. Any changes to the model CRADA are set forth in Appendix C.

Article 2. Definitions

The terms listed in this Article will carry the meanings indicated throughout the CRADA. To the extent a definition of a term as provided in this Article is inconsistent with a corresponding definition in the applicable sections of either the United States Code (U.S.C.) or the Code of Federal Regulations (C.F.R.), the definition in the U.S.C. or C.F.R. will control.

"**Adverse Drug Experience**" or "**ADE**" means an Adverse Event associated with the use of the Test Article, that is, an event where there is a reasonable possibility that the Test Article may have caused the event (a relationship between the Test Article and the event cannot be ruled out), in accordance with the definitions of 21 C.F.R. Part 305, 310, or 312, or other applicable regulations.

"**Adverse Event**" or "**AE**" means any untoward medical occurrence in a Human Subject administered Test Article. An AE does not necessarily have a causal relationship with the Test Article, that is, it can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the Test Article, whether or not it is related to it. See FDA Good Clinical Practice Guideline (from International Conference on Harmonisation (ICH) E6: "Good Clinical Practice: Consolidated Guidance, 62 Federal Register 25, 691 (1997)).

"**Affiliate**" means any corporation or other business entity controlled by, controlling, or under common control with Collaborator at any time during the term of the CRADA. For this purpose, "control" means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of the corporation or other business entity.

"**Annual Report**" means the report of progress of an IND-associated investigation that ICD, as the IND Sponsor, must submit to the FDA within sixty (60) days of the anniversary of the effective date of the IND (pursuant to 21 C.F.R.§ 312.33).

"**Background Invention**" means an Invention conceived and first actually reduced to practice before the Effective Date.

"**Clinical Investigator**" means, in accordance with 21 C.F.R. § 312.3, an individual who actually conducts a clinical investigation, that is, who directs the administration or dispensation of Test Article to a subject, and who assumes responsibility for studying Human Subjects, for recording and ensuring the integrity of research data, and for protecting the welfare and safety of Human Subjects.

"**Collaborator Materials**" means all tangible materials not first produced in the performance of this CRADA that are owned or controlled by Collaborator and used in the performance of the Research Plan. The term "Collaborator Materials" does not include "Test Article" (defined below).

"**Confidential Information**" means confidential scientific, business, financial information, or Identifiable Private Information provided that the information does not include:

(a) information that is publicly known or that is available from public sources;
(b) information that has been made available by its owner to others without a confidentiality obligation;
(c) information that is already known by the receiving Party, or information that is independently created or compiled by the receiving Party without reference to or use of the provided information; or
(d) information that relates to potential hazards or cautionary warnings associated with the production, handling, or use of the subject matter of the Research Plan.

"**Cooperative Research and Development Agreement**" or "**CRADA**" means this Agreement, entered into pursuant to the Federal Technology Transfer Act of 1986, as amended (15 U.S.C. §§ 3710a *et seq.*), and Executive Order 12591 of April 10, 1987.

"**CRADA Data**" means all recorded information first produced in the performance of the Research Plan.

"**CRADA Materials**" means all tangible materials first produced in the performance of the Research Plan other than CRADA Data.

"**CRADA Principal Investigator(s)**" or "**CRADA PI(s)**" means the person(s) designated by the Parties who will be responsible for the scientific and technical conduct of the Research Plan. The CRADA PI may also be a Clinical Investigator.

"**CRADA Subject Invention**" means any Invention of either or both Parties, conceived or first actually reduced to practice in the performance of the Research Plan.

"**Drug Master File**" or "**DMF**" is described in 21 C.F.R. Part 314.420. A DMF is a submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

"**Effective Date**" means the date of the last signature of the Parties executing this Agreement.

"**Government**" means the Government of the United States of America.

"**Human Subject**" means, in accordance with the definition in 45 C.F.R. § 46.102(f), a living individual about whom an investigator conducting research obtains:

(a) data through intervention or interaction with the individual; or
(b) Identifiable Private Information.

"**ICD Materials**" means all tangible materials not first produced in the performance of this CRADA that are owned or controlled by ICD and used in the performance of the Research Plan.

"**IND**" means an "**Investigational New Drug Application**", filed in accordance with 21 C.F.R. Part 312 under which clinical investigation of an experimental drug or biologic (Test Article) is performed in Human Subjects in the United States or intended to support a United States licensing action.

"**Identifiable Private Information**" or "**IPI**" about a Human Subject means private information from which the identity of the subject is or may readily be ascertained. Regulations defining and governing this information include 45 C.F.R. Part 46 and 21 C.F.R. Part 50.

"**Institutional Review Board**" or "**IRB**" means, in accordance with 45 C.F.R. Part 46, 21 C.F.R. part 56, and other applicable regulations, an independent body comprising medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of the Human Subjects involved in a study.

"**Invention**" means any invention or discovery that is or may be patentable or otherwise protected under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act, 7 U.S.C. §§ 2321 *et seq*.

"**Investigator's Brochure**" means, in accordance with the definition in 21 C.F.R. § 312.23(a)(5), a document containing information about the Test Article, including animal screening, preclinical toxicology, and detailed pharmaceutical data, including a description of possible risks and side effects to be anticipated on the basis of prior experience with the drug or related drugs, and precautions, such as additional monitoring, to be taken as part of the investigational use of the drug.

"**Patent Application**" means an application for patent protection for a CRADA Subject Invention with the United States Patent and Trademark Office ("U.S.P.T.O.") or the corresponding patent-issuing authority of another nation.

"**Patent**" means any issued United States patent, any international counterpart(s), and any corresponding grant(s) by a non-U.S. government in place of a patent.

"**Placebo**" means an inactive substance identical in appearance to the material being tested that is used to distinguish between drug action and suggestive effect of the material under study.

"**Protocol**" means the formal, detailed description of a study to be performed as provided for in the Research Plan. It describes the objective(s), design, methodology, statistical considerations, and organization of a trial. For the purposes of this CRADA, the term, Protocol, for clinical research involving Human Subjects, includes any and all associated documents, including informed consent forms, to be provided to Human Subjects and potential participants in the study.

"**Raw Data**" means the primary quantitative and empirical data first collected from experiments and clinical trials conducted within the scope of this CRADA.

"**Research Plan**" means the statement in Appendix A of the respective research and development commitments of the Parties. The Research Plan should describe the provisions for sponsoring the IND, clinical and safety monitoring, and data management.

"**Sponsor**" means, in accordance with the definition in 21 C.F.R. § 312.3, an organization or individual who assumes legal responsibility for supervising or overseeing clinical trials with Test Articles, and is sometimes referred to as the IND holder.

"**Steering Committee**" means the research and development team whose composition and responsibilities with regard to the research performed under this CRADA are described in Appendix A.

"**Summary Data**" means any extract or summary of the Raw Data, generated either by, or on behalf of, ICD or by, or on behalf of, Collaborator. Summary Data may include extracts or summaries that incorporate IPI.

"**Test Article**" means, in accordance with 21 C.F.R. 50.3 (j), any drug (including a biological product), medical device, food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act that is intended for administration to humans or animals, including a drug or biologic as identified in the Research Plan and Appendix B, that is used within the scope of the Research Plan. The Test Article may also be referred to as Investigational Agent, Study Material, or Study Product.

Article 3. Cooperative Research and Development

3.1 **Performance of Research and Development**. The research and development activities to be carried out under this CRADA will be performed solely by the Parties identified on the Cover Page, unless specifically stated elsewhere in the Agreement. The CRADA PIs will be responsible for coordinating the scientific and technical conduct of this project on behalf of their employers. Any Collaborator employees who will work at ICD facilities will be required to sign a Guest Researcher or Special Volunteer Agreement appropriately modified in view of the terms of this CRADA.

3.2 **Research Plan**. The Parties recognize that the Research Plan describes the collaborative research and development activities they will undertake and that interim research goals set forth in the Research Plan are good faith guidelines. Should events occur that require modification of these goals, then by mutual agreement the Parties can modify them through an amendment, according to Paragraph 13.6.

3.3 **Use and Disposition of Collaborator Materials and ICD Materials**. The Parties agree to use Collaborator Materials and ICD Materials only in accordance with the Research Plan and Protocol(s), not to transfer these materials to third parties except in accordance with the Research Plan and Protocol(s) or as approved by the owning or providing Party, and, upon expiration or termination of the CRADA, to dispose of these materials as directed by the owning or providing Party.

3.4 **Third-Party Rights in Collaborator's CRADA Subject Inventions**. If Collaborator has received (or will receive) support of any kind from a third party in exchange for rights in any of Collaborator's CRADA Subject Inventions, Collaborator agrees to ensure that its obligations to the third party are both consistent with Articles 6 through 8 and subordinate to Article 7 of this CRADA.

3.5 **Disclosures to ICD**. Prior to execution of this CRADA, Collaborator agrees to disclose to ICD all instances in which outstanding royalties are due under a PHS license agreement and in which Collaborator had a PHS license terminated in accordance with 37 C.F.R. § 404.10. These disclosures will be treated as Confidential Information upon request by Collaborator in accordance with the definition in Article 2 and Paragraphs 8.3 and 8.4.

3.6 **Clinical Investigator Responsibilities**. The Clinical Investigator will be required to submit, or to arrange for submission of, each Protocol associated with this CRADA to the IRB. In addition to the Protocol all associated documents, including informational documents and advertisements, must be reviewed and approved by the IRB before starting the research. The research will be done in strict accordance with the Protocol(s) and no substantive changes in a finalized Protocol will be made unless mutually agreed upon, in writing, by the Parties. Research will not commence (or will continue unchanged, if already in progress) until each substantive change to a Protocol, including those required by either the FDA or the IRB, has been integrated in a way acceptable to the Parties, submitted to the FDA (if applicable) and approved by the IRB.

3.7 **Investigational Applications**.

3.7.1 If an IND is required, ICD will be the IND Sponsor and will submit an IND. All Clinical Investigators must have completed registration documents on file (1572 forms).

3.7.2 When ICD files the IND, Collaborator agrees to provide ICD background data and information necessary to support the IND. Collaborator further agrees to provide a letter of cross-reference to all pertinent regulatory filings sponsored by Collaborator. Collaborator's employees will be reasonably available to respond to inquiries from the FDA regarding information and data contained in the Collaborator's IND, DMF, other filings, or other information and data provided to ICD by the Collaborator pursuant to this Article 3.

3.7.3 If Collaborator supplies Confidential Information to ICD in support of an IND filed by ICD, this information will be protected in accordance with the corresponding confidentiality provisions of Article 8.

3.7.4 Collaborator may sponsor its own clinical trials and hold its own IND for studies performed outside the scope of this CRADA. These studies, however, should not adversely affect the ability to accomplish the goal of the Research Plan, for example, by competing for the same study population. All data from those clinical trials are proprietary to Collaborator for purposes of this CRADA.

3.8 **Test Article Information and Supply**. Collaborator agrees to provide ICD without charge and on a schedule that will ensure adequate and timely performance of the research, a sufficient quantity of formulated and acceptably labeled, clinical-grade Test Article (and, as required by the Protocol(s), Placebo) to complete the clinical trial(s) agreed to and approved under this CRADA. Collaborator will provide a Certificate of Analysis to ICD for each lot of the Test Article provided.

3.9 **Test Article Delivery and Usage**. Collaborator will ship the Test Article and, if required, Placebo to ICD in containers marked in accordance with 21 C.F.R. § 312.6. ICD agrees that the Clinical Investigators will keep appropriate records and take reasonable steps to ensure that the Test Article is used in accordance with the Protocol(s) and applicable FDA regulations. In addition, ICD agrees that the Test Article (and all Confidential Information supplied by Collaborator relating to the Test Article) will be used solely for the conduct of the CRADA research and development activities. Furthermore, ICD agrees that no analysis or modification of the Test Article will be performed without Collaborator's prior written consent. At the completion of the Research Plan, any unused quantity of Test Article will be returned to Collaborator or disposed as directed by Collaborator. Pharmacy contacts at ICD will be determined by ICD and communicated to Collaborator.

3.10 **Monitoring**. Subject to the restrictions in Article 8 concerning IPI, and with reasonable advance notice and at reasonable times, ICD will permit Collaborator or its designee(s) to monitor the conduct of the research, as well as to audit source documents containing Raw Data, to the extent necessary to verify compliance with FDA Good Clinical Practice (International Conference on Harmonisation (ICH) E6: "Good Clinical Practice: Consolidated Guidance; 62 Federal Register 25, 691 (1997)) and the Protocol(s).

3.11 **FDA Meetings/Communications**. All meetings with the FDA concerning any clinical trial within the scope of the Research Plan will be discussed by Collaborator and ICD in advance. Each Party reserves the right to take part in setting the agenda for, to attend, and to participate in these meetings. ICD will provide Collaborator with copies of FDA meeting minutes, all transmittal letters for IND submissions, IND safety reports, formal questions and responses that have been submitted to the FDA, Annual Reports, and official FDA correspondence, pertaining either to the INDs under this CRADA or to the Clinical Investigators on Protocols performed in accordance with the Research Plan, except to the extent that those documents contain the proprietary information of a third party or dissemination is prohibited by law.

Article 4. Reports

4.1 **Interim Research and Development Reports**. The CRADA PIs should exchange information regularly, in writing. This exchange may be accomplished through meeting minutes, detailed correspondence, circulation of draft manuscripts, Steering Committee reports, copies of Annual Reports and any other reports updating the progress of the CRADA research. However, the Parties must exchange updated Investigator's Brochure, formulation and preclinical data, and toxicology findings, as they become available.

4.2 **Final Research and Development Reports**. The Parties will exchange final reports of their results within six (6) months after the expiration or termination of this CRADA. These reports will set forth the technical progress made; any publications arising from the research; and the existence of invention disclosures of potential CRADA Subject Inventions and/or any corresponding Patent Applications.

4.3 **Fiscal Reports**. If Collaborator has agreed to provide funding to ICD under this CRADA and upon the request of Collaborator, then concurrent with the exchange of final research and development reports according to Paragraph 4.2, ICD will submit to Collaborator a statement of all costs incurred by ICD for the CRADA. If the CRADA has been terminated, ICD will specify any costs incurred before the date of termination for which ICD has not received funds from Collaborator, as well as for all reasonable termination costs including the cost of returning Collaborator property or removal of abandoned Collaborator property, for which Collaborator will be responsible.

4.4 **Safety Reports**. In accordance with FDA requirements ICD, as the IND Sponsor, will establish and maintain records and submit safety reports to the FDA, as required by 21 C.F.R. § 312.32 and 21 C.F.R. 812.150(b)(1), or other applicable regulations. In the conduct of research under this CRADA, the Parties will comply with specific ICD guidelines and policies for reporting ADEs and AEs, as well as procedures specified in the Protocol(s). ICD must provide Collaborator with copies of all Safety Reports concurrently with their submission to the FDA, and with any other information affecting the safety of Human Subjects in research conducted under this CRADA.

4.5 **Annual Reports**. ICD will provide Collaborator a copy of the Annual Report concurrently with the submission of the Annual Report to the FDA. Annual Reports will be kept confidential in accordance with Article 8.

Article 5. Staffing, Financial, and Materials Obligations

5.1 **ICD and Collaborator Contributions**. The contributions of any staff, funds, materials, and equipment by the Parties are set forth in Appendix B. The Federal Technology Transfer Act of 1986, 15 U.S.C. § 3710a(d)(1) prohibits ICD from providing funds to Collaborator for any research and development activities under this CRADA.

5.2 **ICD Staffing**. No ICD employees will devote 100% of their effort or time to the research and development activities under this CRADA. ICD will not use funds provided by Collaborator under this CRADA for ICD personnel to pay the salary of any permanent ICD employee. Although personnel hired by ICD using CRADA funds will focus principally on CRADA research and development activities, Collaborator acknowledges that these personnel may nonetheless make contributions to other research and development activities, and the activities will be outside the scope of this CRADA.

5.3 **Collaborator Funding**. Collaborator acknowledges that Government funds received by Collaborator from an agency of the Department of Health and Human Services may not be used to fund ICD under this CRADA. If Collaborator has agreed to provide funds to ICD then the payment schedule appears in Appendix B and Collaborator will make payments according to that schedule. If Collaborator fails to make any scheduled payment, ICD will not be obligated to perform any of the research and development activities specified herein or to take any other action required by this CRADA until the funds are received. ICD will use these funds exclusively for the purposes of this CRADA. Each Party will maintain separate and distinct current accounts, records, and other evidence supporting its financial obligations under this CRADA and, upon written request, will provide the other Party a Fiscal Report according to Paragraph 4.3, which delineates all payments made and all obligated expenses, along with the Final Research Report described in Paragraph 4.2.

5.4 **Capital Equipment**. Collaborator's commitment, if any, to provide ICD with capital equipment to enable the research and development activities under the Research Plan appears in Appendix B. If Collaborator transfers to ICD the capital equipment or provides funds for ICD to purchase it, then ICD will own the equipment. If Collaborator loans capital equipment to ICD for use during the CRADA, Collaborator will be responsible for paying all costs and fees associated with the transport, installation, maintenance, repair, removal, or disposal of the equipment, and ICD will not be liable for any damage to the equipment.

Article 6. Intellectual Property

6.1 **Ownership of CRADA Subject Inventions, CRADA Data, and CRADA Materials**. Subject to the Government license described in Paragraph 7.5, the sharing requirements of Paragraph 8.1 and the regulatory filing requirements of Paragraph 8.2, the producing Party will retain sole ownership of and title to all CRADA Subject Inventions, all copies of CRADA Data, and all CRADA Materials produced solely by its employee(s). The Parties will own jointly all CRADA Subject Inventions invented jointly and all CRADA Materials developed jointly.

6.2 **Reporting**. The Parties will promptly report to each other in writing each CRADA Subject Invention reported by their respective personnel, and any Patent Applications filed thereon, resulting from the research and development activities conducted under this CRADA. Each Party will report all CRADA Subject Inventions to the other Party in sufficient detail to determine inventor ship, which will be determined in accordance with U.S. patent law. These reports will be treated as Confidential Information in accordance with Article 8. Formal reports will be made by and to the Patenting and Licensing Offices identified on the Contacts Information Page herein.

6.3 **Filing of Patent Applications**. Each Party will make timely decisions regarding the filing of Patent Applications on the CRADA Subject Inventions made solely by its employee(s), and will notify the other Party in advance of filing. Collaborator will have the first opportunity to file a Patent Application on joint CRADA Subject Inventions and will notify PHS of its decision within sixty (60) days of an Invention being reported or at least thirty (30) days before any patent filing deadline, whichever occurs sooner. If Collaborator fails to notify PHS of its decision within that time period or notifies PHS of its decision not to file a Patent Application, then PHS has the right to file a Patent Application on the joint CRADA Subject Invention. Neither Party will be obligated to file a Patent Application. Collaborator will place the following statement in any Patent Application it files on a CRADA Subject Invention: "This invention was created in the performance of a Cooperative Research and Development Agreement with the **[INSERT into Agency's model as appropriate: National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention]**, an Agency of the Department of Health and Human Services. The Government of the United States has certain rights in this invention." If either Party files a Patent Application on a joint CRADA Subject Invention, then the filing Party will include a statement within the Patent Application that clearly identifies the Parties and states that the joint CRADA Subject Invention was made under this CRADA.

6.4 **Patent Expenses**. Unless agreed otherwise, the Party filing a Patent Application will pay all preparation and filing expenses, prosecution fees, issuance fees, post issuance fees, patent maintenance fees, annuities, interference expenses, and attorneys' fees for that Patent Application and any resulting Patent(s). If a license to any CRADA Subject Invention is granted to Collaborator, then Collaborator will be responsible for all expenses and fees, past and future, in connection with the preparation, filing, prosecution, and maintenance of any Patent Applications and Patents claiming exclusively licensed CRADA Subject Inventions and will be responsible for a pro-rated share, divided equally among all licensees, of those expenses and fees for non-exclusively licensed CRADA Subject Inventions. Collaborator may waive its exclusive option rights at any time, and incur no subsequent financial obligation for those Patent Application(s) or Patent(s).

6.5 **Prosecution of Patent Applications**. The Party filing a Patent Application will provide the non-filing Party with a copy of any official communication relating to prosecution of the Patent Application within thirty (30) days of transmission of the communication. Each Party will also provide the other Party with the power to inspect and make copies of all documents retained in the applicable Patent Application or Patent file. The Parties agree to consult with each other regarding the prosecution of Patent Applications directed to joint CRADA Subject Inventions. If Collaborator elects to file and prosecute Patent Applications on joint CRADA Subject Inventions, then Collaborator agrees to use the U.S.P.T.O. Customer Number Practice and/or grant PHS a power(s) of attorney (or equivalent) necessary to assure PHS access to its intellectual property rights in these Patent Applications. PHS and Collaborator will cooperate with each other to obtain necessary signatures on Patent Applications, assignments, or other documents.

Article 7. Licensing

7.1 **Background Inventions**. Other than as specifically stated in this Article 7, nothing in this CRADA will be construed to grant any rights in one Party's Background Invention(s) to the other Party, except to the extent necessary for the Parties to conduct the research and development activities described in the Research Plan.

7.2 **Collaborator's License Option to CRADA Subject Inventions**. With respect to Government rights to any CRADA Subject Invention made solely by an ICD employee(s) or made jointly by an ICD employee(s) and a Collaborator employee(s) for which a Patent Application was filed, PHS hereby grants to Collaborator an exclusive option to elect an exclusive or nonexclusive commercialization license. The license will be substantially in the form of the appropriate model PHS license agreement and will fairly reflect the nature of the CRADA Subject Invention, the relative contributions of the Parties to the CRADA Subject Invention and the CRADA, a plan for the development and marketing of the CRADA Subject Invention, the risks incurred by Collaborator, and the costs of subsequent research and development needed to bring the CRADA Subject Invention to the marketplace. The field of use of the license will not exceed the scope of the Research Plan.

7.3 **Exercise of Collaborator's License Option**. To exercise the option of Paragraph 7.2 Collaborator must submit a written notice to the PHS Patenting and Licensing Contact identified on the Contacts Information Page (and provide a copy to the ICD Contact for CRADA Notices) within three (3) months after either (i) Collaborator receives written notice from PHS that the Patent Application has been filed or (ii) the date on which Collaborator files the Patent Application. The written notice exercising this option will include a completed "Application for License to Public Health Service Inventions" and will initiate a negotiation period that expires nine (9) months after the exercise of the option. If PHS has not responded in writing to the last proposal by Collaborator within this nine (9) month period, the negotiation period will be extended to expire one (1) month after PHS so responds, during which month Collaborator may accept in writing the final license proposal of PHS. In the absence of Collaborator's exercise of the option, or upon election of a nonexclusive license, PHS will be free to license the CRADA Subject Invention to others. These time periods may be extended at the sole discretion of PHS upon good cause shown in writing by Collaborator.

7.4 **Government License in ICD Sole CRADA Subject Inventions and Joint CRADA Subject Inventions**. Pursuant to 15 U.S.C. § 3710a(b)(1)(A), for CRADA Subject Inventions owned solely by ICD or jointly by ICD and Collaborator, and licensed pursuant to the option of Paragraph 7.2, Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the CRADA Subject Invention or have the CRADA Subject Invention practiced throughout the world by or on behalf of the Government. In the exercise of this license, the Government will not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. § 552(b)(4) or which would be considered privileged or confidential if it had been obtained from a non-federal party.

7.5 **Government License in Collaborator Sole CRADA Subject Inventions**. Pursuant to 15 U.S.C. § 3710a(b)(2), for CRADA Subject Inventions made solely by an employee of Collaborator, Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the CRADA Subject Invention or have the CRADA Subject Invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

7.6 **Third Party License**. Pursuant to 15 U.S.C. § 3710a(b)(1)(B), if PHS grants Collaborator an exclusive license to a CRADA Subject Invention made solely by an ICD employee or jointly with a Collaborator employee, the Government will retain the right to require Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the CRADA Subject Invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or, if Collaborator fails to grant a license, to grant a license itself. The exercise of these rights by the Government will only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by federal regulations, and such requirements are not reasonably satisfied by Collaborator; or (iii) Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. § 3710a(c)(4)(B). The determination made by the Government under this Paragraph is subject to administrative appeal and judicial review under 35 U.S.C. § 203(b).

7.7 **Third-Party Rights In ICD Sole CRADA Subject Inventions**. For a CRADA Subject Invention conceived prior to the Effective Date solely by an ICD employee that is first actually reduced to practice after the Effective Date in the performance of the Research Plan, the option offered to Collaborator in Paragraph 7.2 may be restricted if, prior to the Effective Date, PHS had filed a Patent Application and has either offered or granted a license in the CRADA Subject Invention to a third party. Collaborator nonetheless retains the right to apply for a license to any such CRADA Subject Invention in accordance with the terms and procedures of 35 U.S.C. § 209 and 37 C.F.R. Part 404.

7.8 **Joint CRADA Subject Inventions Not Exclusively Licensed by Collaborator**. If Collaborator does not acquire an exclusive commercialization license in a joint CRADA Subject Invention in all fields of use then, for those fields of use not exclusively licensed to Collaborator, each Party will have the right to use the joint CRADA Subject Invention and to license its use to others, and each Party will cooperate with the other, as necessary, to fulfill international licensing requirements. The Parties may agree to a joint licensing approach for any remaining fields of use.

Article 8. Rights of Access and Publication

8.1 **Right of Access to CRADA Data and CRADA Materials**. ICD and Collaborator agree to exchange all CRADA Data and to share all CRADA Materials. If the CRADA is terminated, both Parties agree to provide CRADA Materials in quantities needed to complete the Research Plan. Such provision will occur before the termination date of the CRADA or sooner, if required by the Research Plan. If Collaborator possesses any human biological specimens from clinical trials under the CRADA, the specimens must be handled as described in the Protocol or as otherwise directed by ICD before the termination date of the CRADA.

8.2 **Use of CRADA Data and CRADA Materials**. The Parties will be free to utilize CRADA Data and CRADA Materials internally for their own purposes, consistent with their obligations under this CRADA. The Parties may share CRADA Data or CRADA Materials with their Affiliates, agents or contractors provided the obligations of this Article 8.2 are simultaneously conveyed.

8.2.1 **CRADA Data**.
Collaborator and ICD will use reasonable efforts to keep CRADA Data confidential until published or until corresponding Patent Applications are filed. To the extent permitted by law, each Party will have the right to use any and all CRADA Data in and for any regulatory filing by or on behalf of the Party.

8.2.2 **CRADA Materials**.
Collaborator and ICD will use reasonable efforts to keep descriptions of CRADA Materials confidential until published or until corresponding Patent Applications are filed. Collaborator acknowledges that the basic research mission of PHS includes sharing with third parties for further research those research resources made in whole or in part with NIH funding. Consistent with this mission and the tenets articulated in "Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts", December 1999, available at http://ott.od.nih.gov/NewPages/RTguide_final.html, following publication either Party may make available to third parties for further research those CRADA Materials made jointly by both PHS and Collaborator. Notwithstanding the above, if those joint CRADA Materials are the subject of a pending Patent Application or a Patent, or were created using a patent-pending or patented material or technology, the Parties may agree to restrict distribution or freely distribute them. Either Party may distribute those CRADA Materials made solely by the other Party only upon written consent from that other Party or that other Party's designee.

8.3 **Confidential Information**. Each Party agrees to limit its disclosure of Confidential Information to the amount necessary to carry out the Research Plan, and will place a confidentiality notice on all this information. A Party orally disclosing Confidential Information to the other Party will summarize the disclosure in writing and provide it to the other Party within fifteen (15) days of the disclosure. Each Party receiving Confidential Information agrees to use it only for the purposes described in the Research Plan. Either Party may object to the designation of information as Confidential Information by the other Party.

8.4 **Protection of Confidential Information**. Confidential Information will not be disclosed, copied, reproduced or otherwise made available to any other person or entity without the consent of the owning or providing Party except as required by a court or administrative body of competent jurisdiction, or federal law or regulation. Each Party agrees to use reasonable efforts to maintain the confidentiality of Confidential Information, which will in no instance be less effort than the Party uses to protect its own Confidential Information. Each Party agrees that a Party receiving Confidential Information will not be liable for the disclosure of that portion of the Confidential Information which, after notice to and consultation with the disclosing Party, the receiving Party determines may not be lawfully withheld, provided the disclosing Party has been given a reasonable opportunity to seek a court order to enjoin disclosure.

8.5 **Human Subject Protection**. The research to be conducted under this CRADA involves Human Subjects or human tissues within the meaning of 45 C.F.R. Part 46, and all research to be performed under this CRADA will conform to applicable federal laws and regulations. Additional information is available from the HHS Office for Human Research Protections (http://www.hhs.gov/ohrp/).

8.6 **Duration of Confidentiality Obligation**. The obligation to maintain the confidentiality of Confidential Information will expire at the earlier of the date when the information is no longer Confidential Information as defined in Article 2 or three (3) years after the expiration or termination date of this CRADA, except for IPI, for which the obligation to maintain confidentiality will extend indefinitely. Collaborator may request an extension to this term when necessary to protect Confidential Information relating to products not yet commercialized.

8.7 **Publication**. The Parties are encouraged to make publicly available the results of their research and development activities. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about a CRADA Subject Invention, CRADA Data, or CRADA Materials, the other Party will have thirty (30) days to review proposed manuscripts and three (3) days to review proposed abstracts to assure that Confidential Information is protected. Either Party may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to file a Patent Application.

Article 9. Representations and Warranties

9.1 **Representations of ICD**. ICD hereby represents to Collaborator that:

9.1.1 ICD has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that ICD's official signing this CRADA has authority to do so.

9.1.2 To the best of its knowledge and belief, neither ICD nor any of its personnel involved in this CRADA is presently subject to debarment or suspension by any agency of the Government which would directly affect its performance of the CRADA. Should ICD or any of its personnel involved in this CRADA be debarred or suspended during the term of this CRADA, ICD will notify Collaborator within thirty (30) days of receipt of final notice.

9.2 **Representations and Warranties of Collaborator**. Collaborator hereby represents and warrants to ICD that:

9.2.1 Collaborator has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that Collaborator's official signing this CRADA has authority to do so.

9.2.2 Neither Collaborator nor any of its personnel involved in this CRADA, including Affiliates, agents, and contractors are presently subject to debarment or suspension by any agency of the Government. Should Collaborator or any of its personnel involved in this CRADA be debarred or suspended during the term of this CRADA, Collaborator will notify ICD within thirty (30) days of receipt of final notice.

9.2.3 Subject to Paragraph 12.3, and if and to the extent Collaborator has agreed to provide funding under Appendix B, Collaborator is financially able to satisfy these obligations in a timely manner.

9.2.4 The Test Article provided has been produced in accordance with the FDA's current Good Manufacturing Practice set out in 21 C.F.R. §§ 210-211 and ICH QA7, and meets the specifications cited in the Certificate of Analysis and Investigator's Brochure provided.

Article 10. Expiration and Termination

10.1 **Expiration**. This CRADA will expire on the last date of the term set forth on the Summary Page. In no case will the term of this CRADA extend beyond the term indicated on the Summary Page unless it is extended in writing in accordance with Paragraph 13.6.

10.2 **Termination by Mutual Consent**. ICD and Collaborator may terminate this CRADA at any time by mutual written consent.

10.3 **Unilateral Termination**. Either ICD or Collaborator may unilaterally terminate this CRADA at any time by providing written notice at least sixty (60) days before the desired termination date. ICD may, at its option, retain funds transferred to ICD before unilateral termination by Collaborator for use in completing the Research Plan. If Collaborator terminates this Agreement before the completion of all approved or active Protocol(s), then Collaborator will supply enough Test Article (and Placebo, if applicable) to complete these Protocol(s) unless termination is for safety concerns.

10.4 **Funding for ICD Personnel**. If Collaborator has agreed to provide funding for ICD personnel and this CRADA is mutually or unilaterally terminated by Collaborator before its expiration, then Collaborator agrees that funds for that purpose will be available to ICD for a period of six (6) months after the termination date or until the expiration date of the CRADA, whichever occurs sooner. If there are insufficient funds to cover this expense, Collaborator agrees to pay the difference.

10.5 **New Commitments**. Neither Party will incur new expenses related to this CRADA after expiration, mutual termination, or a notice of a unilateral termination and will, to the extent feasible, cancel all outstanding commitments and contracts by the termination date. Collaborator acknowledges that ICD will have the authority to retain and expend any funds for up to one (1) year subsequent to the expiration or termination date to cover any unpaid costs obligated during the term of the CRADA in undertaking the research and development activities set forth in the Research Plan.

10.6 **Collaborator Failure to Continue Development**. If Collaborator suspends development of the Test Article without the transfer of its active development efforts, assets, and obligations to a third party within ninety (90) days of discontinuation, Collaborator agrees that ICD may continue developing the Test Article. In that event, the following will apply:

10.6.1 Collaborator agrees to transfer to ICD all information necessary to enable ICD to contract for the manufacture of the Test Article and, unless abandoned for reasons relating to safety as determined by the data safety monitoring board, to provide the Test Article (and Placebo, if any) in Collaborator's inventory to ICD.

10.6.2 Further, Collaborator hereby grants to ICD a nonexclusive, irrevocable, world-wide, paid-up license to practice, or have practiced for or on behalf of the Government, any Background Invention that Collaborator may currently have or will obtain on the Test Article, its manufacture, or on any method of using the Test Article for the indication(s) described in the Research Plan, including the right to sublicense to third parties.

Article 11. Disputes

11.1 **Settlement**. Any dispute arising under this CRADA which is not disposed of by agreement of the CRADA Principal Investigators will be submitted jointly to the signatories of this CRADA. If the signatories, or their designees, are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) will propose a resolution. Nothing in this Paragraph will prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.

11.2 **Continuation of Work**. Pending the resolution of any dispute or claim pursuant to this Article 11, the Parties agree that performance of all obligations will be pursued diligently.

Article 12. Liability

12.1 **NO WARRANTIES**. EXCEPT AS SPECIFICALLY STATED IN ARTICLE 9, THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO ANY MATTER WHATSOEVER, INCLUDING THE CONDITIONS OF THE RESEARCH OR ANY INVENTION OR MATERIAL, WHETHER TANGIBLE OR INTANGIBLE, MADE OR DEVELOPED UNDER OR OUTSIDE THE SCOPE OF THIS CRADA, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY INVENTION OR MATERIAL, OR THAT A TECHNOLOGY UTILIZED BY A PARTY IN THE PERFORMANCE OF THE RESEARCH PLAN DOES NOT INFRINGE ANY THIRD-PARTY PATENT RIGHTS.

12.2 **Indemnification and Liability**. Collaborator agrees to hold the Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of the use by Collaborator for any purpose of the CRADA Data, CRADA Materials or CRADA Subject Inventions produced in whole or part by ICD employees under this CRADA, unless due to the negligence or willful misconduct of ICD, its employees, or agents. The Government has no statutory authority to indemnify Collaborator. Each Party otherwise will be liable for any claims or damages it incurs in connection with this CRADA, except that ICD, as an agency of the Government, assumes liability only to the extent provided under the Federal Tort Claims Act , 28 U.S.C. Chapter 171.

12.3 ***Force Majeure***. Neither Party will be liable for any unforeseeable event beyond its reasonable control and not caused by its own fault or negligence, which causes the Party to be unable to perform its obligations under this CRADA, and which it has been unable to overcome by the exercise of due diligence. If a *force majeure* event occurs, the Party unable to perform will promptly notify the other Party. It will use its best efforts to resume performance as quickly as possible and will suspend performance only for such period of time as is necessary as a result of the *force majeure* event.

Article 13. Miscellaneous

13.1 **Governing Law**. The construction, validity, performance and effect of this CRADA will be governed by U.S. federal law, as applied by the federal courts in the District of Columbia. If any provision in this CRADA conflicts with or is inconsistent with any U.S. federal law or regulation, then the U.S. federal law or regulation will preempt that provision.

13.2 **Compliance with Law**. ICD and Collaborator agree that they will comply with, and advise any contractors, grantees, or agents they have engaged to conduct the CRADA research and development activities to comply with, all applicable Executive Orders, statutes, and HHS regulations relating to research on human subjects (45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56) and relating to the appropriate care and use of laboratory animals (7 U.S.C. § 2131 *et seq*.; 9 C.F.R. Part 1, Subchapter A). ICD and Collaborator will advise any contractors, grantees, or agents they have engaged to conduct clinical trials for this CRADA that they must comply with all applicable federal regulations for the protection of Human Subjects, which may include the Standards for Privacy of Individually Identifiable Health Information set forth in 45 C.F.R. Part 164. Collaborator agrees to ensure that its employees, contractors, and agents who might have access to a "select agent or toxin" (as that term is defined in 42 C.F.R. §§ 73.4-73.5) transferred from ICD is properly licensed to receive the "select agent or toxin".

13.3 **Waivers**. None of the provisions of this CRADA will be considered waived by any Party unless a waiver is given in writing to the other Party. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, will not be deemed a waiver of any rights of any Party.

13.4 **Headings**. Titles and headings of the articles and paragraphs of this CRADA are for convenient reference only, do not form a part of this CRADA, and will in no way affect its interpretation.

13.5 **Severability**. The illegality or invalidity of any provisions of this CRADA will not impair, affect, or invalidate the other provisions of this CRADA.

13.6 **Amendments**. Minor modifications to the Research Plan may be made by the mutual written consent of the CRADA Principal Investigators. Substantial changes to the CRADA, extensions of the term, or any changes to Appendix C will become effective only upon a written amendment signed by the signatories to this CRADA or by their representatives duly authorized to execute an amendment. A change will be considered substantial if it directly expands the range of the potential CRADA Subject Inventions, alters the scope or field of any license option governed by Article 7, or requires a significant increase in the contribution of resources by either Party.

13.7 **Assignment**. Neither this CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party. The Collaborator acknowledges the applicability of 41 U.S.C. § 15, the Anti Assignment Act, to this Agreement. The Parties agree that the identity of the Collaborator is material to the performance of this CRADA and that the duties under this CRADA are nondelegable.

13.8 **Notices**. All notices pertaining to or required by this CRADA will be in writing, signed by an authorized representative of the notifying Party, and delivered by first class, registered, or certified mail, or by an express/overnight commercial delivery service, prepaid and properly addressed to the other Party at the address designated on the Contacts Information Page, or to any other address designated in writing by the other Party. Notices will be considered timely if received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Notices regarding the exercise of license options will be made pursuant to Paragraph 7.3. Either Party may change its address by notice given to the other Party in the manner set forth above.

13.9 **Independent Contractors**. The relationship of the Parties to this CRADA is that of independent contractors and not agents of each other or joint venturers or partners. Each Party will maintain sole and exclusive control over its personnel and operations.

13.10 **Use of Name; Press Releases**. By entering into this CRADA, the Government does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to either this CRADA or to any patent or other intellectual-property license or agreement that implements this CRADA by Collaborator, its successors, assignees, or licensees. Collaborator will not in any way state or imply that the Government or any of its organizational units or employees endorses any product or services. Each Party agrees to provide proposed press releases that reference or rely upon the work under this CRADA to the other Party for review and comment at least five (5) business days before publication. Either Party may disclose the Title and Abstract of the CRADA to the public without the approval of the other Party.

13.11 **Reasonable Consent**. Whenever a Party's consent or permission is required under this CRADA, its consent or permission will not be unreasonably withheld.

13.12 **Export Controls**. Collaborator agrees to comply with U.S. export law and regulations. If Collaborator has a need to transfer any CRADA Materials made in whole or in part by ICD, or ICD Materials, or ICD's Confidential Information to a person located in a country other than the United States, to an Affiliate organized under the laws of a country other than the United States, or to an employee of Collaborator in the United States who is not a citizen or permanent resident of the United States, Collaborator will acquire any and all necessary export licenses and other appropriate authorizations.

13.13 **Entire Agreement**. This CRADA constitutes the entire agreement between the Parties concerning the subject matter of this CRADA and supersedes any prior understanding or written or oral agreement.

13.14 **Survivability**. The provisions of Paragraphs 3.3, 3.4, 3.8, 4.2, 4.3, 5.3, 5.4, 6.1-9.2, 10.3-10.6, 11.1, 11.2, 12.1-12.3, 13.1-13.3, 13.7, 13.10 and 13.14 will survive the expiration or early termination of this CRADA.

SIGNATURES BEGIN ON THE NEXT PAGE

SIGNATURE PAGE

ACCEPTED AND AGREED

BY EXECUTING THIS AGREEMENT, EACH PARTY REPRESENTS THAT ALL STATEMENTS MADE HEREIN ARE TRUE, COMPLETE, AND ACCURATE TO THE BEST OF ITS KNOWLEDGE. COLLABORATOR ACKNOWLEDGES THAT IT MAY BE SUBJECT TO CRIMINAL, CIVIL, OR ADMINISTRATIVE PENALTIES FOR KNOWINGLY MAKING A FALSE, FICTITIOUS, OR FRAUDULENT STATEMENT OR CLAIM.

FOR ICD:

/s/ Douglas R. Lowy, M.D.	8/2/2011
Signature	Date

Typed Name: Douglas R. Lowy, M.D.
Title: Deputy Director, NCI

FOR COLLABORATOR:

/s/ Anthony J. Cataldo	8/5/2011
Signature	Date

Typed Name: Anthony J. Cataldo
Title: Chairman & Chief Executive Officer

CONTACTS INFORMATION PAGE

CRADA Notices

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Patenting and Licensing

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Division Director, Division of Technology Development and Transfer
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For Collaborator (if separate from above):

(see above)

Delivery of Materials Identified In Appendix B (if any)

For ICD:

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For Collaborator:

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SUMMARY PAGE

EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION, RELEASE THIS SUMMARY PAGE TO THE PUBLIC.

TITLE OF CRADA: Cooperative Research and Development Agreement for the Development and Evaluation of the NCI Proprietary Adoptive Cell Transfer Immunotherapy Using Tumor Infiltrating Lymphocytes in Patients with Metastatic Melanoma, Utilizing Genesis Biopharma's Business Development Expertise in Adoptive Cell Transfer Immunotherapy

PHS [ICD] Component:	National Cancer Institute
ICD CRADA Principal Investigator:	Steven A. Rosenberg, M.D., Ph.D.
Collaborator:	Genesis Biopharma, Inc.
Collaborator CRADA Principal Investigator:	Anthony J. Cataldo
Term of CRADA:	Five (5) years from the Effective Date

ABSTRACT OF THE RESEARCH PLAN:

The principal goal of this CRADA is to develop and evaluate effective adoptive cell transfer-based immunotherapies (ACT) using Tumor Infiltrating Lymphocytes (TIL), where the ACT/TIL therapy approach is proprietary to the NCI, for the treatment of patients with metastatic melanoma utilizing the business development expertise and resources of Genesis Biopharma, Inc.. Specifically this CRADA will (1) support the *in vitro* development of improved methods for the large scale generation and selection of TIL with anti-tumor reactivity from patients with metastatic melanoma based on ACT therapies developed by and proprietary to the NCI Surgery Branch, to be used for large scale production of TIL for the ACT treatment of metastatic melanoma; (2) develop these approaches for large scale TIL generation that are in accord with Good Manufacturing Practice (GMP) procedures suitable for use in treating patients with metastatic melanoma; and (3) develop clinical trials using these improved methods of large scale TIL generation as well as improved patient preparative regimens with the goal of commercializing the ACT/TIL therapy approach for treating patients with metastatic melanoma.

PUBLIC HEALTH SERVICE
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
FOR INTRAMURAL-PHS CLINICAL RESEARCH

APPENDIX A

RESEARCH PLAN

Title of CRADA
Cooperative Research and Development Agreement for the Development and Evaluation of the NCI Proprietary Adoptive Cell Transfer Immunotherapy Using Tumor Infiltrating Lymphocytes in Patients with Metastatic Melanoma, Utilizing Genesis Biopharma's Business Development Expertise in Adoptive Cell Transfer Immunotherapy

NCI Principal Investigator
Steven A. Rosenberg, M.D., Ph.D.
Chief, Surgery Branch
Center for Cancer Research (CCR)
National Cancer Institute (NCI)

Collaborator Principal Investigator
Anthony J. Cataldo
Chairman & Chief Executive Officer
Genesis Biopharma, Inc.

Term of CRADA
Five (5) years from the date of the final CRADA signature.

GOALS OF THIS CRADA

The principal goal of this CRADA is to develop and evaluate improved adoptive cell transfer-based immunotherapies (ACT) using Tumor Infiltrating Lymphocytes (TIL), where the ACT/TIL therapy approach is proprietary to the NCI, for the treatment of patients with metastatic melanoma utilizing the business development expertise and resources of Genesis Biopharma, Inc.. Specifically this CRADA will 1) support the *in vitro* development of improved methods for the generation and selection of TIL with anti-tumor reactivity from patients with metastatic melanoma based on ACT developed by and proprietary to the NCI Surgery Branch, to be used for large scale production of TIL for the ACT treatment of metastatic melanoma; 2) develop these approaches for large scale TIL generation that are in accord with Good Manufacturing Practice (GMP) procedures suitable for use in treating patients with metastatic melanoma; and 3) develop clinical trials using these improved methods of large scale TIL generation as well as improved patient preparative regimens with the goal of commercializing the ACT/TIL therapy approach for treating patients with metastatic melanoma. The scope of this CRADA, including any *in vitro* and *in vivo* testing conducted by Dr. Steven A. Rosenberg and members of the NCI Surgery Branch within the CCR is strictly limited to the development of these ACT/TIL therapies for treating patients with metastatic melanoma, utilizing Genesis Biopharma's expertise in the large scale production of adoptive cell transfer immunotherapies. Additional research or clinical activities involving current or prospective NCI Surgery Branch adoptive immunotherapy protocols are outside the scope of this CRADA unless and until the Parties mutually agree to these studies which shall be added by written amendment to this CRADA

INTRODUCTION

Melanoma is the sixth leading cancer in both men and women. Metastatic melanoma has a poor prognosis with five-year survival of less than 5%. FDA-approved treatments for metastatic melanoma include aldesleukin (Interleukin-2, a cytokine), ipilimumab (a monoclonal antibody) and dacarbazine chemotherapy. Aldesleukin has an objective clinical response rate of about 13% and a complete response rate of 4-5%. In a recent trial that led to FDA approval, ipilimumab had an objective response rate of 7% in 540 patients with 0.6% complete responses, though a 3.6 month improvement in median survival was seen. Dacabarzine-based chemotherapy has a clinical response rate of about 12% but few complete responders or long-term survivors. Recent clinical trials evaluating an experimental BRAF inhibitor (Plexicon 4032) in 132 patients reported an overall response rate of 52% but only 2.3% were complete responses and the great majority of responses appeared to be transient. More effective treatment for metastatic melanoma is needed.

The NCI Surgery Branch has extensive experience in the development of its proprietary adoptive cell transfer (ACT) therapies for the treatment of patients with metastatic cancer. Initial cell transfer studies utilized tumor infiltrating lymphocytes (TIL) with anti-tumor activity obtained from resected tumor specimens from patients with metastatic melanoma. In a series of consecutive clinical trials utilizing the adoptive transfer of TIL plus IL-2, three preparative lymphodepleting regimens were evaluated prior to the cell infusion. These included a non-myeloablative chemotherapy regimen consisting of cyclophosphamide and fludarabine either alone, or in conjunction with 2Gy total body irradiation or 12Gy total body irradiation. In these three clinical trials objective response rates of 49%, 52% and 72% were seen including complete durable regressions in 13%, 20% and 40% of patients with metastatic melanoma. The overall objective response rate using RECIST criteria in these 93 patients was 56% with a complete response rate of 22%. Of the 20 complete responders in these trials 19 patients are in ongoing complete response from 3 to over 7 years. Similar objective response rates and survival were seen irrespective of any prior treatment that the patient had received.

The results of ACT treatment using TIL in patients with metastatic melanoma in the NCI Surgery Branch as described above represent the best reported results for the treatment of these patients. Despite these results and the need for improved treatments for patients with metastatic melanoma, ACT using TIL is not widely available and only a few centers (largely those led by scientists trained in the NCI Surgery Branch) have it available as an experimental treatment for their patients. The treatment is complex since it requires the growth of cells extracted from a resected cancer, selection of the appropriate cells for adoptive transfer based on *in vitro* testing, followed by the *in vitro* expansion of these cells and infusion to the patient after the administration of a lymphodepleting preparative regimen. In many ways this is the ultimate "personalized" treatment for cancer since a new drug is created for each patient. Conventional pharmaceutical companies seek "off-the-shelf" drugs in a vial that can easily be widely distributed and thus until recently there was little commercial interest in the development of cell-based therapies for cancer.

Extensive research is needed to improve and simplify all aspects of ACT using autologous TIL. The NCI Surgery Branch is exploring new ways to grow TIL and simplify the *in vitro* procedures needed to select the appropriate cell types for infusion. For the treatment to be made more widely available, it is necessary for the NCI Surgery Branch to work with a corporate partner interested in developing these improved procedures for TIL development *in vitro*, emphasizing the requirements of Good Manufacturing Practice (GMP) needed to obtain FDA approval for these procedures. The recent approval of the Provenge treatment for patients with prostate cancer by the Dendreon Corporation has demonstrated that approaches to ship cells to a central facility, manipulate them and return them for patient treatment can be FDA approvable and can form the basis of a successful commercial effort. This recent approval has stimulated considerable interest in the commercial development of ACT/TIL treatment.

Expertise of the Parties

Dr. Steven A. Rosenberg has extensive experience in the development and application of his proprietary adoptive cell-based therapies (ACT) for patients with cancer. His laboratory has developed *in vitro* techniques for generating anti-tumor T cells obtained from patient tumors (TIL) under conditions suitable for subsequent infusion. Dr. Rosenberg and his colleagues in the NCI Surgery Branch have extensive experience in the development of cell-based reagents and the conduct of clinical trials utilizing these cells in immunotherapeutic protocols.

Genesis Biopharma, Inc. ("Genesis") has assembled a team of senior level scientists and clinicians who have experience in the application of cell-based immunotherapies to help guide the commercial development of ACT therapy for the treatment of metastatic melanoma based on the NCI Surgery Branch proprietary technologies for TIL preparation and administration of ACT to patients. Genesis is developing GMP facilities to perform this work emphasizing the development and evaluation of improved techniques for TIL generation that meet GMP standards as well as to conduct clinical trials of ACT/TIL therapy designed to meet the standards of the FDA to achieve approval for the commercialization of this treatment approach. Thus the combination of the scientific and clinical expertise of the NCI Surgery Branch with the scientific and clinical expertise of Genesis, and availability of Genesis' GMP production facilities, represents an ideal opportunity that can lead to the commercialization of the ACT/TIL treatment approach for patients with metastatic melanoma, making these treatments more widely available to patients in need.

The NCI Surgery Branch and Genesis thus have complementary expertise and facilities that can develop technologies and clinical treatment approaches that have the potential to improve cell transfer therapy and make it more widely available to patients through commercialization by Genesis.

EXPERIMENTAL PLAN

The experimental details that follow are approximate and may be changed upon mutual agreement of the NCI and Collaborator. Any change in the scope of this CRADA will be by mutual consent and written Amendment to the CRADA.

I. Develop improved methods for the generation and selection of TIL with anti-tumor reactivity from patients with metastatic melanoma based on adoptive cell transfer therapies proprietary to and developed by the NCI Surgery Branch, for use in the large scale production of TIL for this ACT treatment of metastatic melanoma

Simplified and better methods for TIL selection and growth are needed to supplement current NCI Surgery Branch efforts in order to expand ACT/TIL therapy to greater numbers of patients with melanoma. Studies of improved methods for TIL selection will be investigated by the NCI Surgery Branch. This will include use of *in vitro* assays of specificity that are based on specific blocking of Class I MHC (Major Histocompatibility Complex) molecules that can provide evidence for the specific recognition of autologous tumor and use of sensitive assays of the upregulation of molecules such as 4-1-BB or others on the lymphocyte cell surface. Such studies in the NCI Surgery Branch may also include the separation of phenotypically different lymphocyte subsets present in TIL such as central memory, effector memory and terminally differentiated effector cells. NCI Surgery Branch studies in mice have shown that lymphocyte subsets such as central memory cells can be more effective in the adoptive immunotherapy of experimental tumors and this needs to be studied in humans in the metastatic melanoma setting. Such studies would form the basis for TIL selection and generation for use in the large scale production of TIL for the treatment of patients with metastatic melanoma.

II. Develop approaches to large scale TIL generation that are in accord with Good Manufacturing Practice (GMP) procedures suitable for their use in treating patients with metastatic melanoma

The selection and growth of autologous TIL from patients with metastatic melanoma is a vital part of the successful use of this approach. Prior NCI Surgery Branch methods for TIL growth involved extensive *in vitro* testing using multiple cell lines and fresh tissue samples as well as the growth of cells in up to 40 2-liter culture bags using large amounts of medium to treat each patient. Under this CRADA, studies will be conducted of improved methods for the generation of the large numbers of TIL necessary for patient treatment. These studies will explore the use of alternate culture vessels including those that involve the use of gas permeable membranes. The NCI Surgery Branch has begun some of these studies but extensive additional studies are required to optimize cell growth including the determination of the best concentrations of feeder cells, timing of media change and concentrations of growth factors such as IL-2 (commercially available). These studies will be conducted by the NCI Surgery Branch with advice, input and expertise provided by Genesis. Techniques thus described will need to be adapted to meet the GMP requirements of the Food and Drug Administration for infusion into patients. This may require modification of the procedures developed in the NCI Surgery Branch. Genesis and the NCI Surgery Branch will work together to develop Standard Operating Procedures (SOP) for large scale TIL growth, selection and testing that meet the approval of the FDA. Joint meetings with the FDA will be required to define the exact format and criteria need to meet FDA approval.

III. Develop clinical trials using these improved methods of large scale TIL generation as well as improved patient preparative regimens to treat patients with metastatic melanoma

Clinical trials will be designed and implemented to evaluate the clinical effectiveness of ACT/TIL therapy resulting from large scale techniques in patients with metastatic melanoma based on the proprietary NCI Surgery Branch technology and approaches developed in the first two parts of this Experimental Plan. Genesis and the NCI Surgery Branch, will work together to develop a multiinstitutional clinical trial evaluating the clinical effectiveness of the administration of autologous TIL generated using Genesis technology to patients with metastatic melanoma that can potentially be used as a licensing trial for FDA approval. The NCI Surgery Branch does not have a suitable GMP facility that will meet FDA standards for the conduct of such a trial. Exploratory pilot trials may be necessary prior to beginning a licensing trial and these may be conducted in the Surgery Branch alone or in conjunction with other multicenter sites associated with Genesis. The development and conduct of a licensing trial will require the GMP expertise of Genesis and the extensive experience of the NCI Surgery Branch working together. TIL for this trial will be produced on a large scale by Genesis at a central facility for distribution to participating multicenter sites (including the NCI Surgery Branch). An IND with the FDA will be filed by Genesis which will serve as the Coordinating Center for such a trial. The goal of such a trial will be to generate data to support the approval by the FDA of this ACT/TIL therapy approach. *In vitro* testing of patient samples from such a trial will evaluate the activity and persistence level of the transferred cells in the circulation of treated patients and will be conducted by the NCI Surgery Branch both for any pilot trials that are performed as well as for the large multiinstitutional trial that is planned.

Surgery Branch, NCI

- Develop and test new improved and simplified *in vitro* methods for the selection and growth of TIL with anti-tumor activity for large scale preparations that can be used in clinical cell transfer studies. As described in the Experimental Plan above, this will include evaluation of new growth techniques, culture vessels, and tests to be used in selection of appropriate cells (based on both functional and phenotypic criteria) to optimize the effectiveness of the adoptive transfer.

- Perform *in vitro* studies of the immunologic parameters surrounding the new cell transfer clinical protocol(s) by analyzing the phenotypic and functional properties of the transferred cells and their persistence in the patient following adoptive transfer in all clinical trials conducted under this CRADA, as outlined in Section III above.

Genesis

- Develop, implement and evaluate *GMP proc*edures for the large scale production of TIL suitable for infusion into p**a**tients with metastatic melanoma.

- Consult with the FDA to determine the appropriate clinical trial design necessary to secure approval for the commercial development of TIL therapy for patients with metastatic melanoma and sponsor the IND for this new clinical protocol Serve as the coordinating center for the multicenter licensing clinical trial.

- Supply TIL in sufficient quantities to the NCI Surgery Branch and other multicenter sites to complete the planned clinical trials (including the licensing trial) needed for FDA approval of ACT/TIL. Support the establishment of a central facility for the processing and provision of TIL for the studies under this CRADA.

Surgery Branch, NCI and Genesis

- Develop SOP for large scale TIL growth, selection and testing to support the FDA approval of the ACT/TIL therapy approach. Attend joint meetings with the FDA to define the exact format and criteria needed in the clinical trial(s) to obtain FDA approval.

- Develop, conduct and evaluate a multiinstitutional clinical trial (to include the NCI Surgery Branch as a clinical trial site) for patients with metastatic melanoma treated with TIL that can be used as a licensing trial required for FDA approval and subsequent commercialization of ACT/TIL.

- Exchange information and expertise to further the successful development of TIL therapy for patients with metastatic melanoma.

RELATED NCI AND COLLABORATOR AGREEMENTS: NONE

RELATED INTELLECTUAL PROPERTY AND BUSINESS/SCIENTIFIC EXPERTISE OF THE PARTIES

NCI Surgery Branch

1) PCT/US03/27873 entitled "Immunotherapy with *In Vitro*-Selected Antigen-specific Lymphocytes After Nonmyeloablative Lymphodepleting Chemotherapy", filed 9/5/03. Inventors: Mark E. Dudley, Steven A. Rosenberg, John R. Wunderlich. This is inclusive of all U.S. continuing applications and divisionals, and foreign applications.

2) USSN 12/869,390 entitled "Adoptive Cell Therapy with Young T Cells", filed 8/26/10. Inventors: Mark E. Dudley and Steven A. Rosenberg. This is inclusive of all U.S. continuing applications and divisionals.

3) USSN 61/446,200 entitled "Methods of Growing Tumor Infiltrating Lymphocytes in Gas-Permeable Containers", filed 3/22/11. Inventors: Steven A. Rosenberg, Mark E. Dudley, et al.

Genesis Biopharma, Inc.

Genesis has applied to NIH for a license to NIH owned intellectual property under the license application A-196-2011. Collaborator desires to license NIH owned intellectual property that includes the patents describing the NCI proprietary ACT/TIL therapy approach to be developed under this CRADA.

Genesis Biopharma, Inc. is a publicly traded biotechnology company developing therapies for the treatment of cancer. Genesis Biopharma's lead therapeutic candidate will be an autologous cell therapy product using tumor infiltrating lymphocytes for the treatment of metastatic melanoma to be developed under this CRADA. Genesis Biopharma has a partnership with a major manufacturer for the provision of TIL for clinical trials to be conducted under this CRADA as well as post-regulatory approval. The manufacturing facility is cGMP certified and inspected by FDA.

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APPENDIX B

STAFFING, FUNDING AND MATERIALS/EQUIPMENT CONTRIBUTIONS OF THE PARTIES

Staffing Contributions:

ICD will provide scientific staff and other support necessary to conduct the research and other activities described in the Research Plan. ICD's scientific staff will include ICD's CRADA Principal Investigator and technical staff.

ICD estimates that 3-5 person-years of effort per year will be required to complete the CRADA research.

Collaborator will provide scientific staff and other support necessary to conduct the research and other activities described in the Research Plan. Collaborator's scientific staff will include Collaborator's Principal Investigator and technical staff.

Collaborator estimates that 3-5 person-years of effort per year will be required to complete the CRADA research.

Funding Contributions:

Collaborator agrees to provide funds in the amount of $1,000,000.00 per year of the CRADA for ICD to use to acquire technical, statistical, and administrative support for the research activities, as well as to pay for supplies and travel expenses. Collaborator will provide funds in the amount of $250,000.00 on a quarterly basis. The first quarterly installment of $250,000.00 will be due within thirty (30) days of the Effective Date. Each subsequent installment will be due within thirty (30) days of each quarterly anniversary of the Effective Date. Collaborator agrees that ICD can allocate the funding between the various categories in support of the CRADA research as ICD's CRADA PI sees fit.

CRADA PAYMENTS:

Collaborator will make checks payable to the National Cancer Institute and will reference the CRADA number 02734 and title "CRADA for the Development and Evaluation of the NCI Proprietary Adoptive Cell Transfer Immunotherapy Using Tumor Infiltrating Lymphocytes in Patients with Metastatic Melanoma, Utilizing Genesis Biopharma's Business Development Expertise in Adoptive Cell Transfer Immunotherapy" on each check, and will send them via trackable mail or courier to:
CRADA Funds Coordinator
Technology Transfer Center, NCI
6120 Executive Blvd., Suite 450
Rockville, MD 20852

CRADA Travel Payments:
Travel arrangements for all Government staff will be made in accordance with the Federal Travel Rules and Regulations, whether arranged by ICD and funded using either appropriated funds or CRADA funds, or arranged and funded directly by Collaborator.

Materials/Equipment Contributions:

ICD will provide the following ICD Materials for use under this CRADA: None

Collaborator will provide the following Collaborator Materials and/or capital equipment for use under this CRADA:

Test Article:	Autologous Tumor Infiltrating Lymphocytes (TIL) grown and processed under GMP conditions, suitable for use in clinical trials under this CRADA.
Collaborator Materials:	None
Capital Equipment:	None

If either Party decides to provide additional Materials for use under this CRADA, those materials will be transferred under a cover letter that identifies them and states that they are being provided under the terms of the CRADA.

PUBLIC HEALTH SERVICE
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
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APPENDIX C

MODIFICATIONS TO THE MODEL CRADA

Amend the Definition of "Background Invention" in Article 2 to read as follows:

"**Background Invention**" means an Invention conceived and first actually reduced to practice before the Effective Date or an Invention conceived and first actually reduced to practice by either Party outside the scope of the Research Plan.

Amend the Definition of "CRADA Data" in Article 2 to read as follows:

"**CRADA Data**" means all recorded information first produced in the performance of the Research Plan. Expressly excluded from the definition of CRADA Data is all Genesis Biopharma data which relate to Genesis Biopharma's autologous cell therapy product generated outside the scope of this CRADA.

Amend the Definition of "CRADA Materials in Article 2 to read as follows:

"**CRADA Materials**" means all tangible materials first produced in the performance of the Research Plan other than CRADA Data. Expressly excluded from the definition of CRADA Materials are Genesis Biopharma materials which relate to Genesis Biopharma's autologous cell therapy product generated outside the scope of this CRADA.

Amend the Definition of "Raw Data" in Article 2 to read as follows:

"**Raw Data**" means the primary quantitative and empirical data first collected from experiments and clinical trials conducted within the scope of this CRADA. Expressly excluded from the definition of Raw Data is all Genesis Biopharma data which relate to Genesis Biopharma's autologous cell therapy product generated outside the scope of this CRADA.

Amend Section 3.1 to read as follows:

Performance of Research and Development. The research and development activities to be carried out under this CRADA will be performed solely by the Parties identified on the Cover Page, unless specifically stated elsewhere in the Agreement. The CRADA PIs will be responsible for coordinating the scientific and technical conduct of this project on behalf of their employer. Any Collaborator employees or consultants who will work at ICD facilities will be required to sign a Guest Researcher or Special Volunteer Agreement appropriately modified in view of the terms of this CRADA.

Amend Section 4.1 to read as follows:

Interim Research and Development Reports. The CRADA PIs ~~should~~ shall exchange information in writing every three (3) months during the course of this CRADA. This exchange of information may be accomplished through meeting minutes, detailed correspondence, circulation of draft manuscripts, Steering Committee reports, copies of Annual Reports, and any other reports updating the progress of the CRADA research. However, the Parties must exchange updated Investigator's Brochure, formulation and preclinical data, and toxicology findings, as they become available. In addition, all CRADA research meetings between the Collaborator and consultants, and the ICD scientific and clinical employees will be organized in advance through the office of ICD Principal Investigator, and the Collaborator President and Chief Operating Officer, and the Vice President, NIH Research Program Liaison of Genesis Biopharma, Inc.. All meetings, telephone and video conferences will be held at mutually agreeable times and dates to allow all relevant Collaborator and consultants, and ICD employees to participate.

Amend Section 8.3 to read as follows:

8.3 Confidential Information. Each Party agrees to limit its disclosure of Confidential Information to the amount necessary to carry out the Research Plan, and will place a confidentiality notice on all this information. A Party orally disclosing Confidential Information to the other Party will summarize the disclosure in writing and provide it to the other Party within fifteen (15) days of the disclosure. Each Party receiving Confidential Information agrees to use it only for the purposes described in the Research Plan. Either Party may object to the designation of information as Confidential Information by the other Party. Notwithstanding any other provision in this Agreement, although certain information concerning Collaborator Materials or Test Article provided under this Agreement is confidential and will be so stamped, Collaborator recognizes that the NIH PI may need to disclose certain information concerning CONFIDENTIAL materials to patients (or to physicians or scientists where such disclosure is made in order to directly facilitate the ongoing treatment of a patient, or the development of a treatment for a patient). Collaborator hereby authorizes such limited disclosures and the NIH PI agrees to promptly acknowledge to Collaborator the making of any such disclosure.

Amend Section 8.4 to read as follows:

8.4 Protection of Confidential Information. Subject to Paragraph 8.3, Confidential Information will not be disclosed, copied, reproduced or otherwise made available to any other person or entity without the consent of the owning or providing Party except as required by a court or administrative body of competent jurisdiction, or federal law or regulation. Each Party agrees to use reasonable efforts to maintain the confidentiality of Confidential Information, which will in no instance be less effort than the Party uses to protect its own Confidential Information. Each Party agrees that a Party receiving Confidential Information will not be liable for the disclosure of that portion of the Confidential Information which, after notice to and consultation with the disclosing Party, the receiving Party determines may not be lawfully withheld, provided the disclosing Party has been given a reasonable opportunity to seek a court order to enjoin disclosure.

Amend Section 8.6 to read as follows:

8.6 Duration of Confidentiality Obligation. The obligation to maintain the confidentiality of Confidential Information as described in Paragraph 8.3, will expire at the earlier of the date when the information is no longer Confidential Information as defined in Article 2 or three (3) years after the expiration or termination date of this CRADA, except for IPI, for which the obligation to maintain confidentiality will extend indefinitely. Collaborator may request an extension to this term when necessary to protect Confidential Information relating to products not yet commercialized.

Amend Section 13.2 to read as follows:

13.2 **Compliance with Law**. ICD and Collaborator agree that they will comply with, and advise any contractors, grantees, or agents they have engaged to conduct the CRADA research and development activities to comply with, all applicable Executive Orders, statutes, and HHS regulations relating to research on human subjects (45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56) and relating to the appropriate care and use of laboratory animals (7 U.S.C. § 2131 *et seq*.; 9 C.F.R. Part 1, Subchapter A). ICD and Collaborator will advise any contractors, grantees, or agents they have engaged to conduct clinical trials for this CRADA that they must comply with all applicable federal regulations for the protection of Human Subjects, which may include the Standards for Privacy of Individually Identifiable Health Information set forth in 45 C.F.R. Part 164. Collaborator agrees to ensure that its employees, contractors, and agents who might have access to a "select agent or toxin" (as that term is defined in 42 C.F.R. §§ 73.4-73.5) transferred from ICD is properly licensed to receive the "select agent or toxin". ICD agrees that it will comply with all NIH and NCI policies, rules and guidelines, and will act accordingly with the recommended procedures in the National Cancer Institute brochure "What every scientists should know about Employee Invention Reports (EIR) and patents."