

## LEIDOS BIOMEDICAL

### COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

This Cooperative Research and Development Agreement (“CRADA” or “Agreement”) has been adopted for use by Leidos Biomedical Research, Inc., the National Cancer Institute’s Operations and Technical Support (OTS) contractor to the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC) and a Federal Laboratory.

This Cover Page identifies the Parties to this Agreement:

**Leidos Biomedical Research, Inc.**

hereinafter referred to as “Leidos Biomedical”,  
having offices at 1050 Boyles Street, Frederick, Maryland 21702,  
created and operating under the laws of Delaware

and

**[Insert Collaborator’s official name],**

hereinafter referred to as the “Collaborator”,  
having offices at **[Insert Collaborator’s address],**  
created and operating under the laws of **[Insert State of Incorporation].**

**CRADA TITLE:** \_\_\_\_\_

**CRADA NUMBER:** Leidos Biomedical assigned

## **Article 1. Introduction**

This Agreement is made under authority of the Federal Technology Transfer Act, 15 U.S.C. §3710a. This Agreement is governed by the terms of §3710a and consistent with the terms of the Operations and Technical Support (OTS) contract between Leidos Biomedical and the National Cancer Institute (NCI) in the National Institutes of Health (NIH).

The Agreement includes a cover page, the agreement terms, a signature page, a contacts page, a summary page, a joint work statement (“Joint Work Statement”) attached as Appendix A, and the staffing, funding, and materials contributions of the Parties attached as Appendix B. The Parties are interested in collaborating on a joint project and in transferring research materials or confidential information between the Parties as described in the Joint Work Statement.

## **Article 2. Definitions**

The terms listed in this Article will carry the meanings indicated throughout the Agreement. 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.

- 2.1 **“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.
- 2.2 **“Background Invention”** means an invention conceived and first actually reduced to practice before the Effective Date.
- 2.3 **“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 Joint Work Statement.
- 2.4 **“Confidential Information”** means confidential scientific, business, or financial 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 Joint Work Statement.

- 2.5 “**CRADA Data**” means all recorded information first produced in the performance of the Joint Work Statement.
- 2.6 “**CRADA Materials**” means all tangible materials first produced in the performance of the Joint Work Statement other than CRADA Data.
- 2.7 “**CRADA Subject Invention**” means any invention of either or both Parties, conceived or first actually reduced to practice in the performance of the Joint Work Statement.
- 2.8 “**Effective Date**” is the date which the agreement takes effect, which occurs on the date of the last signature of the Parties executing this Agreement.
- 2.9 “**Government**” means the Government of the United States of America.
- 2.10 “**Invention**” means any invention or discovery that is or may be patentable or otherwise protected under Title 35 of the United States Code.
- 2.11 “**Joint Work Statement**” means the description in Appendix A of the respective research and development commitments of the Parties.
- 2.12 “**Leidos Biomedical Materials**” means all tangible materials not first produced in the performance of this CRADA that are owned or controlled by Leidos Biomedical and used in the performance of the Joint Work Statement.
- 2.13 “**Patent Application**” means an application for patent protection for a CRADA Subject Invention with the United States Patent and Trademark Office or the corresponding patent-issuing authority of another nation.
- 2.14 “**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.
- 2.15 “**Principal Investigator(s)**” or “**PI(s)**” means the person(s) designated by the Parties who will be responsible for the scientific and technical conduct under the Joint Work Statement and this Agreement.
- 2.16 “**Research Tools**” includes the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.
- 2.17 “**Research Tool Policy, NIH**” as stated in “NIH Principles and Guidelines for Sharing of Biomedical Resources -- Final (December 1999)” provides guidance concerning appropriate terms for disseminating research tools developed with federal funds. The Research Tool Policy should be considered when disseminating, patenting, and licensing biomedical research resources.

### **Article 3. Cooperative Research and Development**

- 3.1 **Performance of Research and Development.** The Joint Work Statement will be performed solely by the Parties identified on the Cover Page unless specifically stated elsewhere in this Agreement. The interim research goals in the Joint Work Statement are good faith guidelines. If events occur that require modification of these goals, then by mutual agreement the Parties can modify the goals by amendment.
- 3.2 **Use and Disposition of Collaborator Materials and Leidos Biomedical Materials.** The Parties agree to use Collaborator Materials and Leidos Biomedical Materials and to transfer these materials to third parties only in accordance with this Agreement or as approved by the owning or providing Party. Upon expiration or termination of the CRADA, the Parties agree to dispose of these materials as directed by the owning or providing Party.
- 3.3 **Third-Party Rights in CRADA Subject Inventions.** If the Collaborator elects to conduct a portion of the Joint Work Statement through a third party (e.g., as a contractor of the Collaborator), then the Collaborator agrees to notify Leidos Biomedical and to ensure that any agreement between the Collaborator and the third party will be consistent with the Collaborator's obligations under this CRADA. In particular, to the extent any Invention the third party may make would be a CRADA Subject Invention if it had been made by an employee of the Collaborator, then the Collaborator shall seek to secure a commitment by the third party to assign its related inventions to Collaborator, and any such invention shall thereafter be treated as a CRADA Subject Invention in all respects. If Leidos Biomedical elects to conduct a portion of the Joint Work Statement through a subcontractor, Leidos Biomedical agrees to notify Collaborator. As a result, the subcontractor may acquire rights in CRADA Subject Inventions in accordance with applicable law, including but not limited to 35 U.S.C. § 202. The Collaborator shall be responsible for negotiating an agreement with the subcontractor regarding the allocation of the rights to any CRADA Subject Invention the contractor makes, solely or jointly, under the subcontract. The Collaborator shall be informed in advance of the proposed selection of any subcontractor and shall have an opportunity to object to the particular entity chosen, provided that said objection shall not be without reasonable justification. The final selection of any such subcontracting entity shall be at the sole discretion of Leidos Biomedical.

### **Article 4. Reports**

- 4.1 **Interim Research and Development Reports.** The PIs should exchange information regularly, in writing, through meeting minutes, annual reports, detailed correspondence, circulation of draft manuscripts, or by other means. Reports are exchanged annually at a minimum.
- 4.2 **Final Research and Development Reports.** The Parties will exchange final reports of their results within four (4) months after the expiration or termination by mutual consent of this CRADA or four (4) months after Leidos Biomedical ends work on the Joint Work

Statement in case of unilateral termination by Collaborator. 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 provides funding to Leidos Biomedical under this CRADA, then concurrent with the exchange of the final research and development report, Leidos Biomedical will submit to Collaborator a statement of all costs incurred by Leidos Biomedical for the CRADA. If the CRADA has been terminated, Leidos Biomedical will specify any costs incurred before the date of termination for which Leidos Biomedical 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.

## **Article 5. Staffing, Financial, and Materials Obligations**

- 5.1 **Leidos Biomedical and Collaborator Contributions.** The contributions of any staff, funds, materials, and equipment by the Parties are set forth in Appendix B. Under §3710a(d)(1), Leidos Biomedical is prohibited from providing funds to the Collaborator for activities performed under this Agreement.
- 5.2 **Collaborator Funding.** If Collaborator has agreed to provide funds to Leidos Biomedical, Collaborator will make payments according to the schedule in Appendix B. If Collaborator fails to make any scheduled payment, Leidos Biomedical will not be obligated to perform any research and development activities specified herein or to take any other action required by this Agreement until the funds are received. Leidos Biomedical 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. Any unused funds at the conclusion of the performance of the Joint Work Statement will be returned to the Collaborator.
- 5.3 **Capital Equipment.** Collaborator's commitment, if any, to provide Leidos Biomedical with capital equipment to enable the research and development activities under the Joint Work Statement appears in Appendix B. If Collaborator transfers to Leidos Biomedical the capital equipment or provides funds for Leidos Biomedical to purchase it, then Leidos Biomedical shall be the custodian of the equipment on behalf of the FFRDC and shall dispose of the equipment as directed by the Government and in accordance with the terms of the OTS contract at the conclusion of the CRADA. If Collaborator loans capital equipment to Leidos Biomedical 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 Leidos Biomedical 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 terms of this Agreement, 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 copies of CRADA Data 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 Agreement. Each Party will report all CRADA Subject Inventions to the other Party in sufficient detail to determine inventorship in accordance with U.S. patent law.
- 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 Leidos Biomedical of its decision within thirty (30) days after an invention is reported or before any patent filing deadline, whichever occurs sooner. If Collaborator fails to notify Leidos Biomedical of its decision within that time period or notifies Leidos Biomedical of its decision not to file a Patent Application, then Leidos Biomedical has the right to file a Patent Application on the joint CRADA Subject Invention. Neither CRADA 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 Leidos Biomedical, Inc., the Operations and Technical Support contractor for the Frederick National Laboratory for Cancer Research, an FFRDC in 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 Agreement.
- 6.4 **Patent Expenses.** Unless agreed otherwise, the Party or assignee 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 an exclusive license to any CRADA Subject Invention is granted to Collaborator, then Collaborator is 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.
- 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 United States Patent and Trademark Office (USPTO) Customer Number Practice and/or grant Leidos Biomedical a power(s) of attorney (or equivalent) necessary to assure access to its intellectual property rights in these Patent Applications. Leidos Biomedical 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.** Unless specifically stated in this Agreement, no grant to any rights in a Party's Background Invention(s) to the other Party will be construed, except to the extent necessary for the performance of the Joint Work Statement.
- 7.2 **Government License in Collaborator Sole and Exclusively Licensed CRADA Subject Inventions.** For CRADA Subject Inventions made solely by an employee of Collaborator or exclusively licensed by 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. 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.
- 7.3 **Collaborator's Exclusive License Option to CRADA Subject Inventions.** For any CRADA Subject Invention made solely by an Leidos Biomedical employee(s) or made jointly by an Leidos Biomedical employee(s) and a Collaborator employee(s), Leidos Biomedical grants to Collaborator an exclusive option to negotiate for reasonable compensation an exclusive or nonexclusive commercialization license for a field of use that does not to exceed the scope of the Joint Work Statement. The license will fairly reflect the nature of the CRADA Subject Invention, the relative contributions of the Parties to the CRADA Subject Invention and the CRADA, and other factors as appropriate.
- 7.4 **Exercise of Collaborator's Exclusive License Option.** To exercise the exclusive license option, Collaborator has three (3) months after the Collaborator filed the Patent Application or after the Collaborator receives written notice that Leidos Biomedical filed the Patent Application, to submit a written request to Leidos Biomedical to negotiate an exclusive license. Collaborator has three (3) more months after submitting the license request to negotiate and execute the exclusive license with Leidos Biomedical. In the absence of Collaborator's exercise of the license option, or upon election of a

nonexclusive license, Leidos Biomedical may license the CRADA Subject Invention to others. These time periods may be extended upon good cause shown in writing by Collaborator.

- 7.5 **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. 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.** Leidos Biomedical and Collaborator agree to exchange all CRADA Data and to share all CRADA Materials. If this Agreement is terminated, both Parties agree to provide CRADA Materials in quantities needed to complete the Joint Work Statement. Such provision will occur before the termination date of the Agreement or sooner, if required by the Joint Work Statement.
- 8.2 **Use of CRADA Data and CRADA Materials.** The Parties will be free to use CRADA Data and CRADA Materials for their own purposes, consistent with their obligations under this Agreement. The Parties may share CRADA Data or CRADA Materials with the Government, Affiliates, agents or contractors provided the obligations of this Article are simultaneously conveyed.
- (a) CRADA Data. Collaborator and Leidos Biomedical 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.
- (b) CRADA Materials. Collaborator and Leidos Biomedical will use reasonable efforts to keep descriptions of CRADA Materials confidential until published or until corresponding Patent Applications are filed.
- (c) Collaborator acknowledges that the basic research mission of NIH and Leidos Biomedical includes sharing with third parties for further research those research tools made in whole or in part with NIH funding. Consistent with this mission, following publication either Party may make available to third parties for further research those CRADA Materials made jointly by both Leidos Biomedical and Collaborator. Notwithstanding the above, if those joint CRADA Materials are the subject of a pending Patent Application or a Patent, 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 Joint Work Statement, and will place a confidentiality notice on all such 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 Joint Work Statement. Either Party may object to the designation of information as Confidential Information by the other Party.
- 8.4 **Government Access to Confidential Information.** Leidos Biomedical may disclose Confidential Information to NCI and other Government users of the OTS contract as necessary to carry out the Joint Work Statement or as part of the OTS contract oversight. The Government recipients will keep all such information confidential according to policy and to the extent permitted by law.
- 8.5 **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.
- 8.6 **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 or three (3) years after the expiration or termination date of this Agreement. 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. If a publication results from the work to be performed in the Joint Work Statement, the determination of authorship shall be in keeping with generally accepted standards in the research field for determining authorship. Before either Party submits a publication or otherwise intends to publicly disclose information about a CRADA Subject Invention, CRADA Data or CRADA Materials, the Parties agree to provide a copy of the proposed paper or poster thirty (30) days in advance of submission for publication review to ensure that Confidential Information is protected. If the proposed disclosure is an abstract, the Parties agree to provide a copy of the abstract five (5) days in advance of submission to ensure the protection of Confidential Information. 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**

- 9.1 Both Parties hereby represent to the other that they have the requisite power and authority to enter into this Agreement and to perform according to its terms, and that officials signing this Agreement have authority to do so.
- 9.2 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.

## **Article 10. Duration Term and Termination**

- 10.1 **Duration Term.** The duration term of this Agreement is stated on the Summary Page. The term may be extended only by written amendment.
- 10.2 **Termination by Mutual Consent.** Leidos Biomedical and Collaborator may terminate this Agreement at any time by mutual written consent.
- 10.3 **Unilateral Termination.** Either Leidos Biomedical or Collaborator may unilaterally terminate this Agreement at any time by providing written notice at least sixty (60) days before the desired termination date. Leidos Biomedical may, at its option, retain funds transferred to Leidos Biomedical before unilateral termination by Collaborator for use in completing the Joint Work Statement.
- 10.4 **Funding for Leidos Biomedical Personnel.** If Collaborator has agreed to provide funding for Leidos Biomedical personnel and this Agreement is mutually or unilaterally terminated by Collaborator before its expiration, then Collaborator agrees that funds for that purpose will be available to Leidos Biomedical for a period of six (6) months after the termination date or until the expiration date of the Agreement, 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 Agreement 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 Leidos Biomedical 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 Agreement in undertaking the research and development activities set forth in the Joint Work Statement.

## **Article 11. Disputes**

- 11.1 **Settlement.** Any dispute arising under this Agreement which is not disposed of by agreement of the Principal Investigators will be submitted jointly to the signatories of this

Agreement. The signatories, or their designees, will work jointly to resolve the dispute within thirty (30) days after notification of an ongoing dispute from the Principal Investigators. Nothing in this Paragraph will prevent either Party from pursuing any 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 JOINT WORK STATEMENT DOES NOT INFRINGE ANY THIRD-PARTY PATENT RIGHTS.

- 12.2 **Indemnification and Liability.** Collaborator agrees to indemnify and to hold the Government and Leidos Biomedical harmless for all damages, costs, and expenses, including attorneys' fees, arising from the commercialization or use of any Intellectual Property transferred by the Government or Leidos Biomedical, including, but not limited to, the making, using, selling, or exporting of products, processes, or services derived from the transferred technology. Each Party otherwise will be liable for any claims or damages it incurs in connection with this Agreement.

- 12.3 **Force Majeure.** Neither Party will be liable for any unforeseeable event ((including, without limitation, fire, explosion, earthquake, storm, flood, strike, lockout, labor difficulties, war, insurrection, riot, act of God or the public enemy, or any law, act, regulation or government or court order) 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 Agreement, 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 Agreement will be governed in accordance with the laws of the State of Maryland and Federal law, as appropriate.

- 13.2 **Compliance with Law.** Leidos Biomedical and Collaborator agree that they will comply with, and advise their contractors and agents to comply with all applicable statutes, Executive Orders, regulations, and NIH policies relating to research, in particular those governing the use of human subjects and human source materials/data in research and the appropriate care and use of laboratory animals (45 C.F.R. Part 46; 7 U.S.C. §§ 2131 *et seq.*; 9 C.F.R. Part 1, Subchapter A).
- 13.3 **Waivers.** None of the provisions of this Agreement will be considered waived by either 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 Agreement are for convenient reference only, do not form a part of this Agreement, and will in no way affect its interpretation.
- 13.5 **Severability.** The illegality or invalidity of any provisions of this Agreement will not impair, affect, or invalidate the other provisions of this Agreement.
- 13.6 **Amendments.** Minor modifications to the Joint Work Statement may be made by the mutual written consent of the Principal Investigators. Substantial changes to the Agreement or extensions of the term will become effective only upon a written amendment signed by the signatories to this Agreement 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, extends the duration, or requires a significant increase in the contribution of resources by either Party.
- 13.7 **Assignment.** Neither this Agreement nor any rights or obligations of either Party hereunder will be assigned or otherwise transferred by either Party without the prior written consent of the other Party, except that in the event the prime contract of Leidos Biomedical with the National Cancer Institute is succeeded by a successor contractor selected by the National Cancer Institute, this Agreement may be assigned to the successor contractor. This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties hereto.
- 13.8 **Notices.** All notices pertaining to or required by this Agreement will be in writing, signed by an authorized representative of the notifying Party, and delivered by first class, registered, or certified mail, by an express/overnight commercial delivery service, prepaid and properly addressed to the other Party at the address designated on the contacts page, or to any other address designated in writing by the other Party. Alternatively notices may be made by electronic mail, if agreed to by both Parties, and receipt must be confirmed by the intended recipient. Notices regarding the exercise of

license options will be made pursuant to Paragraph 7.4. 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 Agreement is that of independent contractors and not agents of each other or joint venturers or partners.
- 13.10 **Use of Name; Press Releases.** By entering into this Agreement, the Leidos Biomedical does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to either this Agreement or to any patent or other intellectual-property license or agreement that implements this Agreement by Collaborator, its successors, assignees, or licensees. Collaborator will not in any way state or imply that Leidos Biomedical or its employees endorse any product or service. Each Party agrees to provide proposed press releases that reference or rely upon the work under this Agreement to the other Party for review and comment at least seven (7) days prior to publication. Either Party may disclose the Summary Page 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 Agreement, 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 Leidos Biomedical, or Leidos Biomedical Materials, or Leidos Biomedical'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 Agreement constitutes the entire agreement between the Parties concerning the subject matter of this Agreement and supersedes any prior understanding or written or oral agreement.
- 13.14 **Survivability.** The provisions of Paragraphs 3.2, 3.3, 3.4, 4.2, 4.3, 5.2, 5.3, 6.1-9.2, 10.3-10.5, 11.1, 12.1-12.3, and 13.1-13.3, 13.10, 13.14 will survive the expiration or early termination of this Agreement.

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 LEIDOS BIOMEDICAL:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Typed Name

\_\_\_\_\_  
Title

FOR COLLABORATOR:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Typed Name

\_\_\_\_\_  
Title

**CONTACTS PAGE**

**LEIDOS BIOMEDICAL**

**COLLABORATOR**

**CRADA Notices**

Division Director  
1050 Boyles Street  
Frederick, Maryland 21702  
Tel: 301-846-  
email:

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**Reporting Subject Inventions, Patenting and Licensing** (if different from above)

Division Director  
1050 Boyles Street  
Frederick, Maryland 21702  
Tel: 301-846  
email:

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**Delivery of Materials Identified In Appendix B (if any)**

Principal Investigator  
1050 Boyles Street  
Frederick, Maryland 21702  
Tel: 301-846-  
email:

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**Research and Development Reports**

Division Director  
1050 Boyles Street  
Frederick, Maryland 21702  
Tel: 301-846-  
email:

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**Fiscal Reports**

Division Director  
1050 Boyles Street  
Frederick, Maryland 21702  
Tel: 301-846-  
email:

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SUMMARY PAGE

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

CRADA TITLE: \_\_\_\_\_

Leidos Biomedical: \_\_\_\_\_

Leidos Biomedical Principal Investigator: \_\_\_\_\_

Collaborator: \_\_\_\_\_

Collaborator Principal Investigator: \_\_\_\_\_

TERM OF CRADA: \_\_\_\_\_ (\_\_\_\_) years from the Effective Date.

ABSTRACT OF THE JOINT WORK STATEMENT:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

APPENDIX A

JOINT WORK STATEMENT

## APPENDIX B

### STAFFING, FUNDING AND MATERIALS/EQUIPMENT CONTRIBUTIONS OF THE PARTIES

#### *Staffing Contributions:*

Leidos Biomedical will provide scientific staff and other support necessary to conduct the research and other activities described in the Joint Work Statement. Leidos Biomedical's scientific staff will include Leidos Biomedical's Principal Investigator and technical staff.

Leidos Biomedical estimates that \_\_\_\_\_ person-years of effort per year will be required to complete the CRADA research. (RECOMMENDED)

Collaborator will provide scientific staff and other support necessary to conduct the research and other activities described in the Joint Work Statement. Collaborator's scientific staff will include Collaborator's Principal Investigator or technical staff.

Collaborator estimates that \_\_\_\_\_ person-years of effort per year will be required to complete the CRADA research. (RECOMMENDED)

#### *Funding Contributions:*

Collaborator agrees to provide funds in the amount of \$\_\_\_\_\_ per year of the CRADA for Leidos Biomedical 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 equal annual installments. The first installment will be due within thirty (30) days of the Effective Date. Each subsequent installment will be due within thirty (30) days of each anniversary of the Effective Date. Collaborator agrees that Leidos Biomedical can allocate the funding between the various categories in support of the CRADA research as Leidos Biomedical's PI sees fit.

#### CRADA PAYMENTS:

Collaborator will make checks payable to Leidos Biomedical, Inc. and will reference the CRADA number and title on each check, and will send them via trackable mail or courier to:

General Accounting  
Leidos Biomedical Inc.  
1050 Boyles Street  
Frederick, Maryland 21702

*Materials/Equipment Contributions:*

Leidos Biomedical will provide the following Leidos Biomedical Materials for use under this CRADA:

If Leidos Biomedical decides to provide additional Leidos Biomedical 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.

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

Collaborator Materials:

Capital Equipment: