

COLLABORATION AGREEMENT

This Agreement is made by and between the **Leidos Biomedical Research, Inc.**, the prime Operations and Technical Support (“OTS”) contractor of the National Cancer Institute (“NCI”) for the Frederick National Laboratory for Cancer Research (“FNLCR”), (hereinafter referred to as "**Leidos Biomed**"), and **Entity 1** (hereinafter referred to as “Entity”). Jointly or individually, Leidos Biomed and Entity shall also be referred to as “Parties” or “Party.”

The purpose of this Agreement is to further advance scientific knowledge and discoveries through the conduct of collaborative research. Recognizing that advances in science and technology that improve public health play a critical role worldwide in the future prosperity and wellbeing of mankind, the Parties desire to set forth in this Agreement a certain framework for the collaborative research activities as outlined in Appendix A “Research Plan”.

Therefore, the Parties agree as follows:

1. Definitions.

- a. “*Confidential Information*” means confidential scientific, business, or financial information provided that the information does not include:
 - i. information that is publicly known or that is available from public sources;
 - ii. information that has been made available by its owner to others without a confidentiality obligation;
 - iii. 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
 - iv. 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.
- b. “*Invention*” shall mean any invention or discovery, made by Entity and/or Leidos Biomed Investigator(s) that is conceived and first actually reduced to practice in the performance of the Research Plan.
- c. “*Joint Inventions*” shall mean any invention or discovery which is made by two or more inventors and at least one inventor is required to assign the rights in the Invention to Entity and at least one inventor is required to assign the rights in the Invention to Leidos Biomed. Such Inventions shall be subject to the terms and conditions stated herein.
- d. “*Principal Investigator*” shall mean the person designated respectively by each of the Parties to this Agreement who will be responsible for the scientific and technical conduct of the research as well as the implementation of the Research Plan. The Principal Investigators shall abide by the legal terms and conditions contained in this Agreement and they should, as far as is reasonably practicable, ensure that researchers and staff in their laboratories under their control abide by the legal terms and conditions contained in this Agreement.

- e. “*Research Materials*” shall mean the materials used in the Research Plan for this Agreement as identified in the Appendix A of this Agreement.
- f. “*Research Plan*” shall refer to the research work, experiments or any other activities, as outlined in the Research Plan attached hereto as Appendix A.
- g. “*Results*” shall refer to all data, information or materials which are developed or derived from the activities carried out under this Agreement by the Parties as described in the Research Plan.
- h. “*Sole Inventions*” shall mean any invention or discovery which is made by one or more inventors all of whom are required to assign their rights in the Invention to a single Party. Such Inventions shall be the sole property of that Party.

2. **Research Materials.** The following terms shall govern any transfer of Research Materials.

- a. To the extent described in the Research Plan, each Party may transfer its proprietary Research Materials to the other Party. To the extent the Parties decide to exchange Research Materials not already in the Research Plan, each such transfer must be agreed upon by the Principal Investigators for each Party in writing prior to the transfer.
- b. **RESEARCH MATERIALS MAY NOT BE USED IN HUMAN SUBJECTS.** Both Parties agree to comply with all U.S. Federal rules and regulations applicable to the Research Plan and the handling of the Research Materials. All Research Materials transferred in connection with this Agreement are experimental in nature and shall be used with prudence and appropriate caution, since not all of their characteristics are known.
- c. Unless otherwise provided for in an amendment to this Agreement, Research Materials owned by a Party will continue to be owned by that Party after any transfer. Each Party will use the other Party’s Research Materials only in work done in the performance of the Research Plan, and only in the laboratory of the Principal Investigators in research by laboratory personnel under the Principal Investigator’s immediate and direct control.
- d. The transfer of Research Materials from the providing Party to the receiving Party shall provide the recipient with no intellectual property or commercial rights in such Research Materials. Unless otherwise provided herein, legal title to any Research Materials transferred hereunder shall be unaffected by this Agreement or the transfer made hereunder.
- e. The receiving Party's Principal Investigator agrees to retain control over the providing Party’s Research Materials and further agrees not to transfer the Research

Materials to other people not under her or his direct supervision without advance written approval of provider. When the research is completed or within thirty (30) days of termination of this Agreement, whichever occurs first, recipient will dispose of the Research Materials as directed by provider.

3. **Confidentiality.**

- a. Subject to Article 8 (Compliance with Laws and Regulations) below, all information that is disclosed by a Party during the term of this Agreement in written form and designated “**CONFIDENTIAL**”, or if orally disclosed, is reduced to writing within thirty (30) days of the date of disclosure and designated “**CONFIDENTIAL**”, shall be regarded as Confidential Information for a period of five (5) years from the execution of this Agreement.
- b. 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. Leidos Biomed may disclose to the NCI any Confidential Information required to be disclosed as a part of its management responsibilities for the FNLCR under its contract with the NCI. NCI has agreed to keep such information as confidential in accordance with the OTS contract and to the extent permitted by law.
- c. 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. If the receiving Party is required by a valid order of a court or other governmental body or otherwise required by law to disclose the other Party’s Confidential Information, it shall give the disclosing Party timely written notice of such requirement before disclosing any such information and shall cooperate with the disclosing Party to seek a protective order, confidential treatment or other appropriate measures requiring, amongst other things, that the information and/or documents so disclosed be used only for the purposes for which the order was issued and parts of the information and/or documents so disclosed be redacted to limit the extent of disclosure.

4. **Results.**

- a. *In General.* Each Party will keep the other Party informed of Results and Inventions obtained and created from its work in connection with the Research Plan in a timely manner. Information shared in accordance with this Article 4 shall be treated as Confidential Information by the Investigators to whom it is disclosed and shall be handled by the Investigators to whom it is disclosed in accordance with the terms of Article 3 (Confidentiality) above. Except as expressly permitted under Article 5 below (Publications), Results and Inventions produced under the Research Plan may not be shared by either Party with individuals or entities not a party to this Agreement without the express written agreement.

- b. The Parties understand, however, that informal scientific exchanges within Entity or within the Leidos Biomed (including with the NCI or other government users of the OTS contract) are not precluded by the foregoing provision. Any non-research use of information, methodologies or discoveries or any other Results and Inventions produced under this Agreement is strictly forbidden unless authorized in advance in writing by Entity or Leidos Biomed.
- c. *Ownership of Inventions.* Subject to the materials, data and results sharing requirements of Article 2 (Research Materials) and paragraph d. below, the producing Party will retain sole ownership of all Inventions produced solely by its employee(s). Inventorship shall be governed by U.S. patent law. Unless otherwise stated herein, the Parties will own jointly all Inventions invented jointly.
- d. Entity acknowledges that as the OTS Contractor, Leidos Biomed is subject to a Determination of Exceptional Circumstances (35 U.S.C. § 202(a)(ii)), through which its rights in any inventions developed under this Agreement are assigned to the U.S. Government.

5. Publications.

- a. It is contemplated that Results of the Research Plan will be jointly published by the Parties. The Parties agree to abide by the policies of journals in which publications will appear as to such matters as the public release or availability of data or materials relating to the publication. Authorship of Results of the Research Plan will be based on contributions to the Research Plan and in accordance with academic standards and custom. Proper acknowledgment will be made for the contributions of each Party to the Results being published. In addition, a Party will not publish non-Results Confidential Information received from another Party in accordance with Article 3 (Confidentiality) without such other Party's written consent. Publication of Results shall include but not be limited to the publication or disclosure of such Results in any press release or related materials, journal, magazine, web site, newspaper article or any other written form of conveyance including posters as are commonly used at scientific meetings and any oral presentation of such Results in any public forum or meeting and pursuant to Article 3 (Confidentiality) no such disclosures may be made without express written permission.
- b. The Parties agree to work together to make the results of their research publicly available, however, before any Party submits a paper or abstract for publication, the other Party shall have thirty (30) days to review the proposed publication to ensure that Confidential Information is protected. The reviewing Party may request in writing that the proposed publication be delayed for up to thirty (30) additional days as necessary to file a patent application.

6. Warranties. EACH PARTY MAKES NO WARRANTY, AND HEREBY DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE RESULTS OF THE RESEARCH PLAN, ITS MATERIALS, OR ANY INVENTION, PROCESS OR

PRODUCT, WHETHER TANGIBLE OR INTANGIBLE, CONCEIVED, DISCOVERED, OR DEVELOPED UNDER THIS AGREEMENT; OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF ANY INVENTION OR PRODUCT MADE UNDER A RESEARCH PLAN.

7. **Indemnification.** No indemnification for any loss, claim, damage, or liability is intended or provided by any Party under this Agreement. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of its activities under this Agreement.
8. **Representation and Use of Name.** By entering into this Agreement, neither Entity nor Leidos Biomed directly or indirectly endorses any product or service provided, or to be provided or utilized, by the other Parties whether directly or indirectly related to this Agreement. Additionally, no Party shall use the names or trademarks of another Party or its employees (including the U.S. Government) in any advertising, promotional or related non-scientific publications without the prior written consent of that other Party.
9. **Compliance with Laws and Regulations.** All research done in connection with the Research Plan, including all use of Research Materials transferred hereunder, will be done in compliance with all applicable laws, governmental regulations and guidelines of the country in which the research is being conducted.
10. **Compliance with Human Subjects Regulations.** The Parties acknowledge that Research Materials provided under this Agreement may have been collected to include personally identifiable protected health information (PHI) or the Research Materials may contain a code used for personally identifiable information with human-sourced or human-derived Research Materials (“Human Materials”). The Research Materials provided to Entity shall at all times be de-identified and Entity shall have no access to any identifying code key. If applicable, the Parties agree to comply with the Privacy Act of 1974, as amended, at 5 U.S.C. §552a (“Privacy Act”) requirements and applicable human subjects regulations and guidance, which may include but is not limited to, 45 C.F.R. Part 46.
11. **Term of Agreement; Duration of Research Plan.** This Agreement shall be deemed effective as of the Effective Date. This Agreement shall continue in effect for a period of two (2) years unless terminated or extended by mutual written agreement of the Parties.
12. **Termination.** Either party may terminate this Agreement without cause at any time upon thirty (30) days written notice to the other Parties, regardless of whether the Research Plan has been completed or not. In addition, in the event of a material breach of this Agreement by a Party, the non-breaching Party may terminate this Agreement immediately upon written notice to the other Parties.
13. **Effects of Termination.** If this Agreement is terminated, any Research Materials received pursuant to this Agreement by a Party shall, at the direction of Research Material-owning Party, be returned or be properly destroyed. The terms of Articles 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 15, 19 and of this Article 13, shall survive any termination of

this Agreement. If a Party is not complying with the terms of the Agreement in connection with the Research Plan, the other Parties shall notify that Party, which shall have thirty (30) days to correct the problem. If, after thirty (30) days, the problem has not been corrected, that Party shall cease and desist from further work under that Research Plan and shall be precluded from working with the other Party's Materials without the other Party's express written permission.

14. **Assignment.** This Agreement is not assignable by a Party, whether by operation of law or otherwise, without the prior written consent of the other Parties.
15. **Legality.** Each party hereby represents that it has full legal power to enter into this Agreement, that it has duly executed and delivered this Agreement, and that this Agreement is its valid and binding obligation based on the terms contained herein. The construction, validity, performance and effect of this Agreement will be governed in accordance with the laws of the State of Maryland.
16. **Cost and Shipping.** In the case where Entity shall ship or transfer any Research Materials to Leidos Biomed, Entity shall bear the cost of packing, shipping and insurance. In the case where Leidos Biomed shall ship or transfer any Research Materials to Entity, Leidos Biomed shall bear the cost of packing, shipping and insurance as appropriate.
17. **Modification.** This Agreement may only be modified or amended by written agreement by the authorized signatories of all Parties. However, the Research Plan may be modified by Entity and Leidos Biomed Principal Investigators, as they believe appropriate, as long as the modifications relate solely to the scientific scope and shall not significantly alter the original intent of the Research Plan and the other Party is notified within seven (7) working days.
18. **Notices.** All notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other Parties at the address designated on the signature page, or to such other address as may be designated in writing by such other Parties. Notices shall be considered timely if such notices are received on or before the established deadline date as verifiable by a Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated Postal Service postmark or obtain a dated receipt from a commercial carrier. Private metered postmarks shall not be acceptable as proof of timely mailing.
19. **Miscellaneous.** This Agreement constitutes the entire understanding between the Parties concerning the subject matter of this collaboration and supersedes any prior understanding or written or oral agreement. Each Party expressly certifies and affirms that the contents of any statements made herein are truthful and accurate to the best of knowledge and belief, and each official signing this Agreement on behalf of a Party further certifies and affirms that the official has the authority to do so. The illegality or invalidity of any provision of this Agreement shall not impair, affect or invalidate the other provisions of this Agreement. The relationship of the Parties is that of independent contractors and not agents of each other or joint venturers or partners. Each Party shall maintain sole and exclusive control over its personnel and operations.

SIGNATURE APPEAR ON NEXT PAGE

ACCEPTED AND AGREED

FOR LEIDOS BIOMEDICAL RESEARCH, INC.

David C. Heimbrook, Ph.D.
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PO Box B, 1050 Boyles Street, Bldg. 428
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Date

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301-846-6308

FOR ENTITY

Name:
Title:
Address:

Date

Contact for Notices:
Name
Title
Address
Telephone

RESEARCH PLAN

Goal of the Research Plan:

Background Information:

Research Plan: