NATIONAL INSTITUTES OF HEALTH

**MATERIALS COOPERATIVE RESEARCH**

**AND DEVELOPMENT AGREEMENT**

This Materials Cooperative Research and Development Agreement (“M-CRADA”) has been adopted for use by the Institutes and Centers (“ICs”) of the National Institutes of Health (“NIH”) for transfers of essential research material(s) from collaborators (hereinafter “Collaborator Research Material”) not otherwise reasonably available for NIH research. It consists of a copy of the NIH Model M-CRADA, a Signature Page, a Contacts Page, and a Summary Page. The research plan (“Research Plan”) is attached as Appendix A and all changes to this model agreement are collected in Appendix B. Appendices A and B are incorporated herein by reference. This M-CRADA involves no exchange of personnel or of any resources other than as described in Appendix A. This M-CRADA is made under authority of the Federal Technology Transfer Act, 15 U.S.C. § 3710a, and is governed by its terms.

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, hereinafter referred to as “Collaborator”, agrees to transfer to DCTD for use in NIH’s Investigator’s (“Recipient”)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ laboratory, the following “Collaborator Research Material”:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.
2. This Collaborator Research Material will be used solely in connection with the Research Plan by Recipient in his/her laboratory under suitable containment conditions.

2a. Are the Collaborator Research Materials of human origin?

 \_\_\_Yes

 \_\_\_No

2b. If Yes in 2(a), were the Collaborator Research Materials collected according to 45 CFR Part 46, “Protection of Human Subjects?”

 \_\_\_Yes (Please provide Assurance Number:\_\_\_\_\_\_\_\_\_\_\_\_)

 \_\_\_No

1. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Collaborator’s written information about this Collaborator Research Material that is stamped "CONFIDENTIAL," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures to Recipient shall be identified as being CONFIDENTIAL by written notice delivered to Recipient within thirty (30) days after the date of the oral disclosure.

Recipient may publish or otherwise publicly disclose the results of the Research Plan, however Collaborator will have thirty (30) days to review proposed manuscripts and three (3) days to review proposed abstracts to assure that CONFIDENTIAL Information is protected, except when a shortened time period under court order or the Freedom of Information Act pertains. Collaborator may request in writing that a proposed publication be delayed for up to thirty (30) additional days as necessary to file a Patent Application. Manuscripts to be submitted for publication by Recipient will be sent to NCI’s Regulatory Affairs Branch [NCICTEPpubs@mail.nih.gov] for forwarding to Collaborator for review as soon as they are received and in compliance with the timelines outlined above. Abstracts to be presented by Recipient will be sent to NCI’s Regulatory Affairs Branch [NCICTEPpubs@mail.nih.gov] for forwarding to Collaborator as soon as they are received, preferably no less than three days prior to submission, but prior to presentation or publication, to allow for preservation of U.S. or foreign patent rights. In all oral presentations or written publications concerning the Research Plan, Recipient will acknowledge Provider's or Collaborator’s contribution of this Collaborator Research Material unless requested otherwise.

1. This Collaborator Research Material represents a significant investment on the part of Collaborator and is considered proprietary to Collaborator. Recipient therefore agrees to retain control over this Collaborator Research Material, and further agrees not to transfer the Collaborator Research Material to other people not under her or his direct supervision without advance written approval of Collaborator. Collaborator reserves the right to distribute the Collaborator Research Material to others and to use it for its own purposes. When the Research Plan is completed or one (1) year has elapsed, whichever occurs first, or the M-CRADA is terminated, the Collaborator Research Material will be disposed of as directed by Collaborator at Collaborator’s expense.

4a. Recipient shall, within six (6) months after completing the project described in the Research Plan or after the expiration or termination of this Materials CRADA, provide Collaborator with a final written report setting out the results of the Research Plan, including Data, detailed results, publications arising from the research; and the existence of invention disclosures of potential Subject Inventions.

1. This Collaborator Research Material is provided as a service to the research community. Collaborator makes no representations that the use of the Collaborator Research Material will not infringe any patent or proprietary rights of third parties. It is the intention of DCTD/NCI that Collaborator not be liable for any claims or damages arising from DCTD/NCI’s use of the Collaborator Research Material; however, no indemnification is provided or intended.
2. The DCTD/NCI shall promptly report to Collaborator in writing each Subject Invention and any patent applications filed thereon resulting from the research conducted under this M-CRADA that is reported to DCTD/NCI by its employees. Collaborator agrees to keep all information provided to Collaborator confidential until the information is published or the patent issues. “Subject Invention” means any invention, conceived or first actually reduced to practice under this M-CRADA, that is or may be patentable under 35 U.S.C. § 101 or § 161, protectable under 7 U.S.C. § 2321, or otherwise protectable by other types of U.S. or foreign intellectual property rights.
3. Other than as specifically stated in this Article 7, nothing in this M-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 activities described in the Research Plan.

7a. With respect to Government rights to any CRADA Subject Invention made solely by an IC employee(s) or made jointly by an IC employee(s) and a Collaborator employee(s) for which a Patent Application has been filed, PHS hereby offers to the Collaborator the following options and grants:

7a1. For CRADA Subject Inventions that would be described in Patent Applications that claim the use and/or the composition of the Collaborator Research Material(s): PHS hereby grants to Collaborator: (i) an option to elect a royalty-free (except for patent prosecution and maintenance fees for Patent Applications and Patents claiming such CRADA Subject Inventions, which will be pro-rated and divided equally among all licensees), world-wide, non-exclusive license for commercial purposes with the right to sublicense to Affiliates or collaborators working on behalf of Collaborator for Collaborator’s development purposes; (ii) a time limited option to negotiate an exclusive, or co-exclusive, if applicable, world-wide, royalty bearing license for commercial purposes, including the right to grant sublicenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and PHS; and (iii) an option to elect a paid-up, nonexclusive, royalty-free, world-wide license for research purposes only. NIH retains the right to make and use any CRADA Subject Inventions covered by this Paragraph 7.a.1 for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so, this license is in addition to the Government use licenses granted in Section 7.4 and 7.5 below.

7a.2 For CRADA Subject Inventions pursuant to research under this CRADA not covered under Paragraph 7.a.1, including those that use non-publicly available CRADA Data or specimens from patients treated with Collaborator Research Material under the CRADA, (including specimens obtained from NCI CTEP-funded tissue banks) PHS hereby grants to Collaborator: (i) an option to elect a paid-up nonexclusive, nontransferable, royalty-free, world-wide license for research purposes only; and (ii) an option to elect a nonexclusive, royalty-free, world-wide license to: (a) disclose such CRADA Subject Inventions to a regulatory authority when seeking marketing authorization of the Collaborator Research Material, and (b) disclose such CRADA Subject Inventions on a product insert or other promotional material regarding the Collaborator Research Material after having obtained marketing authorization from a regulatory authority. Notwithstanding the above, PHS is under no obligation to file a Patent Application or maintain patent prosecution for any such CRADA Subject Inventions.

7a.3. In addition, for Inventions made which are or may be patentable or otherwise protectable, as a result of research utilizing the Collaborator Research Material(s), unreleased or non-publicly available CRADA Data or Collaborator Research Material-treated specimens outside the scope of approval granted by the NCI CTEP (Unauthorized Inventions): PHS hereby grants to Collaborator an option to elect a royalty-free (except for all out of pocket Patent prosecution and maintenance costs for Patent Applications and Patents claiming such inventions, which will be pro-rated and divided equally among all licensees) exclusive or co-exclusive commercial license to Unauthorized Inventions. The NIH will retain a nonexclusive, nontransferable, irrevocable, paid-up license from the Collaborator to practice the invention or have the invention practiced throughout the world by or on behalf of the Government.

7.a.4. In addition to the license options to CRADA Subject Invention(s) contained in Paragraphs 7.a.2 and 7.a.3 above, PHS hereby grants to Collaborator an exclusive option to CRADA Subject Inventions to elect an exclusive or nonexclusive commercialization license to such Inventions. The field of use of this license option will not exceed the scope of the Research Plan.

1. To exercise the option of Paragraph 7, 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 NIH Contact for M-CRADA Notices) within three (3) months after the Collaborator receives written notice from NIH that the patent application has been filed. 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 NIH 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 NIH. In the absence of Collaborator’s exercise of the option, or upon election of a nonexclusive license, NIH will be free to license the Subject Invention to others. These time periods may be extended at the sole discretion of NIH upon good cause shown in writing by Collaborator.
2. Pursuant to 15 U.S.C. § 3710a(b)(1)(A), for Subject Inventions made under this M-CRADA by a NIH employee(s) or jointly by such employee(s) and employees of the Collaborator under this M-CRADA, and licensed to Collaborator, the Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the Subject Invention or have the Subject Invention practiced throughout the world by or on behalf of the Government for research or other Government purposes. In the exercise of such license, the Government shall 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 as such if it had been obtained from a non-Federal party.
3. Pursuant to 15 U.S.C. § 3710a(b)(2), for Subject Inventions made solely by Collaborator employees under this M-CRADA, the Collaborator grants to the Government, a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.
4. Pursuant to 15 U.S.C. § 3710a(b)(1)(B), if NIH grants an exclusive license or co-exclusive license to a Subject Invention made wholly by NIH employees or jointly with a Collaborator under this M-CRADA, the Government shall retain the right to require the Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the Subject Invention in Collaborator’s licensed field of use on terms that are reasonable under the circumstances; or if the Collaborator fails to grant such a license, to grant the license itself. The exercise of such rights by the Government shall 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 the Collaborator; or (iii) the 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).
5. If the research under this M-CRADA uses Collaborator Research Material in combination with another Collaborator Research Material or research material supplied to NCI pursuant to a CTA or CRADA between NCI and an entity not a Party to this CRADA (hereinafter referred to as “Third Party”), the access and use of Multi-Party Data by the Collaborator and Third Party shall be co-exclusive as follows:

12a. NCI will provide both Collaborator and Third Party with notice regarding the existence and nature of the agreements governing their collaborations with NIH, the design of the proposed combination research and the existence of any obligations that might restrict NCI’s participation in the proposed combination research.

12b. Collaborator shall agree to permit use of the Multi-Party Data from this research by Third Party to the extent necessary to allow Third Party to develop, obtain regulatory approval for, or commercialize its own Collaborator Research Material(s). However, this provision will not apply unless Third Party also agrees to Collaborator’s reciprocal use of Multi-Party Data.

12c. Collaborator and Third Party must agree in writing that each will use the Multi-Party Data solely for the development, regulatory approval, and commercialization of its own Collaborator Research Material(s).

1. Any dispute arising under this M-CRADA that is not disposed of by agreement of the Principal Investigators shall be submitted jointly to the signatories of this M-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) shall propose a resolution. Nothing in this paragraph shall 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.
2. The illegality or invalidity of any provisions of this M-CRADA shall not impair, affect or invalidate the other provisions of this M-CRADA.
3. Neither this M-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 M-CRADA and that the duties under this M-CRADA are nondelegable.
4. All notices pertaining to or required by this M-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 8. Either Party may change its address by notice given to the other Party in the manner set forth above. The NIH component that is the Party for all purposes of this M-CRADA is the Bureau(s), Institute(s), Center(s) or Division(s) listed on the Cover page herein.
5. By entering into this M-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 M-CRADA or to any patent or other intellectual property license or agreement that implements this M-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 service. Each Party agrees to provide proposed press releases that reference or rely upon the work under this M-CRADA 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.
6. Either NIH or Collaborator may unilaterally terminate this M-CRADA at any time by providing written notice at least sixty (60) days before the desired termination date.
7. This M-CRADA constitutes the entire agreement between the Parties concerning the subject matter of this M-CRADA and supersedes any prior understanding or written or oral agreement.
8. The construction, validity, performance and effect of this M-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 M-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.
9. This M-CRADA shall be effective upon execution by the Parties. The term of this M-CRADA is twelve (12) months from execution. When the Research Plan is completed or twelve (12) months has elapsed, whichever occurs first, or the M-CRADA is terminated, the Collaborator Research Material will be disposed of as directed by Collaborator.
10. The provisions of Paragraphs 3, 5-12 and14 shall survive the termination of this M-CRADA.

# SIGNATURES BEGIN ON THE NEXT PAGE

**SIGNATURE PAGE**

**ACCEPTED AND AGREED**

By executing this M-CRADA, 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 NIH (IC):

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

Signature Date

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Typed Name

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

Title

FOR COLLABORATOR:

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

Signature Date

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Title

**CONTACTS PAGE**

M-CRADA Notices

For IC: For Collaborator:

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Tel: Tel:

Fax: Fax:

Patenting and Licensing

For NIH: For Collaborator (if separate from above):

Division Director, Division of Technology \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Development and Transfer \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

NIH Office of Technology Transfer \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6011 Executive Boulevard, Suite 325 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Rockville, Maryland 20852‑3804 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel: 301‑496‑7057 Tel:

Fax: 301‑402‑0220 Fax:

**Delivery of Materials Identified In Paragraph 1**

**For IC:**

IC Contact:

IC Address:

IC Phone Number:

IC Fax:

IC contact e-mail

**For Collaborator:**

Collaborator Contact:

Collaborator Address:

Collaborator Phone Number:

Collaborator Fax:

Collaborator contact e-mail:

**SUMMARY PAGE**

Either party may, without further consultation or permission,

release this summary page to the public.

TITLE OF M-CRADA: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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NIH Institute/Center (IC): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IC Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

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

ABSTRACT OF THE RESEARCH PLAN:

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APPENDIX A

**RESEARCH PLAN**

The Research Plan should be a short, concise explanation of the research project that will be conducted by NIH using the materials provided under the M-CRADA.

**APPENDIX B**

**EXCEPTIONS OR MODIFICATIONS TO THIS M-CRADA**