

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 of the National Institutes of Health (hereinafter "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 Cover Page, a copy of the model agreement, 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 not described in Appendix A. This Agreement 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 NIH's investigator, _____, the following "Collaborator Research Material":

2. This Collaborator Research Material will be used solely in connection with the Research Plan by NIH's investigator in his/her laboratory under suitable containment conditions.

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

Yes

No

2(b). 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

3. In all oral presentations or written publications concerning the Research Plan, NIH will acknowledge Collaborator's contribution of this Collaborator Research Material unless requested otherwise. To the extent permitted by law and unless otherwise directed by a court or administrative body of competent jurisdiction, each Party agrees to treat in confidence, for a period of three (3) years from the date of the disclosure, any of the disclosing Party's written information about this Collaborator Research Material that is stamped "confidential" or any of the disclosing Party's oral information about this Collaborator Research Material that is identified in writing as being confidential within ten (10) days of the oral disclosure, except for:

- (a) information that is publicly known or that becomes publicly available from public sources;
- (b) information that has been made available by the disclosing Party 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

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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.

NIH may publish or otherwise publicly disclose the results of the research, but if Collaborator has given confidential information to NIH such public disclosure may be made only after Collaborator has had thirty (30) days to review the proposed disclosure to determine if it contains any confidential information, except when a shortened time period under court order or the Freedom of Information Act pertains.

4. This Collaborator Research Material represents a significant investment on the part of Collaborator and is considered proprietary to Collaborator. NIH's investigator 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.

5. This Collaborator Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO NIH WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. 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 NIH that Collaborator not be liable for any claims or damages arising from NIH's use of the Collaborator Research Material; however, no indemnification is provided or intended.

6. The NIH 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 NIH 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.

7. With respect to Government intellectual property rights to any Subject Invention made solely by an NIH employee(s) or jointly with Collaborator for which a patent or other intellectual property application is filed, NIH hereby grants to the Collaborator an exclusive option to elect an exclusive or nonexclusive commercialization license. The license will be substantially in the form of the appropriate model Public Health Service (PHS) license agreement and will fairly reflect the nature of the Subject Invention, the relative contributions of the Parties to the Subject Invention and the M-CRADA, a plan for the development and marketing of the Subject Invention, the risks incurred by Collaborator, and the costs of subsequent research and development needed to bring the Subject Invention to the marketplace. The field of use of the license will not exceed the scope of the Research Plan. This option does not apply to Subject Inventions conceived prior to the effective date of this M-CRADA that are reduced to practice

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under this M-CRADA, if prior to that reduction to practice, NIH has filed a patent application on the Subject Invention and has licensed it or offered to license it to a third party.

8. 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.

9. 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 invention or have the invention practiced throughout the world by or on behalf of the Government. 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.

10. 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.

11. Pursuant to 15 U.S.C. §3710a(b)(1)(B), if NIH grants an 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 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(2).

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12. 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 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 article 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.

13. The illegality or invalidity of any provisions of this M-CRADA shall not impair, affect or invalidate the other provisions of this M-CRADA.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

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20. 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.

21. The provisions of Articles 3, 5-12 and 14 shall survive the termination of this M-CRADA.

SIGNATURES BEGIN ON THE NEXT PAGE

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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 NIMH:

Name:

Date

FOR THE COLLABORATOR:

Name:

Date

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CONTACTS INFORMATION PAGE

M-CRADA Notices

Patenting and Licensing

For NIH:

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
Fax: 301-402-0220

For Collaborator:

Collaborator Contact:
Collaborator Address:
Collaborator Phone Number:
Collaborator Fax:
Collaborator contact e-mail:

Delivery of Materials Identified In Article 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:

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SUMMARY PAGE

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

TITLE OF M-CRADA:

NIH Component:

NIH Principal Investigator:

Collaborator:

Collaborator Principal Investigator:

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

ABSTRACT OF THE RESEARCH PLAN:

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Revised NIH Model M-CRADA

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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 with the materials provided under the M-CRADA.

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APPENDIX B

EXCEPTIONS OR MODIFICATIONS TO THIS M-CRADA

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