NATIONAL INSTITUTES OF HEALTH

MATERIALS COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

This Materials Cooperative Research and Development Agreement ("Materials CRADA") has been adopted for use by the National Institutes of Health ("NIH") for transfers of essential research material ("Research Material") not otherwise reasonably available for NIH research.

1. _____, hereinafter referred to as "Collaborator," agrees

to transfer to NIH's investigator, _____, the following "Research Material":

_____
_____
_____
_____.

This Materials CRADA involves no other exchange of personnel or resources. All changes to this model agreement are contained in Appendix B, which is incorporated herein by reference. This Agreement is made under authority of the Federal Technology Transfer Act, 15 U.S.C. § 3710a, and is governed by its terms.

2. This Research Material will be used solely in connection with the research plan ("Research Plan"), attached as Appendix A, by NIH's investigator in his/her laboratory under suitable containment conditions.

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

___Yes
___No

2(b). If Yes in 2(a), were the 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 Research Material unless requested otherwise. To the extent permitted by law, 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 Research Material that is stamped "CONFIDENTIAL" or any of the disclosing Party's oral information about this Research Material that is identified in writing as "CONFIDENTIAL" within ten (10) days of the oral disclosure, except for information that was previously known to the receiving Party or that is or becomes publicly available or which is disclosed to the receiving Party without a confidentiality obligation. NIH may publish or otherwise publicly disclose the results of the Research Plan, 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 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 Research Material, and further agrees not to transfer the 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 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 Materials CRADA is terminated, the Research Material will be disposed of as directed by Collaborator.

5. This 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 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 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 Materials 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 in the performance of the research plan during the term of this Materials 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 not made solely by the Collaborator's employees 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, which is substantially in the form of the appropriate model NIH license agreement. This option does not apply to Subject Inventions conceived prior to the effective date of this CRADA that are reduced to practice under this 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. The terms of the license will fairly reflect the nature of the invention, the relative contributions of the Parties to the Subject Invention and the CRADA, the risks incurred by the 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 be commensurate with the scope of the research plan.

8. Within three (3) months after NIH provides notice to the Collaborator that the patent or other intellectual property application is filed, the license option must be exercised by written notice mailed to the designated NIH official. Exercise of this option by the Collaborator initiates a license negotiation period that expires nine (9) months after the patent or other intellectual property application filing date. If the last proposal by the Collaborator has not been responded to in writing by NIH within this nine (9) month period, the negotiation period shall be extended to expire one (1) month after NIH so responds, during which month the Collaborator may accept in writing the final license proposal of NIH. In the absence of such acceptance or an extension of the time limits by NIH, NIH will be free to license such intellectual property rights to others. In the event that Collaborator elects the option for an exclusive license, but no such license is executed during the negotiation period, NIH agrees not to make an offer on more favorable terms to third party for a period of six (6) months without first offering Collaborator the same terms to be offered to the third party. These times may be extended at the sole discretion of NIH upon good cause shown in writing by the Collaborator.

9. Pursuant to 15 U.S.C. § 3710a(b)(1)(A), for Subject Inventions made under this Materials CRADA by a NIH employee(s) or jointly by such employee(s) and employees of the Collaborator under this Materials 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 Materials 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 Materials 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).

12. Any dispute arising under this Materials CRADA that is not disposed of by agreement of the Principal Investigators shall be submitted jointly to the signatories of this Materials 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 Materials CRADA shall not impair, affect or invalidate the other provisions of this Materials CRADA.

14. Neither this Materials 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 Materials CRADA shall be in writing and shall be signed by an authorized representative and shall be delivered by hand or sent by certified mail, return receipt requested, with postage prepaid, to the addresses indicated on the signature page for each Party. Notices regarding the exercise of license options shall be made pursuant to Article 8. Any Party may change such 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 Materials CRADA is the Bureau(s), Institute(s), Center(s) or Division(s) listed on the Cover page herein.

16. By entering into this Materials CRADA, NIH does not directly or indirectly endorse any product or service provided, or to be provided, whether directly or indirectly related to either this Materials CRADA or to any patent or other intellectual property license or agreement which implements this

Materials CRADA by its successors, assignees, or licensees. The Collaborator shall not in any way state or imply that this Materials CRADA is an endorsement of any such product or service by the U.S. Government or any of its organizational units or employees.

17. Either the NIH or the Collaborator may unilaterally terminate this entire Agreement at any time by giving written notice at least thirty (30) days prior to the desired termination date.

18. This Materials CRADA constitutes the entire agreement between the Parties concerning the subject matter of this Materials CRADA and supersedes any prior understanding or written or oral agreement.

19. This Materials CRADA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

20. The undersigned expressly certify and affirm that the contents of any respective statements made or reflected in this Materials CRADA are truthful and accurate.

21. This Materials CRADA shall be effective upon execution by the Parties. The term of this Materials CRADA is twelve (12) months from execution.

22. The provisions of Articles 3, 5-10, 14 and 20 shall survive the termination of this Materials CRADA.

SIGNATURES BEGIN ON THE NEXT PAGE

FOR NIH:

_____ _____

Date

_____

Mailing Address for Notices:

_____

_____

_____

_____

FOR THE COLLABORATOR:

_____ _____

Date

_____

Mailing Address for Notices:

_____

_____

_____

_____

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 CRADA. It should include a short abstract for public release which summarizes the project.

APPENDIX B

EXCEPTIONS OR MODIFICATIONS TO THIS CRADA