Introduction

This proposed model cooperative research and development agreement (CRDA) is presented in accordance with Section 5 of the Technology Transfer Act of 1986 (15 United States Code (USC) Sec. 3710(g) (1) (B)). In providing this model agreement our intention is to furnish advice and assistance for a generic model from which parties can add to or subtract as they think is appropriate for their particular situation. The definition of cooperative agreement in the Act (15 USC 3710a(d)) excludes a procurement contract, grant, or cooperative agreement. Consequently, the CRDA does not include all the terms and conditions used in these legal instruments nor the required clauses in the Federal Acquisition Regulation (FAR). Of course, an agency or laboratory has the discretion to insert wording from selected clauses of the FAR or may paraphrase such clauses for use in the CRDA. We are available to assist you in any way relating to this matter.

Model Cooperative Research and Development Agreement

This Cooperative Research and Development Agreement ("CRDA"), dated as of _____, is entered into by and between the ABX Company, Inc., a New York Corporation ("ABX"), and the XYZ Center, a laboratory of the X Agency ("XYZ").

A. Whereas, the Congress in enacting the Federal Technology Transfer Act of 1986, Public Law No. 99-502, October 20, 1986, has found that Federal laboratories' developments should be made accessible to private industry, state and local Governments, and has declared that one of the purposes of such Act is to improve the economic, environmental and social well being of the United States by stimulating the utilization of Federally-funded technology developments by such parties;

B. Whereas, the Federal TEchnology Transfer Act of 1986 among other technology transfer improvements has provided each Federal agency with the authority to permit the Director of Government-operated Federal laboratories to enter into cooperative research and development agreements (CRDA) with Federal or non-Federal entities including private firms and organizations for the purpose of providing to (but not funds), or obtaining from, collaborating parties, personnel, services, property, facilities, equipment or other resources toward the conduct of specified research and development efforts which may include the disposition of patent rights in the inventions which may result from collaboration;

C Whereas, XYZ has performed substantial research and development with respect to {For example, radionuclides from rare earth elements with cancer therapy potential and has substantial elements with cancer therapy potential and has substantial expertise in the generation and characterization of monoclonal antibodies and their in-vivo binding abilities, hereinafter referred to as "the Technology"};

D. Whereas, XYZ possesses certain advanced scientific skills, facilities, special equipment, information, computer software, and know-how pertaining to the Technology;

E. Whereas, XYZ desires to pursue the development of the Technology with the objective of developing {For example, cancer therapeutic reagents consisting of specific monoclonal antibodies coupled to specific radionuclides with cell killing potential};

F. Whereas, ABX is interested in the further development of the Technology and its utilizations by private and public {For example, medical institutions};

G. Whereas, ABX desires to provide resources for XYZ's further development of the Technology and subsequently, upon the successful completion of development, carry out a plan for marketing of the {For example, reagents leading to the widespread commercial availability of such reagents};

H. Whereas, XYZ views its collaborations with ABX to develop the Technology and the commitment of ABX to undertake its marketing plan to be in the furtherance of the public interest;

Now, therefore, the parties hereto agree as follows:

Article 1. Definitions

As used in this Agreement, the following terms shall have the following meanings and such meanings should be equally applicable to both the singular and plural forms of the terms defined:

1.1 Cooperative research and development agreement (CRDA) means this agreements as used herein.

1.2 "Invention" means any invention or discovery which is or may be patentable under Title 35 of the United States Code or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 7321 et seq.).

1.3 "Made" in relation to any invention means the conception or first actual reduction to practice of such invention.

1.4 "Proprietary Information" means information which embodies trade secrets developed at private expense or which is confidential business or financial information provided that such information:

(i) Is not generally known or available from other sources without obligations concerning its confidentiality;

(ii) Has not been made available by the owners to others without obligation concerning its confidentiality; and

(iii) Is not already available to the Government without obligation concerning its confidentiality.

1.5 "Subject Data" means all recorded information first produced in the performance of this Agreement.

1.6 "Subject Invention" means any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

Article 2. Cooperative Research

2.1 Statement of Work. Cooperative research performed under this Agreement shall be performed in accordance with the STatement of Work ("SOW") attached hereto as Appendix A. XYZ agrees to perform the cooperative research and to utilize such personnel resources, facilities, equipment, skills, know-how and information as it considers necessary, consistent with its own policies, missions and requirements.

2.2 Review of Work. Periodic conferences shall be held between XYZ and ABX, personnel for the purpose of reviewing the progress of work; however, XYZ shall have exclusive control and supervision over the conduct of all cooperative research. It is understood that the nature of this cooperative research is such that completion within the period of performance specified, or within the limits of financial support allocated, cannot be guaranteed. Accordingly, it is agreed that all cooperative research is to be performed on a best efforts basis.

2.3 Principal Investigation. XYZ agrees to assign a substantial portion of the work to be performed pursuant to the SOW to the "W" Branch. The work will be performed under the supervision of Dr. _____ who as principal investigator has the responsibility for the scientific and technical conduct of this project.

2.4 Scope Change. If at any time Dr. _____ determines that the research data justifies a substantial change in the direction of the work, XYZ shall promptly notify ABX and the parties shall make a good faith effort to agree on any necessary change to the SOW.

2.5 "An alternative" (To the extent that the conduct of sponsored research may require a joint technical effort of ABX and XYZ, the parties agree to establish a joint research and development team (the "Team") which shall conduct sponsored research in accordance with the SOW. Each party shall make available to the Team such unique resources, facilities, equipment, skills, know-how and information as it considers necessary and appropriate. Both parties pledge to support the Team in a mutually cooperative manner, on a best efforts basis, consistent with their respective policies, missions and requirements. The Team shall prepare and submit written reports to both parties, on a periodic basis, setting forth the technical

progress made, identifying such problems as may have been encountered, and establishing goals and objectives requiring further effort. The Team's progress shall be prepared as an unwritten amendment to this Agreement and subsequently subject to the joint supervision of the parties, each of who shall make their own independent judgment regarding the Team's progress and direction. Either party may suggest changes to the SOW or to the scope and direction of the effort which, if agreed to by the other party, shall be implemented by the Team. Although the members of the Team shall be considered as having been delegated to the Team, they shall continue to remain employed by their respective employers with full benefits and salary).

Article 3. Reports

3.1 Quarterly Reports. Commencing three months after the expiration date, XYZ shall submit quarterly written reports to ABX during the term of this Agreement on the progress of its work and the results being obtained and shall make available to ABX, to the extent reasonably requested, other project information in sufficient detail to explain the progress of the work.

3.2 Final Reports. XYZ shall submit a final report of its results within four months after completing the SOW.

Article 4. Financial Obligation

4.1 Advance Payment. The performance of research by XYZ under this Agreement is conditioned on the advance payment by ABX of XYZ's full cost for the performance of such research. (Use this clause only if agency desires advance payment).

4.2 Deposit Account. ABX shall pay ${X} to XYZ for the performance of the research specified by Article 2. Such funds shall be deposited in {Department of Treasury, Special Collaborative Agreement Account No. _____} as follows:

${.4X} to be deposited upon the execution of this Agreement;

${.2%} to be deposited 30 days prior to the beginning of the second budget period;

${.2X} to be deposited 30 days prior to the beginning of the third budget period; and,

${.2X} to be deposited 30 days prior to the beginning of the fourth budget period.

XYZ shall not be obligated to perform any of the research specified herein or to take any other action required by this Agreement if the agreed to funds are not deposited as required by this Article. (An alternate clause establishing an Agency rather than a Treasury deposit account may be used).

4.3 Insufficient and Excess Funds. XYZ shall not be required to continue its research and development activities under this Agreement if the funds provided by ABX are insufficient to cover Xyz's full cost for such continued activities. Funds not expended by XYZ shall be returned to ABX upon XYZ's submission of a final fiscal report to ABX.

4.4 Accounting Records. XYZ shall maintain separate and distinct current accounts, records, and other evidence supporting all its expenditures under this Agreement. XYZ shall provide ABX a semi-annual report accounting for the use of ABX's funds and a final fiscal report within _____ months after completing the SOW or ending its research activities under this Agreement and the completion of the research work. These accounts and records of XYZ shall be available for reasonable inspection and copying by ABX and its authorized representative.

Article 5. Title to Property

5.1 Capital Equipment. All capital equipment developed or acquired under this Agreement shall be the property of XYZ, except that title to the following items of capital equipment provided to XYZ by ABX or acquired by XYZ with funds supplied by ABX shall remain or vest in ABX:_____. Upon completion of the research by XYZ, ABX shall be responsible for all costs attendant to the maintenance, removal, storage and shipping of the above identified capital equipment to ABX.

5.2 Disposal of Toxic or Other Waste (A clause may be necessary to govern the disposal of toxic and other waste resulting from this agreement).

Article 6. Patent Rights

6.1 Reporting. XYZ shall promptly report to ABX each Subject Invention reported to XYZ by its employees. ABX shall promptly report to XYZ each Subject Invention reported to ABX by any of its employees.

6.2 ABX Employee Inventions. XYZ, on behalf of the U.S. Government, waives any ownership rights the U.S. Government may have in Subject Inventions ,made by ABX employees and agrees that ABX shall have the option to retain title to any such employee Subject Invention. ABX shall notify XYZ promptly upon making this election and agrees to timely file patent applications on such Subject Invention at its own expense. ABX agrees to grant to the U.S. Government on its employee's Subject Inventions a nonexclusive, irrevocable, paid-up license in the patents covering a Subject Inventions to practice or have practiced, throughout the world by, or on behalf of the U.S. Government, and such other rights as we specified in Article _____. Such nonexclusive license shall be evidenced by a confirmatory license agreement prepared by ABX in a form satisfactory to XYZ. ABX may release the

right provided for by this paragraph to employee inventors subject to a license in XYZ. (See paragraph 6.4)

6.3 XYZ Employee Invention. (Note: The parties may agree to allow ABX the option of obtaining title to subject invention subject to a paid-up, nonexclusive, irrevocable license in the government. In this event paragraph 6.6 will need to be deleted). XYZ, on behalf of the U.S. Government shall have the initial option to retain title to each Subject Invention Made by its employees and in each Subject Invention Made jointly by an ABX and XYZ employee. In the event that the XYZ informs ABX that it elects to retain title to such joint Subject Invention, ABX agrees to assign whatever right, title and interest ABX has in and to such joint Subject Invention.

6.4 Filing of Patent Applications. The party having the right to retain title and file patent applications on a specific Subject Invention may elect not to file patent applications thereon provided it so advises the other party within 90 days from the date it reports the Subject Invention to the other party. Thereafter, the other party may elect to file patent applications on such Subject Invention and the party initially reporting such Subject Invention agrees to assign its right title and interest in such Subject Invention to the other party and cooperate with such party in the preparation and filing of patent applications thereon. The assignment of the entire right title and interest to the other party pursuant to this paragraph shall be subject to the retention by the party assigning title of a nonexclusive, irrevocable, paid-up license to practice, or have practiced, the Subject Invention throughout the world. In the event neither of the parties to this agreement elect to file a patent application on subject invention, either or both (if a joint invention) may, at their sole discretion and subject to reasonable conditions, release the right to file to the inventor(s) with a license in each party of the same scope as set forth in the immediate preceeding sentence.

6.5 Patent Expenses. The expenses attendant to the filing of patent applications as specified in 6.4 above, shall be borne by the party filing the patent application. Each party shall provide the other party with copies of the patent applications it files on any Subject Invention along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office.

6.6 Exclusive License

6.6.1 Grants. XYZ, on behalf of the Government, hereby agrees to grant to ABX an exclusive license in each U.S. patent application, and patents issued thereon, covering a Subject Invention, which is filed by XYZ on behalf of the U.S. Government subject to the reservation of an irrevocable, royalty-free license to practice and have practiced the Subject Invention on behalf of the U.S. Government,

and such other terms and conditions as are specified by XYZ in such exclusive license.

6.6.2 Exclusive License Terms. Upon filing of a patent application on a Subject Invention by XYZ, ABX shall have the option to acquire a limited term exclusive license in the resulting patents at reasonable royalty rates upon the execution of an exclusive license agreement containing the terms and conditions and substantially in the form specified in Exhibit A. The specific royalty rate and term of exclusivity shall be negotiated promptly after the Subject Invention is filed in the U.S. Patent and Trademark Office, provided however, that this option must be exercised by ABX by written notice to XYZ within ____ months from the date the U.S. Patent Application is so filed. {The reasonable royalty rate for each exclusive license shall be based upon a portion of the selling price of the (item) attributable to the presence of claimed subject matter where such (item) is a machine, article of manufacture, product made by a process, or composition of matter as defined by the claims of the patents. Where the claimed subject matter relates to a process or method to be practiced under the claims of the patent, the royalty will be based upon the net savings attributable to the implementation of said process or method.}

6.6.3 Extension of Exclusive Licenses. The term for each exclusive license acquired by ABX pursuant to 6.6.2 above shall extend from the issuance date of the U.S. patent on the Subject Invention. Requests by ABX for extensions of an exclusive license may be filed at any time prior to the expiration of the exclusive license and must be supported by a factual showing that such a renewal is necessary to permit ABX to recapture its investment and make a reasonable profit. The decision to extend an exclusive license shall be within the sole discretion of XYZ. (Note: If premarketing approval is required by a federal agency, the extended term time period for the patent grant should be taken into consideration by providing for an extension by the period of exclusivity).

Article 7. Data and Publication

7.1 Rights. Subject to the provisions of paragraph 7.3, subject data which is required to be delivered to ABX under this Agreement shall be the property of ABX. ABX shall, upon request, have the right to review all Subject Data first produced under this Agreement which has not been delivered to ABX, except to the extent that such Subject Data is subject to a claim of confidence or privilege by a third party.

7.2 Proprietary Information. ABX shall place a Proprietary notice on all information it delivers to XYZ under this Agreement which it asserts is proprietary. XYZ agrees that any information designated as proprietary which is furnished by ABX to XYZ under this agreement, or in contemplation of this agreement, shall be used by XYZ only for the purpose of carrying out this agreement. Information designated as proprietary shall not be disclosed, copied, reproduced or otherwise

made available in any form whatsoever to any other person, firm, corporation, partnership, association or other entity without the consent of ABX except as such information may be subject to disclosure under the Freedom of Information act (5 U.S.C. 552). XYZ agrees to use its best efforts to protect information designated as proprietary from unauthorized disclosure. ABX agrees that XYZ is not liable for the disclosure of information designated as proprietary which, after notice to and consultation with ABX, XYZ determines may not lawfully be withheld or which a court of competent jurisdiction requires disclosed.

7.3 Release Restrictions. XYZ shall have the right to use all Subject Data for any Governmental purpose, but shall not release such Subject Data publicly except: (i) XYZ when reporting on the results of sponsored research may publish Subject Data subject to the provisions of paragraph 7.4 below, and provided ABX is given a ninety (90) day opportunity to review the manuscript and provide suggestions before publication; and (ii) XYZ may release such Subject Data where such release is required pursuant to a request under the Freedom of Information Act (5 U.S.C. Section 552); provided, however, that such data shall not be released to the public if a patent application is to be filed (35 U.S.C. Section 205) until the party having the right to file has had a reasonable time to file.

7.4 Publication. XYZ and ABX agree to confer and consult prior to the publication of Subject Data to assure that no Proprietary Information is released and that patent rights are not jeopardized. Prior to submitting a manuscript for review which contains the results of the research under this Agreement, or prior to publication if no such review is made, each party shall be offered an ample opportunity to review such proposed publication and to file patent applications in a timely manner, if it is so entitled under this Agreement.

Article 8. Representations and Warranties

8.1 Representations and Warranties of XYZ. XYZ hereby represents and warrants to ABX as follows:

8.1.1 Organization. XYZ is a Federal laboratory of the X Agency and is wholly owned (or leased) by the U.S. Government of the United States whose substantial purpose is the performance of research, development, or engineering by employees of said Government;

8.1.2 Mission. The performance of the activities specified by this Agreement are consistent with the mission of XYZ.

8.1.3 Authority. 8.2.1 (1) All prior reviews and approvals required by regulations or law have been obtained by XYZ prior to the execution of this Agreement. The XYZ official executing this Agreement has the requisite authority to do so.

8.1.4 Statutory compliance. XYZ's Laboratory Director, prior to entering into this Agreement, has given special consideration to the entering into CRDAs with small business firms and consortia involving small business firms.

8.2 Representations and Warranties of ABX. ABX hereby represents and warrants to XYZ as follows:

8.2.1 Corporate Organization. ABX, as of the date hereof, is a corporation duly organized, validly existing and in good standing under the laws of the State of {New York}, and (if applicable) is a wholly owned subsidiary of Y. Inc., a Delaware Corporation.

8.2.2 Power and Authority. ABX has the requisite power and authority to enter into this Agreement and to perform according to the terms thereof.

8.2.3 Due Authorization. The Board of Directors and stockholders of ABX have taken all actions required to be taken by law, ABX's Certificate or Articles of Incorporation, its bylaws or otherwise, to authorize the execution and delivery of this Agreement.

8.2.4 No Violation. The execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under any material agreement binding on ABX or any valid order of any court, or any regulatory agency or other body having authority to which ABX is subject.

Article 9. Termination

9.1 Termination by Mutual Consent. ABX and XYZ may elect to terminate this Agreement, or portions thereof, at any time by mutual consent. In such event the parties shall specify the disposition of all property, patents and other results of work accomplished or in progress, arising from or performed under this Agreement. Upon a termination by mutual consent, XYZ shall not make any new commitments and shall, to the extent feasible, cancel all outstanding commitments that relate to this Agreement or portions thereof mutually terminated, by the termination date, or as soon thereafter as feasible.

9.2 Termination by Unilateral Action

9.2.1 Written Notice. Either party may unilaterally terminate this entire Agreement at any time by giving the other party written notice, not less than 30 days prior to the desired termination date. If ABX unilaterally terminates this Agreement, any exclusive license entered into by the parties shall be simultaneously terminated unless the parties agree to retain such exclusive license.

9.2.2 New Commitments. XYZ shall make no new commitments after receipt of a written termination notice form ABX and shall, to the

extent feasible, cancel all outstanding commitments and contracts by the termination date.

9.3 Termination Costs. Within 90 days following termination of this Agreement, XYZ shall submit a statement of all costs incurred prior to the date of termination and for all termination costs for removal of abandoned property. Any unspent funds provided to XYZ by ABX shall be used to fund termination costs. In the event such funds are insufficient to cover all the termination costs, ABX agrees to promptly meet with XYZ to reach a settlement agreement regarding the payment of the remaining termination costs.

Article 10. Disputes

10.1 Settlement. Any dispute arising under this Agreement which is not disposed of by agreement of the { } shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute.

10.2 If the signatories are unable to jointly receive a dispute within a reasonable period of time after submission of the dispute for resolution, the matter shall be submitted to the head of the agency or his designee for resolution.

10.3 Continuation of Work. Pending the resolution of any dispute or claim pursuant to this Article, the parties agree that performance of all obligations shall be pursued diligently in accordance with the direction of the XYZ signatory.

Article 11. Liability

11.1 Property. The U.S. Government shall not be responsible for damages to any property of ABX provided to XYZ or acquired by XYZ pursuant to this Agreement.

11.2 Sponsor's Employees. ABX agrees to indemnify and hold harmless the U.S. government for any loss, claim,damage, or liability of any kind involving an employee of ABx arising in connection with this Agreement, except to the extent that such loss, claim, damage or liability arises from the negligence of XYZ or its employees. XYZ shall be solely responsible for the payment of all claims for the loss of property, personal injury or death, or otherwise arising out of nay negligent act or omission of its employees in connection with the performance of work under this Agreement.

11.3 No Warranty. Except as specifically stated in ARticle 8, XYZ makes no express or implies warranty as to any matter whatsoever, including the conditions of the research or any invention or product, whether tangible or intangible, made, or developed under this Agreement, or the ownership, merchantability, or fitness for a particular purpose of the research of any invention or product.

11.4 Indemnification. ABX holds the U.S. Government harmless and indemnifies the Government for all liabilities, demands, damages, expenses and losses arising out of the use by ABX, or any party acting on its behalf or under its authorization, of XYZ's research and technical developments or out of any use, sale or other disposition by ABX, or others acting on its behalf or with its authorization, of products made by the use of XYZ's technical developments. This provision shall survive termination of this Agreement.

11.5 Force Majeure. Neither party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such party, which causes such party to be unable to perform its obligations under this Agreement (and which is has been unable to overcome by the exercise of due diligence), including, but not limited to, flood, drought, earthquake, storm, fire, pestilence, lightning and other natural catastrophes, epidemic, war, riot, civic disturbance of disobedience, strikes, labor dispute, or failure, threat of failure, or sabotage of the XYZ facilities, or any order or injunction made by a court or public agency. In the event of the occurrence of such a force majeure event, the party

unable to perform shall promptly notify the other party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the force majeure event.

Article 12. Miscellaneous

12.1 No Benefits. No member of, or delegate to the United States Congress, or resident commissioner, shall be admitted to any share or part of this Agreement, not to any benefit that may arise therefrom; but this provision shall not be construed to extend to this Agreement if made with a corporation for its general benefit.

12.2 Governing Law. The construction validity, performance and effect of this Agreement for all purposes shall be governed by the laws applicable to the Government of the United States.

12.3 Entire Agreement. This Agreement constitutes the entire agreement between the parties concerning the subject matter hereof and supersedes any prior understanding or written or oral agreement relative to said matter.

12.4 Headings. Titles and headings of the Sections and Subsections of this Agreement are for the convenience of references only and do not form a part of this Agreement and shall in no way affect the interpretation thereof.

12.5 Waivers. None of the provisions of this Agreement shall be considered waived by any party hereto unless such waiver is given in writing to all other parties. The failure of any 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, shall not be deemed a waiver of any rights of any party hereto.

12.6 Severability. The illegality or invalidity of any provisions of this Agreement shall not impair, affect or invalidate the other provisions of this Agreement.

12.7 Amendments. If either party desires a modification in this Agreement, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of such modification. Such modification shall not be effective until a written amendment is signed by all the parties hereto by their representatives duly authorized to execute such amendment.

12.8 Assignment. Neither this Agreement 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 except that ABX may assign this Agreement to the successors or assignees of a substantial portion of ABX's business interests to which this Agreement directly pertains.

12.9 Notices. All notices pertaining to or required by this Agreement 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, addressed as follows:

If to ABX: Mr.
Vice President
ABX Company, Inc.
New York, New York

If to XYZ: Dr. John Doe
Laboratory Director
XYZ Center
X Agency
Washington, DC

Any party may change such address by notice given to the other party in the manner set forth above.

12.10 Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors and not as agents of each other or as joint venturers or partners. XYZ shall maintain sole and exclusive control over its personnel and operations.

12.11 Use of Name or endorsements. (a) ABX shall not use the name of the XYZ or X Agency on any product or service which is directly or indirectly related to either this AGreement or any patent license or assignment agreement which implements this Agreement without the prior approval of XYZ. (b) By entering into this Agreement XYZ does not directly or indirectly endorse any product or service provided, or to be provided, by ABX, its successors, assignees, or licensees. ABX shall not in any way imply that this Agreement is an endorsement of any such product or service.

Article 13. Duration of Agreement and Effective Date

13.1 It is mutually recognized that the development program, cannot be rigidly defined in advance, and that the contemplated time periods for completion of each phase are good faith guidelines subject to adjustment by mutual agreement, to fit circumstances as the development program proceeds. In no case will this Agreement extend beyond _____, unless it is revised in accordance with Article 12 of this Agreement.

The provisions of Article 6, _____ shall survive the termination of this Agreement.

13.2 Effective Date.

This Agreement shall enter into force as of the date of the last signature of the parties.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as follows:

For the Company: _____

_____ _____
Date

For the U.S. Government _____

_____

_____

_____

_____ _____
Date

Appendix A
Statement of Work

MAXWELL RESEARCH FOUNDATION - NATIONAL INSTITUTES OF HEALTH RESEARCH AGREEMENT

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Exhibit A - Agreement of Program Participants A

GREEMENT

This Agreement, effective as of _____, is by and between the parties:

MAXWELL RESEARCH FOUNDATION, a corporation organized under the laws of _____ and having its principal offices at _____ (hereinafter "Foundation")

AND

THE NATIONAL INSTITUTES OF HEALTH, a Bureau of the Public Health Service of the Department of Health and Human Services located at _____ Bethesda, Maryland (hereinafter referred to as "N.I.H.");

WITNESSETH THAT;

WHEREAS, the N.I.H. has sought and continues to seek the advancement of knowledge through research;

WHEREAS, the N.I.H. desires that the useful results of its research be made available to society through established avenues of trade and commerce;

WHEREAS, the Foundation has personnel and facilities for the conduct of research, and the know-how and management skills for the development of new products and processes based on scientific research;

WHEREAS, the Foundation seeks to advance scientific research as a source for products for meeting human needs;

WHEREAS, the N.I.H. recognize that each can benefit from a relationship in biomedical research extending over a span of years that will provide present and potential facilities and financial support for the N.I.H., while enhancing the understanding and work of their respective scientists by close interaction among them;

WHEREAS, the N.I.H. and the Foundation believe that Foundation support of biomedical research can lead to enhancement of their respective capabilities and render important long range benefits to the N.I.H., to the Foundation and to society;

WHEREAS, the N.I.H. and the Foundation believe that biomedical inventions are likely to be brought into public use for public benefit through the incentive of the protection of the Patent System utilized by the parties and made available through the Foundation;

WHEREAS, the N.I.H. and the Foundation recognize that the concept of freedom to publish must be preserved by the Agreement and shall be a guiding principle in its administration;

WHEREAS, the N.I.H. and the Foundation recognize that the N.I.H. guidelines on Conflicts of Interest expresses principles applicable to N.I.H.and Foundation relationships;

WHEREAS, the N.I.H. and the Foundation are prepared to undertake a collaborative effort in the field of biomedicine under the Federal Technology Transfer Act of 1986 and Executive Order 12591 with a focus on _____, where the N.I.H. currently has substantial personnel and facilities for the conduct of research and a field where the Foundation expects to increase its in-house research emphasis; and

WHEREAS, the Foundation proposes to provide significant facility and financial support to the N.I.H. in furtherance of this collaborative effort according to the terms set forth in this Agreement.

NOW, THEREFORE, the parties hereto agree as follows:

ARTICLE I
PURPOSE AND SCOPE OF THIS AGREEMENT

The purpose of the present Agreement is to provide a framework within the Federal Technology Transfer Act of 1986 and Executive Order

12591 to govern conduct of this collaborative effort under which multiple research Projects (as hereinafter defined) can be undertaken. This Agreement is designed to recite the provisions which would apply to all Projects authorized by the Advisory Committee under the Program (as hereinafter defined).

ARTICLE II - DEFINITIONS

2.1 "Program" means all research activities performed by or for the N.I.H. under this Agreement which are authorized and funded by the Advisory Committee (as hereinafter defined) and Program Director from financial and facility support provided by the Foundation.

2.2 "Project" means a specific research activity which has been authorized and funded by the Advisory Committee from financial and facility support provided by the Foundation under the Program. Projects shall be of three types:

a) "Exploratory Projects": Those directed to fundamental research on basic scientific questions with a focus on _____.

b) "Specialty Projects": Those directed to applied research with a focus on _____ and in which the Foundation sees more immediate practical utility either in terms of technologies or products or both. These projects can be conducted within Foundation Research facilities with the concurrence of the Advisory Committee;

c) "Construction and Renovation Projects": Those construction and renovation activities directed to physical facilities required to accommodate and enhance the Program.

2.3 "Advisory Committee" means those representatives of the N.I.H. and the Foundation charged with administering the Program. The Advisory Committee comprises a Program Director who shall be Chairman and appointed by the N.I.H., three (3) additional members appointed by the N.I.H., and four (4) members appointed by the Foundation. All members including the Program Director, shall have voting power.

2.4 "Project Investigator" means the scientist in charge of a Project and responsible for its conduct in accordance with the terms of the Project award and the accepted operating policies and procedures of the N.I.H.. A Project Investigator shall be a N.I.H employee qualified to be a principal investigator on N.I.H. research projects.

2.5 "Technical Developments" means any and all inventions, discoveries, advances, know-how, processes, devices, machines, materials, software and other information arising from the Program, whether or not the same are patentable, copyrightable or otherwise protectable by law.

2.6 "Patent" means any patent, certificate of invention, inventors certificate, utility model or similar form of protection, or plant patent or other form of protection of plant material, granted anywhere in the world covering an invention which is a Technical Development, and owned by the N.I.H. or in which the N.I.H. has assignable rights.

2.7 "Assigned Product" means any product covered by a claim or made by or used in a process covered by a claim of an unexpired Patent at the time and in the country wherein the product is manufactured, used or sold, which claim has not been adjudicated invalid in a final adjudication from which there can no longer be an appeal, and which Patent is assigned to the Foundation as provided for in this Agreement.

2.8 "Agreement of Program Participants" means the specimen agreement set forth in Exhibit A attached hereto.

ARTICLE III - TERM OF AGREEMENT

3.1 This Agreement shall be for a period of five (5) years commencing _____ and terminating _____, unless earlier terminated under the provisions of Paragraphs 4.3, 12.2 or 12.3.

3.2 On or about _____, the parties shall enter into discussions as to whether both parties desire to continue the Program beyond the normal termination date of _____. If continuation is mutually desirable the parties shall proceed with negotiations to arrive at mutually acceptable terms and conditions for such continuation. If continuations is not desired by either or both parties, this fact shall be confirmed in writing before the end of the third year of the initial term of this Agreement.

3.3 If, in accordance with Paragraph 3.2 the parties decide not to continue the Program beyond _____, then the Foundation shall have the option of electing to continue its support, on a Project by Project basis, for any Projects started but not completed during the normal term. the Foundation shall make such elections and the parties shall negotiate in good faith mutually acceptable financial terms and time extensions, not to exceed two (2) years in duration, prior to the expiration of this Agreement. All other relevant terms of this Agreement shall apply to such terminal Project continuations.

ARTICLE IV - PROGRAM ADMINISTRATION

4.1 The Program shall be under the direction of the Advisory Committee chaired by the Program Director, _____, who shall be assisted by the seven (7) other Committee members including three (3) members, namely _____, appointed by the N.I.H. and four (4) members, namely, _____ _____, appointed by the Foundation. The N.I.H. and the Foundation representatives on the Advisory

Committee, other than the Program Director, may be changed at appropriate intervals by either of the parties with timely notice to the other party.

4.2 All actions to approve, defer or disapprove Program activities and to fund new Projects, to provide supplemental or continuation support to previously approved Projects or activities, and to discontinue previously approved Projects or activities shall be taken in convened meeting of the Advisory Committee. Any such action shall require approval of a majority of the members of the Advisory Committee, i.e., at least five (5) of the eight (8) members.

4.3 Should the Program Director or any member of the Advisory Committee be unable to continue service, a replacement shall be promptly appointed by the appropriate party. Program Director replacements shall be mutually acceptable to the Foundation and the N.I.H.; provided, however, that acceptance by the Foundation shall not be unreasonably withheld. If the N.I.H. cannot nominate an acceptable replacement for the Program Director within one (1) month following the inability of the Program Director to continue service, the Foundation may suspend its financial support for the Program until an acceptable Program Director is appointed. If such suspension continues beyond six (6) months, the Foundation may summarily treat this Agreement as breached under provisions of Paragraph 12.2 and the ninety (90) day notice provision of Paragraph 12.2 is not applicable.

4.4 The Program Director shall convene a meeting of the Advisory Committee at least once each calendar quarter and otherwise as frequently as necessary to act on Program matters and pending proposals, to review the financial status and progress of active Projects, to deal with unanticipated problem areas, and to consider other matters concerned with the effectiveness of the Program. Except in an emergency, notice of a scheduled meeting and an agenda therefore shall be issued not less than two (2) weeks prior to any such meeting. Any Advisory Committee member may request convening of special meetings and may have any matter related to the conduct of the Program placed on the Advisory Committee agenda for the next or forthcoming meeting by making such a request in writing to the Program Director sufficiently in advance of the meeting to allow adequate preparation for a productive discussion of the matter.

4.5 The Program Director shall, after each meeting of the Advisory Committee, distribute to all Committee members, whether present at the meeting or not, a written summary of matters considered and actions taken.

4.6 Should a member of the Advisory Committee not be able to attend a given meeting, an alternate representative may be designated by so notifying the Program Director on a meeting by meeting basis. If the Program Director is unable to attend a meeting of the Advisory Committee, he may designate another N.I.H. member of the Advisory Committee to chair the meeting and perform the functions of the

Program Director at that meeting. However, it is understood by the parties that the effectiveness of the Advisory Committee will be promoted by continuity of membership and regular attendance at meetings by members.

ARTICLE V - PROJECT SELECTION AND IMPLEMENTATION

5.1 The Advisory Committee shall decide on both the Exploratory and Specialty Projects which are to be supported under the Program. The Advisory Committee shall strive to identify and fund Projects in which the N.I.H. enjoys scientific leadership and in which the Foundation has a meaningful interest.

5.2 The Advisory committee has ultimate responsibility for identification and selection of all Projects as well as for overall and ongoing direction of the Program. As a general guide, the parties to this Agreement intend for the Program to embrace two (2) types of Projects, namely, Exploratory Projects and Specialty Projects. Ultimately during the term of this Agreement, it is expected that approximately eighty percent (80%) of the research effort would be directed toward fundamental questions (Exploratory Projects) while twenty percent (20%) would be directed toward specific products (Specialty Projects). The parties hereto recognize that facility renovation and construction is to be funded as a Program activity within the limitation of the financial support specified in Article VIII hereof.

5.3 Following the identification of a field of interest by the Advisory Committee the Program Director shall seek Project proposals from N.I.H. investigators functioning within the field of interest described in this arrangement.

5.4 Project proposals, continuations and supplements thereto shall be on forms provided by the Program Director. The Program Director shall provide copies of Project proposals to all members of the Advisory Committee at least one (1) month prior to the Committee meeting at which such requests are to be considered.

5.5 Whenever the Advisory Committee has identified a field of research of mutual interest, and has received an acceptable Project proposal, a Project may be created by the authorization of the Advisory Committee in writing. The Project authorization shall identify the Project Investigator, define the research activities to be pursued, the level of effort to be devoted to the Project by the Project Investigator, include a budget covering all costs of such research, define the time duration, facility use and such other terms and conditions as may be agreed to and be approved by the Project Investigator consistent with the purposes and conditions of this Agreement.

5.6 With concurrence of the Advisory Committee, and in furtherance of productive interaction between scientists of the Foundation and those of the N.I.H., the Foundation representatives on the Committee shall designate a the Foundation Project Scientist who shall act as the primary contact with each Project Investigator during the conduct of a given Project.

5.7 The Program Director shall submit to the Foundation in writing summary reports of all important findings and results as soon as available and detailed annual Program reports on each anniversary of this Agreement. The annual reports shall include summaries and conclusions for each active Project.

ARTICLE VI
INTERACTION BETWEEN THE FOUNDATION AND THE N.I.H.

6.1 To optimize the mutual benefit and collaboration intended by this Program, the parties desire that there be mutually productive and continuing interchanges between N.I.H. and the Foundation scientists. Accordingly, the N.I.H. will ensure that all N.I.H. scientists engaged in the Program are available to appropriate the Foundation scientists for consultation in the area of their respective Projects. Temporary office space at the N.I.H. shall be made available to collaborating the Foundation scientists. Further, selected specialty projects may be undertaken by N.I.H. investigators with Foundation research facilities.

6.2 The N.I.H. agrees to permit individual scientists and technicians from the Foundation, with the consent of the Program Director and Project Investigator and at the Foundation's expense, to spend appropriate periods of time in N.I.H. laboratories where Project research is being conducted to learn techniques developed therein, to participate is mutually desirable, and to facilitate the transfer of Technical Developments to the Foundation. The Foundation agrees that its employees who are permitted to train and function in the laboratories of the N.I.H. pursuant to this paragraph shall be required to observe the applicable policies of the N.I.H..

6.3 It is anticipated that interaction between the Project Investigators and the Foundation Project Scientists will identify facilities and capabilities of the Foundation which may be used by N.I.H. scientists to enhance the progress of Projects. Moreover, it is appropriate that evaluation of the potential of research leads and products be addressed through the interaction of the Project Investigators and the the Foundation Project Scientists.

ARTICLE VII - SCIENTIFIC REVIEW PANEL

7.1 To assess the scientific merit and cost effectiveness of Projects supported by the Program, the parties hereto recognize the need for periodic review by an independent panel of scientists.

7.2 During the third year of the initial term of this Agreement and every two (2) years thereafter, the Advisory Committee shall commission a scientific review panel comprising at least four (4) distinguished scientists, not employees of the Foundation or N.I.H., to review al then-current Project work and to appraise the direction of the Program, both qualitatively and quantitatively. Composition of the review panel should be designed to include scientists having clinical and pharmaceutical orientation as well as academic orientation.

7.3 The review panel shall be required to issue a confidential report to the Advisory committee and to the Director of N.I.H. and the Chief Executive Officer of the Foundation stating its views, conclusions and recommendations regarding the scientific merit and cost effectiveness of the Program and Projects and the impact of the Program on the respective institutions involved.

7.4 Costs of the scientific review shall be paid from Program funds.

VIII - PROGRAM FINANCES

8.1 The Foundation hereby agrees to provide to the N.I.H. for the total support of the Program during the five (5) year term of this Agreement, the total amount of _____, to be adjusted according to Paragraph 8.2, which shall cover both direct and indirect expenses of the N.I.H.. The N.I.H. agrees that this funding shall be disbursed solely in support of the Program.

8.2 Payment by the Foundation to the N.I.H. of the amount specified in Paragraph 8.1 shall be limited to the year budget amount recited in the following schedule which are subject to (i) annual adjustment for inflation in accordance with this Paragraph 8.2, and (ii) budget underruns carried forward from one year to the next with approval of the Advisory Committee in accordance with Paragraph 8.9. The parties hereto believe the following expenditure schedule reflects the appropriate allocation of funds:

Agreement Year	Exploratory Projects	Specialty Projects	Construction and Renovation Projects	Year Budget
82/83	$_____	$_____	$ (See Para.8.4)	$_____
83/84	$_____	$_____	$	$_____
84/85	$_____	$_____	$	$_____
85/86	$_____	$_____	$	$_____
86/87	$_____	$_____	$	$_____
Total	$_____	$_____	$	$_____

The initial agreement year shall run from the effective date of this Agreement through _____. Subsequent agreement years shall run from _____.

The agreement year budgets above recited, commencing with the second agreement year (_____), shall be adjusted using the GNP Deflator Index in the following manner:

(a) A base index will consist of an average of the GNP Deflator Index figures for the four (4) quarters from 19__ through 19__.

(b) An index for each agreement year, commencing with the second agreement year, will consist of an average of the four (4) quarterly GNP Deflator Index figures covering the period April through the following March immediately preceding the start of each agreement year. (For example the index for the second agreement year will be the average of the GNP Deflator Index figures for the four (4) quarters covering _____ 19__ through _____ 19__.)

(c) Each agreement year budget as stated above shall be adjusted prior to the commencement of the relevant agreement year by applying a multiplier derived as follows:

$$\text{multiplier} = 1 + \frac{\text{Agreement yr. index - base index}}{\text{base index}}$$

For purposes of this Agreement the "GNP Deflator Index" shall mean the quarterly revised Implicit Price Deflator for the Gross National Product as reported by the United States Department of Commerce, Bureau of Economic Analysis. Since it is normal for a quarterly GNP Deflator Index to be revised shortly after it is first published, calculations herein shall be based on the final index for a quarter, if available, and otherwise on the most recent revision available on June 1 immediately preceding the start of the agreement year for which calculations are made.

8.3 It is recognized that the occurrence of expenditures during an agreement year is primarily dependent on Project spending plans authorized by the Advisory committee during the current and any prior years. Nevertheless, the Foundation is not obligated to reimburse the N.I.H. for expenditures incurred during, or carried forward into, any agreement year in excess of the total amount of the agreement year budget shown on the expenditure schedule in Paragraph 8.2, as it may have been adjusted under the provisions of Paragraph 8.2 and 8.9, unless the parties mutually agree to modify said total amount by formal amendment to this Agreement.

8.4 All Program funds shall be administered by the Program Director who shall allot funds, with the approval of the Advisory Committee as specified in Article IV, to Project participants. By unanimous consent the Advisory Committee may reallocate among Project types up to 10% of the total funds for any agreement year specified in

the schedule of Paragraph 8.2, as such annual total may have previously been modified by the Foundation under Paragraph 8.3 or by the Advisory Committee under Paragraph 8.9. Such reallocation of agreement year funds may be among the Exploratory Project type, the Specialty Project type and the Construction and Renovation Project type. The Program Director shall monitor spending of funds budgeted for individual Projects and may make adjustments among expense categories of an approved Project budget upon justified requests of Project Investigators. The Program Director shall keep the Advisory Committee informed of financial matters which might indicate a significant departure from Project plans previously approved by the Committee. The Program Director's financial records on all segments of the Program and Projects shall be available for review by any member of the Advisory Committee.

8.5 Approved funds for individual Projects or for support of the Program shall be maintained by the Institute Accounting Services Department with operating responsibility for the project in separate accounts for each such activity. Spending for each account shall be under the direct control of the Program Director or his delegated Project Investigator, respectively, who shall be furnished with the Accounting Services standard monthly statements of spending against their accounts.

8.6 The accounting records of Program activity shall be available for audit by The Foundation, using its own internal or outside auditors, during the normal business hours of the N.I.H..

8.7 The N.I.H. shall submit monthly invoices with supporting details to the Foundation showing actual spending by N.I.H. expense category for each Project for which reimbursement of expenditures is being requested. Each invoice shall also show cumulative expenditures to date for each such Project against the approved Project budget and cumulative total Program expenditures for the agreement year against the current agreement year budget shown on the expenditure schedule in paragraph 8.2 as it may have been previously adjusted under the provisions of Paragraphs 8.2 and 8.9.

8.8 The Foundation agrees to pay the N.I.H. promptly upon receipt and approval of the N.I.H.'s invoices provided under Paragraph 8.7 up to the level of the agreement year budget set forth in Paragraph 8.2, as such agreement year budget may have been adjusted under the provisions of Paragraphs 8.2 and 8.9.

8.9 If in any agreement year there is an overrun of the agreement year budget the excess expenditures shall be carried forward and be paid from the following agreement year budget. If in any agreement year there is an underrun of the agreement year budget (hereinafter in this paragraph "the current agreement year budget"), then with the unanimous consent of the ADvisory Committee the underrun amount may be carried over as an addition to the following agreement year budget. The approved amount from the current agreement year budget which is to be carried over shall be adjusted by a multiplier calculated by dividing the multiplier from Paragraph 8.2 for the following agreement

year budget by the multiplier for the current agreement year budget. The thus adjusted amount to be carried over shall then be added to the following agreement year budget after the following agreement year budget has been adjusted in the usual manner.

8.10 Unless otherwise provided in the project award, title to all items of equipment purchased with Program funds shall vest in the N.I.H. at the time of purchase.

8.11 Upon termination of this Agreement for any reason the N.I.H. shall provide a final accounting of Program funds to the Foundation within ninety (90) days following such termination. During said ninety (90) days the N.I.H. shall liquidate all outstanding obligations incurred prior to termination but shall not incur additional obligations. The balance of funds remaining shall thereupon be returned to the Foundation unless required for completion of Projects in accordance with Paragraph 3.3.

8.12 Indirect costs invoiced under Paragraph 8.7 shall, through _____, 19__, be at a fixed rate of fifty percent (50%) of invoiced direct costs. Indirect costs invoiced by the N.I.H. for any activity performed in whole or in part by any agreementor shall not exceed the indirect costs which would have been invoiced had such activity been performed wholly by the N.I.H.. If the N.I.H.'s indirect costs rise by ten percent (10%), i.e., to fifty five percent (55%) or more, then upon the N.I.H.'s request the Foundation agrees that it will negotiate the N.I.H.'s request to increase the rate of indirect costs from fifty percent (50%) under this Agreement, taking into consideration relevant factors, including relative increases in indirect costs made in other research agreements, including other government agreements.

ARTICLE IX - PUBLICATIONS AND REVIEW OF TECHNICAL DEVELOPMENTS

9.1 The Government members participating in Projects are at liberty to publish the results of their research subject to the provisions of Paragraphs 9.1, 9.2, 9.3, 9.4 and 9.5. Project awards will require that participants provide copies of all abstracts and articles, in the best form then available, proposed to be submitted for publication in sufficient time to permit the Program Director to provide same to a Foundation member of the Advisory Committee at least one (1) month prior to submission to a publisher or other third party. The Program Director shall immediately determine that a Foundation member has received a copy of each such proposed abstract and article. The Program Director shall also promptly provide to a the Foundation member a final copy of each abstract and article as submitted for publication.

9.2 The Foundation shall promptly review such proposed abstracts and articles to determine if potentially patentable Technical Developments are disclosed and shall promptly thereafter inform the N.I.H. whether delay of submission for publication or other public disclosure for a reasonable time will be required to establish Patent rights of reasonable scope. Disputes concerning such delays shall be referred to the Advisory Committee.

9.3 As to verbal presentations and discussions, the parties recognize that it is impractical to provide a complete review system for Patent purposes and that considerable discretion must be left in the investigator. It is the intent of the N.I.H. and the Foundation to provide the investigators guidance sufficient to avoid any divulgations that would compromise the establishment of the best possible Patent position.

9.4 The reporting and evaluation as provided for in Paragraphs 9.1 and 9.2 notwithstanding, the Foundation representatives on the Advisory Committee are exposed to all Program and Project plans before commencement and such representatives have full opportunity and right to follow the progress of any and all Projects. Through this mechanism the assigned the Foundation Project Scientists and the Foundation shall determine as early as practicable the potential for establishing Patent rights and its interest in obtaining a license of such rights. As soon as such potential is determined by the Foundation the parties shall cooperate on immediate actions necessary to the establishment of such rights, including, if necessary delay of publication for a reasonably brief period of time to conduct any further research or take other actions that may be necessary to file appropriate and adequate Patent applications.

9.5 All scientific publications reporting research results from Program activities shall acknowledge that support for such research was provided by the Foundation.

9.6 Upon written request to the Advisory Committee, the Foundation shall receive adequate samples of all available scientific materials isolated or developed in the Program, and shall have the right to use the same for research and/or commercial purposes, but subject to the provisions herein with respect to confidentiality, Patents and licenses. The Foundation's rights to receive and use samples as provided in this Paragraph 9.6 shall not be denied but shall be subject to reasonable modification for good reason as deemed necessary by the Advisory Committee.

ARTICLE X - CONFIDENTIALITY

10.1 Technical Developments and Patents shall be the sole and exclusive property of the N.I.H. subject to the license rights provided under Article XI.

10.2 The Foundation shall take reasonable precautions to safeguard, in a manner comparable to that used to protect its own confidential technical information, unpublished Technical Developments and not disclose the same to others for a period of two (2) years after receipt; provided, however, that the Foundation shall not be liable for unauthorized disclosure of Technical Developments in spite of such precautions. With respect to any particular identified Technical Development for which good cause can be shown, the N.I.H. may extend the two (2) year period for an additional period of two (2) years by notice in writing to the Foundation stating reasonable

justification therefor and that to the N.I.H.'s knowledge none of the exceptions of Paragraph 10.3 is applicable. After said initial two (2) year period or extension thereof the Foundation shall be under no restrictions as to revelation of any Technical Developments. Subject to the provisions herein with respect to Patents and licenses, the Foundation shall at all times be free to use Technical Developments.

10.3 The the Foundation obligation specified in Paragraph 10.2 shall not extend to Technical Developments which:

a) become a part of the public domain or of the public knowledge through no fault of the Foundation; or

b) were in the possession of the Foundation prior to disclosure by the N.I.H., and such possession by the Foundation is documented; or

c) are received by the Foundation lawfully and properly from a third party; or

d) have been revealed in patent applications.

10.4 Close cooperation between the Foundation personnel and N.I.H. personnel in the conduct of activities required by or contributing to the purposes of this Agreement may involve the disclosure of the Foundation confidential information to such N.I.H. personnel. Since, as a practical matter the N.I.H. is not able to make commitments of confidentiality on behalf of its faculty nor control the confidential information disclosed to them, it shall advise all Program and Project participants that they will be required to sign in advance of receiving the Foundation confidential information personal commitments of confidentiality as the Foundation deems necessary in the circumstances.

ARTICLE XI - PATENTS AND LICENSING

11.1 Whenever the N.I.H. reasonable feels a need therefor it may request the Foundation to provide in writing a preliminary indication of its current interest in commercializing Technical Developments resulting from a Project. However, the Foundation shall not be obligated to carry out commercialization.

11.2 The Foundation shall have the right and obligation to monitor progress of each Project through its representatives on the Advisory Committee and through access to N.I.H. Program participants and reports, or by such other arrangements as may be mutually acceptable to the Foundation, the Program Director, and the Project Investigators as appropriate. The primary purpose of such monitoring is to detect potentially patentable inventions as early as possible. The N.I.H. shall have the obligation to disclose promptly to the Foundation all potentially patentable or scientifically novel Technical Developments.

11.3 When in the judgment of the Foundation potentially patentable inventions are developed within a Project, the Foundation shall make a report of such to the N.I.H., with its views of further research that may be necessary to establish the nature and scope of these inventions, and to the extent then possible its opinion of the potential importance of such invention to commercialization prospects, and its interests concerning the licensing by the Foundation under any Patents that may be obtained covering such inventions. The information in said report shall be retained in confidence by the N.I.H. and used only for purposes of this Agreement.

11.4 When in the judgment of the N.I.H. potentially patentable inventions are developed which have not yet been identified by the Foundation through the processes described in Paragraphs 11.2 and 11.3 the N.I.H. shall make a report of such to the Foundation, including all available results and conclusions. Thereupon, the Foundation shall prepare and make its report to the N.I.H. as specified in Paragraph 11.3.

11.5 When the Foundation has indicated its interest in a license under prospective Patent rights to an invention it shall promptly cause its patent attorneys to file and prosecute in good faith a United States Patent application on such invention. The Foundation shall also effect the filing and good faith prosecution of foreign Patent applications corresponding to the United States application in whatever countries the Foundation by written notice to the N.I.H. indicates its interest in a license under prospective Patent rights.

11.6 Until such time as the Foundation notifies the N.I.H. in writing that it no longer has an interest in a license, or until the expiration of the time specified in Paragraph 11.14 during which time the Foundation has not given notice of its election to take a license, the Foundation agrees to bear the cost for filing and prosecution of Patent applications under Paragraph 11.5 and the issuance and maintenance of Patents thereon. The Foundation shall not be required to prosecute any such Patent application beyond the point of final rejection by the assigned Primary Examiner in the United States Patent and Trademark Office or the equivalent stage of prosecution if a foreign application. The N.I.H., at no cost or obligation or liability to the Foundation, may take action to file or prosecute any Patent application or have issued or maintain any Patent on which the Foundation elects not to take such action. Any such election by the Foundation shall be promptly communicated to the N.I.H. and in adequate time to allow the N.I.H. to take such action if it so desires. The Foundation's right to a license thereunder shall not thereby be diminished.

11.7 With respect to Patent applications filed and prosecuted and Patents issued or maintained by the Foundation under Paragraphs 11.5 and 11.6, the N.I.H. at its own expense may designate and retain patent counsel of its own who shall be permitted to review such Patent applications and proposed responses to Patent Office actions thereon and issuance and maintenance of Patents and to consult with the Foundation's patent attorneys before the Foundation takes action

thereon. However, the control of such filings, prosecutions, issuances and maintenances shall rest with the Foundation unless it elects to relinquish such control to the N.I.H. under Paragraph 11.6 by timely written notice. The N.I.H. may at any time elect by notice in writing to the Foundation to assume at N.I.H.'s cost those activities undertaken by the Foundation under Paragraphs 11.5, 11.6, and 11.7 on behalf of the N.I.H. in regard to any Patent application or Patent, and the Foundation's right to a license thereunder shall not thereby be diminished.

11.8 Title to all Patent applications and Patents issuing thereon covering Technical Developments made only by N.I.H. or non-the Foundation personnel or jointly with the Foundation personnel shall be in the N.I.H.. Any royalties payable with respect to the latter shall take into consideration the relative contributions of the N.I.H. and the Foundation coinventors.

11.9 The parties, including the inventors, Project Investigators and Program Director, shall do all acts necessary or desirable to provide the Foundation patent attorney with all information and records and execution of all documents necessary or desirable in the evaluation of Technical Developments, and in the filing and prosecution of Patent applications thereon, and in obtaining the issuance and maintenance of any Patents issuing from such Patent applications.

11.10 The N.I.H. shall take all necessary and desirable actions, including the signing of Agreements of Program Participants (Exhibit A) by each of the persons participating in the Program, including the Program Director, all Project Investigators, and all other persons involved in the research, to assure that it acquires sufficient title to all Technical Developments, Patent applications and patents from those of its personnel making such so as to be entitled to grant licenses to the Foundation as specified in this Agreement. The Program Director shall maintain a file of such signed Agreements of Program Participants which shall at all times be available to the Foundation representatives and upon request the Program Director shall provide the Foundation copies of specified Agreements.

11.11 In consideration of the Foundation's financial and other support of the Program and of the Patent work and cost thereof to be undertaken by the Foundation under this Article XI, the N.I.H. agrees that it will make no claims against and hereby waives any claim it may have against the Foundation or its employees for injury, loss or damage resulting from acts of omission or commission by the Foundation, its employees or agents, in connection with the preparation, filing and prosecution of Patent applications and the obtaining and maintaining of Patens covering Technical Developments.

11.2 Each inventor of a potentially patentable Technical Development, no later than the time of signing a Patent application thereon, shall be requested to agree, for the considerations recited in Paragraph 11.11, to make no claims against and to waive any claims he or she may have against the Foundation or its employees for injury,

loss or damage resulting from acts of omission or commission by the Foundation, its employees or agents, in connection with the preparation, filing and prosecution of Patent applications and the obtaining and maintaining of Patens covering Technical Developments. Should any inventor decline to so agree, any Patent application on such TEchnical Development shall be filed and prosecuted and Patents obtained and maintained by the N.I.H., at its own cost, and the Foundation's right to a license thereunder shall not thereby be diminished.

11.13 Notwithstanding any other provision of this Agreement, the N.I.H. agrees to hold harmless, indemnify and defend the Foundation and its employees from all liabilities, damages, costs, expenses (including attorneys fees) and losses resulting from any claim or any lawsuit or any settlement thereof made by the N.I.H. or by the Foundation with the N.I.H.'s consent, by the N.I.H.'s employees or third party having an interest through the N.I.H. or its employees, and arising out of acts of omission or commission in regard to the obligations undertaken by the Foundation or its employees under Paragraphs 11.5, 11.6, 11.7.

11.14 The N.I.H. hereby agrees to grant to the Foundation licenses to make, have made, use and sell under Patents, including the right to grant sublicenses, in such countries as the Foundation may elect. Such election for any Patent shall be made within two (2) years after the filing of a Patent application in the affected country, provided, however, that the Foundation shall not be required to negotiate the terms of a license agreement until after the relevant Patent has issued.

11.15 License grants to the Foundation of rights to Patent applications and Patents issuing thereon for inventions made solely with the Foundation support shall be exclusive for the life of such Patents. For any invention made with the joint support of the Foundation and funds provided by another sponsor, or in which there is a third party inventor, such license shall, whenever legally possible, be exclusive for the life of the Patents. However, if the N.I.H. is unable to grant a license which shall be exclusive for the life of the Patent, then the N.I.H. shall provide the Foundation with the maximum rights permitted by law. In connection with the transfer of Patent rights to be negotiated under this Agreement the parties shall consider the benefits relative to licensing as distinguished from transfer of title.

11.16 The N.I.H. agrees to grant and hereby grants to the Foundation an irrevocable, world-wide, paid-up, non-exclusive license, to make, have made, use and sell, including the right to grant sublicenses, on all Technical Developments licensed under this Paragraph 11.16, and from use, sale or other disposition of products made by use of the said Technical Developments, by the Foundation, its affiliates, sublicensees or any party acting on behalf of same. This provision shall survive termination of this Agreement.

11.17 The N.I.H. agrees to grant to the Foundation licenses on patents secured outside the Program to the extent the N.I.H. has the right to so license and to the extent necessary for the Foundation to practice Technical Developments. For such patents the grant shall be on terms and conditions reasonable in the circumstances and shall include the right to grant sublicenses. the Foundation agrees to indemnify the N.I.H. for liability arising from use of such patents licensed under this Paragraph 11.17 and from use, sale or other disposition of products mad by use of such patents, by the Foundation, its affiliates, sublicensees or any party acting on behalf of same. This provision shall survive termination of this Agreement.

11.18 License grants to the Foundation under Paragraphs 11.14 and 11.15 shall contain at least the following terms and conditions:

a) requirement that the Foundation by its own efforts or through sublicenses during the period of exclusivity make reasonable efforts to effect the lawful introduction of Licensed Products into the marketplace as early as practicable, consistent with the Foundation's sound and reasonable business practice and judgment. The requirement for introduction of a Licensed Product into the marketplace shall be deemed met if, in the exercise of the Foundation's sound and reasonable business practice and judgment, an alternative product serving essentially the same function has been introduced into the marketplace by the Foundation and with essentially the same benefits to the consuming public.

b) the right of the N.I.H. to require the Foundation to grant a non-exclusive sublicense to a responsible party on fair and reasonable terms and conditions in the event the requirement of subparagraph a) above is not met.

c) requirement that during the period of exclusivity the Foundation submit a product development plan specifying its reasonable estimate of the schedule of key events to market entry and provide periodic reports of significant modifications to the plan and progress against the plan to the N.I.H. until market entry is achieved, and requirement that the N.I.H. retain in confidence the information in said plan and reports and use only for purposes of the license.

d) right of the Foundation to sublicense others provided the N.I.H. is notified to whom the sublicense was granted.

e) a royalty schedule based on net selling price of Licensed Product sold by the Foundation or its sublicensees. The N.I.H. and the Foundation recognize that patent protection in only one factor contributing to commercial success of a product or process and that other factors, for example other patented inventions, unpatented know-how, technical and marketing skills, financial contribution and risk, nature and extent of market, nature and extent of competition,

normal trade practices, and condition of the economy also plan an important part. Accordingly, rather than attempt at this time to establish royalty rates, the N.I.H. and the Foundation declare their intentions to negotiate in good faith at the time of licensing, reasonable and fair royalties payable to the N.I.H. by the Foundation on the commercial practice by the Foundation and its sublicensees of each Technical Development covered by a Patent licensed under this Article XI, taking into account the various factors contributing to the commercialization. If the N.I.H. and the Foundation are unable to agree on royalty rates within six (6) months of the commencement of negotiation, the matter may be submitted to arbitration by either party and if so submitted by either party, shall be finally settled by arbitration conducted in accordance with the then-existing rules of conciliation and arbitration of the American Arbitration Association. Any such arbitration shall take place in St. Louis County, Missouri, before three (3) arbitrators, one of who shall be designated by the Foundation, one by the N.I.H. and the third by the two so designated. If one party fails to designate an arbitrator within thirty (30) days after the designation of an arbitrator by the other party, the arbitrator who should have been chosen by the other party shall be appointed by the American Arbitration Association as soon as possible. In the event that the said two arbitrators designated by the parties are unable to agree upon a third arbitrator within thirty (30) days after the nomination of the last of the said two arbitrators, the third arbitrator shall be appointed by the American Arbitration Association as soon as possible. None of the arbitrators need be designated from any panel published by the American Arbitration Association or any other arbitration association. The arbitrators shall apply the laws of the State of Missouri. The decision by the arbitrators shall be binding and conclusive upon the parties, their successors and assigns and they shall comply with such decision in good faith. The N.I.H. and the Foundation each shall pay its own costs and one-half of the costs of the arbitration.

f) provision that when a Licensed Product is sold but not as such and constitutes significantly less than all of the sold, an equitable adjustment shall be made in the net selling price of the thing sold to arrive at the net selling price for royalty calculations. When a Licensed Product is manufactured by or used in a process and the process is only a minor factor in the manufacture or use, an equitable adjustment shall be made in the net selling price.

g) provision that the Foundation payments required to be made to a third party for the right under a third-party

dominating patent to make, use or sell a Licensed Product licensed hereunder shall be credited against one-half of the royalties due the N.I.H. hereunder from sales of the same Licensed Product.

h) right of annual audit to confirm royalties on behalf of the N.I.H. by a firm of accountants to which the Foundation has no reasonable objection.

i) indemnification of the N.I.H. by the Foundation for liability arising from the manufacture, use, sale or other disposition of Licensed Products, by the Foundation or its affiliates, sublicensees or any party acting on behalf of same. This provision is to survive termination of the license agreement.

j) law of Maryland shall apply.

k) Such other provisions as the parties may mutually desire, and, in the case of an exclusive license of an invention jointly supported by the government, such provisions as the government may have validly required the N.I.H. to include.

l) Patent Infringement procedures:

(1) If at any time a third party shall infringe a Patent licensed to the Foundation hereunder, then the Foundation may either (i) obtain a discontinuance of such infringing operations; (ii) bring suit at the Foundation's expense against such infringer in the name of the Foundation, or in the name of the N.I.H. and the Foundation if the N.I.H. is a legally indispensable party; or (iii) permit the N.I.H. at its option to bring such suit at its own expense. The party who brings suit shall control the prosecution and any settlements thereof, and the other party shall be entitled to be represented therein by counsel of its own selection at tis own expense.

(2) From any recovery from such suit or settlement thereof there shall first be paid the expenses of the party bringing the suit, then the expenses of the other party hereto if represented by counsel, and the balance shall be divided two-thirds to the party bringing the suit and one-third to the other party, unless the parties agree otherwise.

(3) Before bringing suit the Foundation shall fully inform the N.I.H., and give careful consideration to the views of the N.I.H. in making its decision whether or not to sue.

(4) If the Foundation decides to sue and N.I.H. is a legally indispensable party, the N.I.H. shall have the

right to assign to the Foundation all of the N.I.H.'s rights, title and interest in the Patent of Patents concerned, in which event suit by the Foundation on such Patent or Patents shall thereafter be brought or continued solely in its name if the N.I.H. is no longer an indispensable party. Patents so assigned by the N.I.H. to the Foundation shall remain subject to the same royalty and all other terms and conditions of this Agreement.

11.19 Commencing with the fourth and subsequent years in which royalties are due to the N.I.H. pursuant to licenses contemplated under this agreement, the Foundation shall be entitled to a credit, not to exceed 25% of the gross royalties due for the commercialization of Licenses Products in each year, (a) of the Foundation's cumulative our-of-pocket costs (excluding the costs of the Foundation's employees) for patent activities under Paragraphs 11.5 and 11.6 and (b) 50% of all payments made prior to the date of crediting by the Foundation to the N.I.H. under Article VIII hereof, which payments can be related to the cost of development of those commercialized Licensed Products.

11.20 Should the Foundation not indicate interest to take a particular license from the N.I.H., or subsequently decide not to enter into the license agreement, or terminate the license agreement, or should such agreement be justifiably terminated by the N.I.H. without challenge or objection by the Foundation, then the N.I.H. shall be free to license to others the subject matter so released, without further obligation to the Foundation. However, such licenses to others shall exclude Licensed Products directly competitive with or substantially equivalent to those the Foundation has licensed.

11.21 Upon the indication by the Foundation of in interest in any Technical Developments and that the Foundation desires to commence activities directed at transferring such technology to its laboratories, then the Program Director shall participate with the Foundation representatives, the Project Investigators and others as may be appropriate to work out mutually acceptable actions to be taken to effect such technology transfer, including activities contemplated under Paragraphs 6.2 and 9.6, all at no added cost to the Foundation.

ARTICLE XII - TERMINATION

12.1 This Agreement shall terminate on _____ unless extended by mutual agreement of the parties under the provisions of Paragraph 3.2; or unless earlier terminated under the provisions of Paragraphs 4.3, 12.2, or 12.3.

12.2 In the event that either party to this Agreement defaults or breaches any of the provisions hereof, the other party reserves the right to terminate this Agreement upon ninety (90) days written notice

to the defaulting party; provided that if the defaulting party, within said ninety (90) day period cures the said default or breach, this Agreement shall continue in full force and effect.

12.3 If either party shall become insolvent, or shall make any assignment for the benefit of creditors, or shall be adjudged bankrupt, or if a receiver or trustee of the property of either party is appointed, the other party on thirty (30) days written notice may terminate this Agreement.

12.4 Notwithstanding the termination of this Agreement for any reason, the provisions of Articles X, XI, and XIII shall remain in effect subject to Paragraph 12.5.

12.5 If the N.I.H. exercises its rights under Paragraphs 12.2 or 12.3 and validly effects the termination of this Agreement it shall be under no further obligation to grant further licenses to the Foundation and the Foundation shall promptly transfer to the N.I.H. the prosecution of allpending Patent applications and the maintenance of all Patents not yet licensed to the Foundation and which the Foundation is prosecuting or maintaining hereunder.

ARTICLE XIII - INDEMNIFICATION

13.1 the Foundation agrees to hold harmless, indemnify and defend the N.I.H. from all liabilities, demands, damages, expenses and losses arising out of use by the Foundation or by any third party acting on behalf of or under authorization from the Foundation, of information or materials received from N.I.H. or out of any use, sale or other disposition by the Foundation or by any third party acting on behalf of or under authorization from the Foundation of products made by use of information or materials received from N.I.H..

13.2 The N.I.H. warrants that it carries sufficient Worker's Compensation insurance to comply with the laws of Maryland and any other state where any of the work pursuant to this Agreement is performed with respect to the N.I.H.'s personnel. Except as provided under Paragraph 13.3 it is expressly understood and agreed that the Foundation shall no be responsible for or obligated in any manner to reimburse the N.I.H. or to pay any compensatory, special, exemplary or consequential or other direct or indirect damages in respect of any loss, property damage, personal injuries or loss of life incurred in performance of the research work under this Agreement other than that attributable in whole or in part to the Foundation's fault or negligence, and the N.I.H. shall defend, indemnify and hold the Foundation harmless (using funds other than those paid to N.I.H. pursuant to the provisions of Article VIII hereof) from any and all claims, costs or liability for any such loss, damage, injuries or loss of life, other than that attributable in whole or in part to the Foundation's fault or negligence.

13.3 The Foundation agrees to defend, indemnify and hold the N.I.H. harmless from any and all claims, costs or liability for any loss, damage, injury or loss of life, other than that attributable in

whole or in part to the N.I.H.'s fault or negligence, arising as a result of any the Foundation Employee working in the laboratories of the N.I.H. as provided under Paragraph 6.2.

ARTICLE XIV - TRANSFER OF INTEREST

14.1 Neither this Agreement, nor any of the rights and obligations stated herein or resulting therefrom, may be assigned, transferred or otherwise disposed of by either party without the prior written consent of the other unless such assignment, transfer or disposition is to a successor to all the business of the transferor which pertain to the subject matter of this Agreement, and provided that such successor shall agree in writing with the other party to assume all the obligations of the transferor to the other party.

14.2 Should it become necessary or desirable for the N.I.H. to subcontract any of the Program research to others, such research shall be performed under a formal subcontract satisfactory to the Foundation by which the subcontractor accepts all appropriate provisions of this Agreement and other such provisions as are necessary.

ARTICLE XV - NOTICE

15.1 Any notice or report required or permitted to be given under provisions of this Agreement shall be in writing and be sent by first class mail or hand delivered:

a) If to the Foundation, to:

with a copy to:

b) If to the N.I.H., to:

with a copy to:

15.2 Either party may change the address or the person(s) designated to receive notice by notifying the other in writing of the change.

ARTICLE XVI - GENERAL PROVISIONS

16.1 Except as provided in Paragraph 9.5, neither party shall use the name of the other party, its affiliated organizations or its personnel in advertising promotional materials or news or press releases pertaining to the subject matter of this Agreement without prior written consent of such other party.

16.2 This Agreement shall be construed under the laws of the State of Maryland.

16.3 No waiver of any default, condition, provisions or breach of this Agreement shall be deemed to imply or constitute a waiver of any other like default, condition, provision or breach of this Agreement.

16.4 The Article headings used in this Agreement are for convenience only and form no part of the Agreement.

16.5 This writing constitutes the entire Agreement between the parties hereto relating to the subject matter of this Agreement and there are no understandings, representations or warranties of any kind except as expressly provided herein. Neither this Agreement, nor any term or provision thereof, may be discharged, waived, released, abandoned, changed or modified except by an instrument in writing signed by a duly authorized representative of each of the parties to this Agreement. If either party desires a modification or change of any kind in this Agreement, the parties shall, upon reasonable notice of the proposed modification or change by the party desiring the change, confer in good faith to determine the desirablitiy of such modification or change.

16.6 The parties agree that it is the intention of neither party to violate any valid federal, state and local laws and regulations; that is any sentence, paragraph, clause, or combination of the same in this Agreement is in violation of any applicable law or regulation, or is unenforceable or void for any reason whatsoever, such sentence, paragraph, clause or combinations of the same shall be inoperative and the remainder of the Agreement shall remain binding upon the parties.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in duplicate by their duly qualified officers.

THIS AGREEMENT CONTAINS A BINDING ARBITRATION PROVISION WHICH MAY BE ENFORCED BY THE PARTIES

By_____

Date_____

By_____

Date_____

EXHIBIT A

AGREEMENT OF PROGRAM PARTICIPANTS

The purpose of the following agreement is to describe the responsibilities of and to enlist the support and cooperation of research participants and to insure compliance with relevant N.I.H. policies.

Therefore, as a participant in a research project under the Biomedical Research Program sponsored and funded by the Foundation Company, I agree to abide by the following terms and conditions:

1. PATENTABLE INVENTIONS:

(a) Participants will promptly disclose to the N.I.H.'s Program Director any potentially patentable invention or novel scientific development they produce in any research Project funded by the Foundation. Such disclosure will occur prior to disclosure to any other non-Program participant.

(b) Participants will, upon request, assign rights to patentable inventions to the N.I.H. so that it may grant required licenses to the sponsor.

(c) Participant inventors will cooperate with the Foundation and N.I.H. patent attorneys in the filing and prosecution of patent applications. Due to the major expense and specialized professional assistance required to pursue patent rights in a research program of this magnitude, the Foundation has assumed this responsibility. The N.I.H. will monitor these efforts and at its option may assume such responsibility on a case by case basis.

(d) In consideration of the Foundation's willingness to file and prosecute patent applications at its own expense, participant inventors will be requested to waive any claim of liability by the Foundation in these efforts. Otherwise, the N.I.H. must assume this responsibility and its expense.

(e) Any royalties from licensed inventions received by the N.I.H. will be distributed as follows: 40% to the research laboratory(ies) in which the invention was made, 40% to the cognizant department(s), and 20% to the School of Medicine.

2. PRODUCTS OF RESEARCH:

(a) New materials, processes, devices, scientific information, and any other research products isolated or developed in a project, whether patentable or not, will be made available to the Foundation for its evaluation and general use.

(b) Such research products may be made available to other research scientists at non-profit institutions according to

normal academic practice. However, recipient scientists should agree not to further distribute such research products and not to use them for the benefit of another commercial firm. Distribution of potentially patentable research products should not be made until the Foundation has evaluated patentability and, if appropriate, filed a patent application.

3. PUBLICATIONS:

(a) Scientific advances made under this research program will be freely reported in the scientific literature.

(b) Two (2) copies of each proposed publication, including abstracts, in the best form then available will be provided to the Program Director at least one (1) month before being submitted for publication.

(c) Based on a review by the Foundation patent attorneys of the proposed article, a brief delay in its submission for publication may be necessary to allow the filing of adequate patent applications. Such brief delay may occasionally be necessary to avoid the loss of patent rights.

(d) Two (2) copies of the final abstract and article as submitted to the publisher shall be simultaneously provided to the Program Director.

(e) Each publication will acknowledge the Foundation Company support of the research being reported.

(f) Prior to the evaluation of research results for potentially patentable inventions, participants will use caution in public or other outside presentations and discussions not to prematurely disclose critical technical information which could result in the loss of patent rights.

4. COOPERATION WITH THE FOUNDATION:

(a) It is intended that there be mutually productive and continual interchange between the N.I.H. and the Foundation scientists. For this purpose a the Foundation Project Scientist will be appointed as the primary company contact with each Project Investigator. Each Project Investigator will be available for consultation with the the Foundation Project Scientist on matters concerning the project.