[redacted] whichever first occurs. Preclinical and clinical data developed by NCI in the course of testing a NEW PRODUCT OR PROCESS that has been developed under a Project Plan shall be considered confidential trade secret information of [redacted] only if the parties agree that it is essential to a patentable invention to which [redacted] has a first option to title or an exclusive license.

To the extent permitted by the Freedom of Information Act, 5 U.S.C. 552, NCI will disclose confidential trade secret information only to employees, agents and others under a contract with NCI to comply with NCI's obligations hereunder pertaining to the use and confidentiality of such information and to inventions arising hereunder. With respect to any licensing agreement which DHHS enters into pursuant to Paragraph j of Attachment A, to Office of Management and Budget (OMB) Circular A-124 (attached hereto as Exhibit A), NCI may disclose only so much confidential trade secret information as shall be required for that purpose, and NCI agrees to inform [redacted] of what information it is disclosing at least 30 days prior to the disclosure. Notwithstanding the foregoing, NCI may not disclose to its licensee pursuant to Paragraph j of Attachment A, to OMB Circular A-124, any of [redacted] confidential trade secret information which is not developed under this Agreement, or license any of the [redacted] Technology" as defined supra.

If DHHS Freedom of Information Officials determine that the Freedom of Information Act requires disclosure of any of the information identified in this Section 4, other than disclosure of an invention which [redacted] or the DHHS may patent under this Agreement but has not filed therefor, [redacted] will be notified in writing fifteen (15) working days prior to the disclosure. The disclosure notification will include copies of the documents to be disclosed. If DHHS Freedom of Information Officials determine that the Freedom of Information Act requires disclosure of information which would identify or be essential to the use of an invention which [redacted] or the DHHS may patent under this Agreement, but has not yet filed an application therefor, such information shall be withheld from disclosure in accordance with 35 U.S.C. §205 until a patent application has been filed.

[redacted] recognizes that one of the purposes to be achieved by this Agreement is to create useful publications in the area of cancer research and agrees to cooperate with NCI in facilitating such publications so long as they do not result in the disclosure of [redacted] confidential trade secret information. Authorship should be determined by customary procedures related to individual contributions. Unless the [redacted] Vice President for Research and Development has otherwise approved the final text of such a publication, NCI agrees that if NCI or any employee, agent or consultant of NCI proposes to publish any information pertaining to the [redacted] Technology or any activities hereunder or the result thereof, NCI will cause the proposed publication to be submitted to [redacted] for review prior to publication. [redacted] agrees to determine within 30 days if said publication contains confidential trade secret information of [redacted] as defined in Section 4, and NCI agrees to delete any such information from the publication. This Agreement does not give [redacted] the right to delay or prohibit publication other than as stated above. Notwithstanding the foregoing, the publication of any preclinical or clinical data developed by NCI in the course of testing a NEW PRODUCT OR PROCESS will not be prohibited or delayed unless such publication would, as agreed by the parties, disclose information essential to a patentable invention. In that event, publication of the data will be delayed no longer than is reasonably required for [redacted] or DHHS to apply for a patent on such invention. In any event, publication will not be delayed more than 60 days.

5. [redacted] and NCI will each maintain research records fully documenting its respective activities hereunder, and will regularly exchange with the other orally and in writing current information in its possession or under its control pertinent to the ongoing development under a Project Plan of the NEW PRODUCT OR PROCESS, and shall collaborate and use its best efforts to advance development under a Project Plan of the NEW PRODUCT OR PROCESS. Without limitation of the foregoing, each party will provide the other with a full written report of its activities hereunder no less frequently than quarterly. Nothing herein will require the disclosure to NCI of information in [redacted] possession in violation of an obligation of confidentiality to a third party.

6. Each Party, in connection with its activities hereunder, will inform the other Party promptly of any invention made by its employees, agents or consultants or jointly by NCI and [redacted] employees, agents or consultants in performance of work under Exhibit B or subsequent Project Plans adopted by the Parties as provided in Section 2.

The DHHS, the parent agency of NCI, shall solely have title to any invention developed under this Agreement by NCI employees in accordance with the provisions of Executive Order 10096. If the DHHS files a patent application on any such invention, NIH and DHHS agree to, and do hereby grant an exclusive, nontransferable, revocable, and royalty-bearing license, including the right to sublicense others, subject to DHHS approval, to [redacted] to manufacture, sell, and use the invention throughout the world for five (5) years from the date of the first commercial sale, or eight (8) years from the date of the license, whichever occurs first, provided that following that expiration [redacted] shall have, and is hereby granted, a worldwide, royalty-free nonexclusive license for the remaining term of the patent. In accordance with procedures established by the DHHS, [redacted] may apply for an extension of the period of its exclusive license.

[redacted] shall have title to any invention developed under this Agreement solely by its employees subject to the reservation by the Government of a nonexclusive, nontransferable, irrevocable paid-up license to practice or have practiced for or on behalf of the United States said invention throughout the world.

The DHHS and [redacted] shall hold joint title to any inventions developed jointly under this Agreement by employees of NCI and employees of [redacted]. DHHS's patent rights shall be administered in accordance with the provisions of Executive Order 10096 and [redacted] patent rights shall be administered in accordance with the provisions of OMB Circular A-124. With respect to its undivided interest in any such joint inventions, DHHS agrees to grant and does hereby grant to [redacted] an exclusive, nontransferable, revocable, and royalty-bearing license, throughout the world, to manufacture, have manufactured, use, lease, sell or otherwise practice the invention.

If a royalty is to be paid by [redacted] under this Section 6, such royalty shall be determined through negotiation with the National Technical Information Service (NTIS), Department of Commerce, but in no case shall the royalty be ~~less~~ [redacted] than five percent (5%) of the net sales price of all patented products sold by [redacted] of its licensees.

Each Party shall file, at its expense, patent applications for subject inventions under this Agreement to which the Party holds title. [redacted] agrees to provide the DHHS copies of any patent applications filed on subject inventions with their serial numbers and filing date. [redacted] agrees to designate as Associate Attorneys on any patent application filed under this Agreement the Chief of the NIH Patent Branch with the right to inspect and make copies of all documents in the Patent and Trademark Office file wrapper.

Add reciprocity

[redacted] agrees to assign to the DHHS patent rights in any patent application filed on a subject invention that it decides to abandon and the DHHS shall have the option of filing applications on any subject invention that [redacted] elects not to patent, in which event [redacted] shall cooperate in the preparation and prosecution of the patent application filed by the DHHS.

[redacted]

10a. To the extent that title to physical materials, including, without limitation, clones, cultures or substances produced therefrom which result from the experimentation and work to be conducted hereunder, vests in the United States Government, it is understood and agreed that [redacted] the United States Government shall have the right to use or authorize others to use such NCI Materials [redacted]

10b. NCI Materials, including but not limited to clones, cultures or substances, produced by or for the U.S. Government prior to, or independent of this Agreement, including, but not limited to those NCI Materials disclosed in U.S. Application Serial No. 574,173, shall remain the property of the U.S. Government. Specifically, if such a DHHS derived clone or its product, even if it is not described as an invention, becomes an integral part of an invention the title to which accrues to [redacted] as a result of this Agreement, DHHS will retain unimpaired ability to further develop alternative options with such clone or product for any other purpose and with any other organization. Access to such NCI Materials by [redacted] shall be governed by standard Government regulations for disposition of Government property. Any previous agreements that the Government has in place relative to title, possession or use of these NCI Materials shall remain in place. NCI agrees to inform [redacted] in advance of any restrictions relating to such NCI Materials which would limit [redacted] proposed use of the NCI Materials.

10c. NCI agrees that, as between NCI and [redacted], the [redacted] Materials are the sole property of [redacted] and, at the request of [redacted], will return the [redacted] Materials. NCI further agrees that any data or information provided to [redacted] by NCI generated from the [redacted] Material provided under this Agreement may be used by [redacted] for submission to regulatory agencies with [redacted] prior NCI approval.

[redacted]. Cetus shall be free, in its sole discretion, to distribute the [redacted] Materials to others for any purpose and to use such [redacted] Material and any data and information generated thereby in obtaining regulatory approvals for products [redacted] develops using the [redacted] Materials.

10d. NCI agrees that it will not use the [redacted] Materials in human beings, without prior approvals by the U.S. Food and Drug Administration, or for any other purpose, including research which it is subject to consulting or licensing obligations to another third party or corporation, unless prior permission is obtained from [redacted].

10e. NCI understands and agrees that the [redacted] Materials are experimental in nature and that they are provided to NCI and Dr. [redacted] by [redacted] WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED, AND WITHOUT ANY REPRESENTATION OR WARRANTY THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHT.

11a. Each party will be responsible for its own compliance with all laws, requirements of Government agencies, and use of due care, and will bear its own expenses in the conduct of experiments hereunder.

11b. NCI's Institutional Review Board for clinical research will review all information related to the safety and efficacy of each product prior to administration of the product to any patient in the course of this Agreement.

11c. At NCI's request, [redacted] will provide NCI with analytical, chemical and other data related to the Material provided by [redacted] hereunder. NCI will use this data to determine the safety and efficacy of the product for clinical use. If impurities are present in the Material preparation which are caused by the use of [redacted] Technology and which prevent the use of the product in patients, [redacted] will use its best efforts to remove such impurities. If such removal is not accomplished satisfactorily, the Project involved may be discontinued at the option of NCI.

11d. Investigational New Drug Applications (IND) for clinical testing conducted by NCI under the Agreement shall be prepared jointly by NCI and [redacted]. Any such IND shall receive the prior approval of the Director, Division [redacted], and the Vice President, Research and Development, [redacted], and shall be coordinated by the Investigational Drug Branch, NCI, and such persons as the Vice President, Research and Development, of [redacted] shall designate. With respect to clinical trials being conducted by NCI under this Agreement, NCI shall serve as sponsor of the IND, and [redacted] may reference the IND, amendments and supplements thereto, and the results of experimentation and clinical trials conducted under this Agreement in any documents which it files with PHS, FDA, or similar foreign regulatory agencies.

12. This Agreement will be binding upon and inure to the benefit of the successors and assigns of [redacted]. Neither Party [redacted] may assign this Agreement or any of its rights hereunder, or delegate any of its duties hereunder, without the prior written consent of [redacted] the other Party.

13. This Agreement and the license herein granted to NCI shall remain in effect for one (1) year from the date when NCI shall have signed this Agreement and thereafter until either party terminates it by giving the other no less than thirty (30) days prior written notice of termination. The rights and obligations of the parties with respect to maintaining the confidentiality of [redacted] trade secret information, and with respect to patentable discoveries and physical materials resulting from experiments hereunder commenced prior to termination of this Agreement, will survive such termination; specifically, NCI may complete the preclinical and clinical testing of such discoveries and materials then in progress, with [redacted] cooperating as necessary in that completion.

14. Neither this Agreement nor any term or provision hereof may be waived in whole or in part except by a written instrument signed by the Vice President, Research and Development, of [redacted] and the Director, Division of [redacted] on behalf of NCI, expressly stating that it is intended to operate as a waiver or modification of this Agreement. If any term or provision of this Agreement shall be invalid or unenforceable to any

extent or in any application, then the remainder of this Agreement, and such term or provision, except to such extent or in such application, shall not be affected thereby, and each and every term and provision of this Agreement shall be valid and enforced to the fullest extent and in the broadest application permitted by law.

15. Press releases, public statements, or official reports by [redacted] or the NCI regarding their collaborative research under this Agreement may be released only after prior review and approval by the Director, Division of [redacted] National Cancer Institute, and by either the President of [redacted] or the Vice President, Research and Development, of [redacted], unless a release or statement is required by law. Such approval shall not be unreasonably delayed or withheld. If a release, statement or report is required by law, the party responsible for complying with that requirement shall notify the other party in writing prior to making the release, statement or report.

16. The validity and interpretation of this Agreement and the legal relations of the parties to it shall be governed by the laws of the State of California and the United States of America. In the event of a conflict between the laws of the State of California and the laws of the United States of America, the laws of the United States of America shall control.

This Agreement is effective as of July 27, 1983.

NATIONAL CANCER INSTITUTE

By: _____

Title: _____

Date: _____

[redacted] CORPORATION

By: [redacted]

Title: EXECUTIVE VICE PRESIDENT

Date: [redacted]

DHHS

By: _____

Title: _____

Date: _____

#2

Collaborative Research Agreement

Between

[redacted] and the
National Cancer Institute (NCI)

WHEREAS there is a need for a rapid, ultrasensitive and quantitative assay for the enzyme, $O^6$ - methylguanine methyltransferase, which catalyzes the removal and transfer of the alkyl group on $O^6$ of a quanine to a cysteine moiety on the protein;

WHEREAS Dr. [redacted] and Dr. [redacted] of NCI have, using probes prepared by [redacted] on a fee paid basis, performed experiments during Phase I of the project demonstrating that the enzyme can be assayed in the envisioned manner;

WHEREAS [redacted] and Drs. [redacted] and [redacted] wish to collaborate to develop an ultrasensitive assay for $O^6$ - methylguanine methyltransferase;

NOW, therefore, it is agreed between the National Cancer Institute and [redacted] as follows:

1. All references in this Agreement to [redacted] include any of its employees who may be responsible for carrying out this Agreement and any reference to the National Cancer Institute or NCI includes Dr. [redacted] and Dr. [redacted], and any other employees of NCI responsible for carrying out this Agreement.

2. During the term of this Agreement, NCI researchers will, during Phase II of the project, prepare extracts from a variety of cells and tumor specimens never previously assayed for the enzyme $O^6$ - methylguanine methyltransferase in order to quantitatively determine the amount of the enzyme that is present. During Phase III of the project, NCI researchers will assist [redacted] in the development of an assay kit and will perform trials using the kit on clinical specimens.

3. During the term of this Agreement, [redacted] will provide free of charge to NCI different DNA probes containing $O^6$ - methylguanine and their equivalent controlled probes. In Phase III of the project, [redacted] will link the relevant probes to solid supports, thus simplifing the assay, and assist NCI in the development of the assay in kit form.

4. NCI agrees to use all materials furnished to it by [redacted] under this Agreement solely for the research purposes of this Agreement.

5. NCI agrees that during the term and any subsequent extension of this Agreement and for a period of three (3) years thereafter, it will not use for any purpose other than the research contemplated under this Agreement or, except to the extent required by the Freedom of Information Act, 5 U.S.C. 552, disclose to any third party, without the prior written consent of [redacted] any Confidential Information. As use herein, "Confidential Information" shall mean trade secrets, business data and technical data received from [redacted] under this Agreement or data and materials developed hereunder, if [redacted] has any patent rights to that material under this Agreement. The provisions of this paragraph shall not apply to Confidential Information which was already known to NCI, or is or becomes publicly known under circumstances involving no breach of this Agreement or other fault of NCI, or is furnished to NCI by a third party who has the right to disclose such information. To the extent permitted by the Freedom of Information Act, 5 U.S.C. 552, NCI further agrees to limit access to any Confidential Information to only those persons who will be engaged in employing such information in the research and to those employees of the Department of Health and Human Services (HHS) who are responsible for responding to requests for records under the Freedom of Information Act. If National Institutes of Health (NIH) or HHS Freedom of Information officials determine that the FOIA requires disclosure of any of [redacted] Confidential Information, [redacted] will be notified in writing ten (10) working days prior to the disclosure and the notification will include a copy of the material that is proposed to be disclosed.

6. NCI and [redacted] will be free to publish the results of the collaborative research, with due regard for determining authorship in accordance with accepted practice and for the nondisclosure of Confidential Information. In

order to protect such information, NCI agrees to give [redacted] at least thirty (30) days to review any proposed article resulting from the collaborative research and NCI will not submit any such article for publication prior to obtaining [redacted] approval. That approval may be withheld only if [redacted] reasonably determines that the article contains Confidential Information.

7. The Department of Health and Human Services, the parent agency of NCI, shall have title to any invention developed under this Agreement by NCI employees unless the material furnished by [redacted] is claimed as a part of the invention. In that event, [redacted] shall have a first option title as defined in Office of Management and Budget (OMB) Circular A-124 (attached hereto at Tab A) and NCI shall have all of the Government rights prescribed therein. If NCI files a patent application on any such invention, NCI and HHS agree and do hereby grant an exclusive, nontransferable, royalty-free license, including the right to sublicense others, to [redacted] to manufacture, sell and use the invention throughout the United States, its territories, possessions and dependencies for a period of five (5) years from the date of the first commercial sale, or eight (8) years from the date of of the license, which ever occurs first, under the terms contained in the standard License Agreement attached hereto at Tab B.

8. [redacted] shall have title to any invention developed under this Agreement solely by its employees. If [redacted] files a patent application on any such invention, [redacted] agrees and does hereby grant to HHS a nonexclusive, nontransferable, irrevocable, paid-up license, including the right to sublicense others, throughout the world, to manufacture, have manufactured, lease or use the invention for governmental purposes.

9. HHS and [redacted] shall hold joint title to any invention developed jointly under this Agreement by employees of NCI and employees of [redacted]. With respect to its portion of any joint invention, HHS shall grant to [redacted] an exclusive, nontransferable, irrevocable, paid-up license, including the right to sublicense others, throughout the world, to manufacture, have manufactured, use, lease, sell or otherwise practice or dispose of its portion of the joint invention, subject to reservation to HHS of a nonexclusive, irrevocable, royalty-free paid-up license, including the right to sublicense others, throughout the world for governmental purposes. With respect to its

portion of any joint invention, [redacted] shall grant to HHS a nonexclusive, irrevocable, royalty-free, paid-up license, including the right to sublicense others, throughout the world for governmental purposes.

10. The term of this Agreement shall be eighteen (18) months from the date of execution of the Agreement, unless extended by written agreement of the parties. This Agreement may be terminated by either party upon thirty (30) days prior written notice and thereafter the parties have no further obligation to supply materials or conduct research. All other rights and obligations set forth herein which vest prior to the termination, shall survive any termination of the Agreement. Upon the termination or conclusion of this Agreement, probes furnished to NCI will be promptly returned to [redacted]. Any kits that have been developed upon the termination or conclusion of the Agreement, will be divided equally between [redacted] and NCI.

11. No indemnification for damages is intended or provided under this Agreement. Each party shall be liable for any damages it incurs as a result of its activities under this Agreement.

This Agreement is effective as of _____.

[redacted]

National Cancer Institute

Assistant Secretary for Health

# 1

PROPOSED AGREEMENT

BETWEEN

[redacted] INC. AND THE NATIONAL CANCER INSTITUTE

WHEREAS [redacted], Inc., [redacted] USA, (hereinafter designated as [redacted]) has developed and is currently sole owner, by virtue of patent rights and ownership of proprietary know-how, of certain technology directed to the encapsulation of core materials, including biological materials and living cells, within semipermeable membranes, to methods of producing such capsules, and to processes employing such capsules (which technology as it presently exists and as it shall be developed or acquired by [redacted] independently of this Agreement, shall hereinafter be designated as "Encapsulation Technology"); and

WHEREAS the National Cancer Institute, a component of the United States Department of Health and Human Services (DHHS), through its Division of Cancer Treatment at the Frederick Cancer Research Facility, Frederick, MD 21701, (hereinafter designated as "NCI") engages in cancer research; and

WHEREAS the parties desire to engage in a joint development program for the application of the Encapsulation Technology to various experimental projects in the area of cancer research;

NOW, THEREFORE, IT IS AGREED BETWEEN DAMON AND NCI AS FOLLOWS:

1. The activities conducted under this Agreement are subject to the provisions of Attachment A to Office of Management and Budget (OMB) Circular A-124, which is attached hereto as Exhibit A, and by this reference made a part hereof. With respect to Exhibit A, the term "Contractor" will mean [redacted], Inc., and the term "Federal Agency" will mean the Department of Health and Human Services.

2. [redacted] and NCI will engage in joint experimentation in the area of cancer research using the Encapsulation Technology. Such experimentation shall be organized into discrete projects each of which is directed toward experimentation with and development of a "NEW PRODUCT OR PROCESS." Each project shall be conducted under the joint direction of an appropriate representative of each of [redacted] and NCI. The scope of each project and particular allocation of responsibilities between the parties with respect to each project will be more particularly specified in a written project plan to be agreed upon by the parties. The NCI may at its option draft the initial proposal for each such plan after consultation with [redacted] and the final form thereof shall be subject to the approval of both parties. The first project plan is attached hereto as Exhibit B, and the signing of this Agreement signifies the parties' approval of that plan. Subsequent project plans shall be deemed to have been adopted by the parties upon the written approval thereof by any officer of [redacted] and the Associate Director, Biological Response Modifiers Program (BRMP) on behalf of the NCI. The attached initial plan and all plans which are subsequently adopted may be modified upon the written approval of any officer of [redacted] and the Associate Director, BRMP, on behalf of NCI.

3. [redacted] grants to NCI a nonexclusive, nonassignable, royalty-free license, without the right to sublicense, to practice the Encapsulation Technology only during the term of this Agreement, solely for the purpose of experimenting with, developing, and using in preclinical and clinical trials a NEW PRODUCT OR PROCESS in accordance with project plans approved and adopted under Section 2 of this Agreement. The Encapsulation Technology shall at all times remain under the control of [redacted]. NCI warrants that it will use the Encapsulation Technology only as authorized by [redacted] in this Agreement or as may be subsequently authorized by [redacted] in writing and agrees that use for any such unauthorized purpose shall, without limiting [redacted] other rights and remedies therefor, have the effect of terminating this Agreement and all of NCI's rights hereunder.

   Nothing in this Agreement shall be deemed to grant to DHHS (including NCI) or to any licensee of DHHS any rights or interests in any of the "Encapsulation Technology," as defined supra, except as specifically set forth in this Section 3.

4. To the extent permitted by the Freedom of Information Act, 5 U.S.C. 552, NCI agrees to use the Encapsulation Technology only in accordance with this Agreement and otherwise to treat the Encapsulation Technology, improvements to it arising from this Agreement and all other information having commercial value which pertains to the nature, manufacture, use and market potential of a NEW PRODUCT OR PROCESS, to which [redacted] has, under this Agreement, a first option to title or an exclusive license, as confidential trade secret information of [redacted] for the term of this Agreement plus an additional three (3) years beyond the term of this Agreement or until it becomes public information by virtue of the issuance of a patent, or by lawful disclosure not emanating from either [redacted] or NCI, whichever first occurs. Preclinical and clinical data developed by NCI in the course of testing a NEW PRODUCT OR PROCESS that has been developed shall be considered confidential trade secret information of [redacted] only if the parties agree that it is essential to a patentable invention to which [redacted] has a first option to title or an exclusive license.

   To the extent permitted by the Freedom of Information Act, 5 U.S.C. 552, NCI will disclose confidential trade secret information only: to employees, agents and others under a contract with NCI to comply with NCI's obligations hereunder pertaining to the use and confidentiality of such information and to inventions arising hereunder. With respect to any licensing agreement which DHHS enters into pursuant to Paragraph j of Attachment A, to Office of Management and Budget (OMB) Circular A-124 (attached hereto as Exhibit A), NCI may disclose only so much confidential trade secret information as shall be required for that purpose, and NCI agrees to inform [redacted] of what information it is disclosing at least 30 days prior to the disclosure. Notwithstanding the foregoing, NCI may not disclose to its licensee pursuant to Paragraph j of Attachment A, to OMB Circular A-124, any of [redacted] confidential trade secret information which is not developed under this Agreement, or license any of the "Encapsulation Technology" as defined supra.

If DHHS Freedom of Information Officials determine that the Freedom of Information Act requires disclosure of any of the information identified in this Section 4, other than disclosure of an invention which [redacted] or the DHHS may patent under this Agreement but has not filed therefor, [redacted] will be notified in writing fifteen (15) working days prior to the disclosure. The disclosure notification will include copies of the documents to be disclosed. If DHHS Freedom of Information Officials determine that the Freedom of Information Act requires disclosure of information which would identify or be essential to the use of an invention which [redacted] or the DHHS may patent under this Agreement, but has not yet filed an application therefor, such information shall be withheld from disclosure in accordance with 35 U.S.C. 205 until a patent application has been filed.

[redacted] recognizes that one of the purposes to be achieved by this Agreement is to create useful publications in the area of cancer research and agrees to cooperate with NCI in facilitating such publications so long as they do not result in the disclosure of [redacted] confidential trade secret information. Authorship should be determined by customary procedures related to individual contributions. Unless a [redacted] employee coauthor (if any) has otherwise approved the final text of such a publication, NCI agrees that if NCI or any employee, agent or consultant of NCI proposes to publish any information pertaining to the Encapsulation Technology or any activities hereunder or the results thereof, NCI will cause the proposed publication to be submitted to [redacted] for review prior to publication. [redacted] agrees to determine within 30 days if said publication contains confidential trade secret information of [redacted] as defined in Section 4, and NCI agrees to delete any such information from the publication. This Agreement does not give [redacted] the right to delay or prohibit publication other than as stated above. Notwithstanding the foregoing, the publication of any preclinical or clinical data developed by NCI in the course of testing a NEW PRODUCT OR PROCESS will not be prohibited or delayed unless such publication would, as agreed by the parties, disclose information essential to a patentable invention. In that event, publication of the data will be delayed no longer than is reasonably required for [redacted] or DHHS to apply for a patent on such invention.

5. Each of [redacted] and NCI will maintain research records fully documenting its respective activities hereunder, and will regularly exchange with the other orally and in writing current information in its possession or under its control pertinent to the ongoing development of the NEW PRODUCT OR PROCESS, and shall collaborate and use its best efforts to advance development of the NEW PRODUCT OR PROCESS. Without limitation of the foregoing, each party will provide the other with a full written report of its activities hereunder no less frequently than quarterly. Nothing herein will require the disclosure to NCI of information in [redacted] possession as to which [redacted] is under an obligation of confidentiality to a third party.

6. NCI will in connection with its activities hereunder inform [redacted] promptly of any invention made by NCI's employees, agent or consultants or jointly by NCI and [redacted] employees, agents or consultants in performance of work hereunder. The party entitled, under this Agreement, to hold title to an

invention arising hereunder (see Sections 7-9), shall be responsible for the preparation, filing and prosecution of each patent application relating thereto, including the costs associated therewith, except as specified in Section 8 below with respect to certain foreign counterpart patent applications which [redacted] may file for and on behalf of the Government. NCI and DHHS shall cooperate, as requested, in the preparation, filing and prosecution of a patent application by [redacted]. If DHHS is preparing a patent application, it will consult closely with [redacted] in advance of filing and give due consideration to [redacted] suggestions.

7. DHHS shall have title to an invention arising hereunder if (i) the only named inventor or inventors are employees of NCI, or (ii) the invention is a clone and/or the antibody produced therefrom which was produced at NCI facilities, and the Encapsulation Technology is not claimed as a part of the invention.

8. In order to receive any license under this section [redacted] must advise NCI in writing, within 90 days after the date on which DHHS files for a United States patent, that [redacted] intends to develop and commercialize the invention which is the subject of the patent application. If the only named inventor or inventors of an invention arising hereunder are employees of NCI (see Section 7(i)), DHHS shall grant and does hereby grant at the time of execution of this Agreement, an exclusive, worldwide, royalty-free license to [redacted] which shall expire on the earlier of five (5) years from the date of the first commercial sale or use of the invention or eight (8) years from the issuance date of a United States patent on the invention; provided that, following that expiration [redacted] shall have, and is hereby granted, a worldwide royalty-free nonexclusive license that will terminate upon the expiration of the patent held by the Government claiming such invention. Each exclusive license granted to [redacted] shall be subject to the reservation to the Government of (1) a right to use the invention for governmental purposes and to grant others royalty-free licenses to use the invention for such governmental purposes, and (2) the march-in and other "Federal Agency" rights set forth in Exhibit A. If an invention arising hereunder is a clone, and/or the antibody produced therefrom which was produced at NCI facilities and the Encapsulation Technology is not claimed as a part of the invention, (see Section 7(ii)), DHHS shall grant and does hereby grant [redacted] a nonexclusive, worldwide, royalty-free license for the life of the patent held by the Government claiming such invention. Each license granted to [redacted] under this section incorporates a right to sublicense, to make, use and sell the invention (and the subject matter of any patent held by the Government claiming such invention).

[redacted] may file foreign counterpart patent applications at its own expense for and on behalf of the United States Government, provided that [redacted] informs the DHHS Patent Branch as to the countries in which it intends to seek patent protection, and the foreign counterpart patent applications are filed within six (6) months after the filing date of the United States patent application. It is understood and agreed that, with respect to all foreign counterpart patent applications so filed, [redacted] shall be solely

responsible for maintaining the foreign patent applications and any patents that may issue thereon, including the payment of all fees and annuities, and that [redacted] may abandon any such patents and patent applications after informing the DHHS Patent Branch of its intention to abandon not less than thirty (30) days prior to the date a response to an official action from the patent examiner or an annuity payment is due, and offering the DHHS the opportunity to assume the prosecution and/or maintenance. [redacted] agrees that its use of such patent rights granted to it hereunder will benefit the public interest. [redacted] will have control over and bear the costs of any actions alleging infringement by third parties of such patents and actions alleging that [redacted] use of such patent infringes their rights. NCI and DHHS agree to cooperate in [redacted] conduct and settlement of any such action.

9a. Except as provided in Section 7(ii), [redacted] shall have a first option to title to a Subject Invention, as defined in Exhibit A, resulting from the performance of work under this Agreement if the inventor was at the time of conception or actual reduction to practice of the Subject Invention, an employee of, agent of, or under contract with [redacted], as provided in Exhibit A.

9b. Except as provided in Section 7(ii), DHHS agrees to execute a written transfer and assignment to [redacted] of its right of title to each invention, and to any patent held by DHHS on such an invention, made jointly by employees of NCI and [redacted] in performance of work under this agreement. The title held by [redacted] under such a transfer and assignment shall be subject to all the applicable terms and conditions of Exhibit A.

9c. With respect to any invention arising hereunder in which [redacted] retains title, DHHS shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced, the invention on behalf of the United States throughout the world. DHHS hereby agrees to execute any releases, waivers, assignments, or other instruments necessary to perfect [redacted] rights under Sections 9a. and 9b. of this Agreement.

10a. To the extent that title to physical materials, including, without limitation, clones, cultures or substances produced therefrom which result from the experimentation and work to be conducted hereunder, vests in the United States Government, it is understood and agreed that: (i) the United States Government shall have the right to use or authorize others to use such materials; and (ii) [redacted] shall have the nonexclusive right to make, use and sell such materials for its own account. Provision of materials by the NCI to [redacted] for production shall not imply transfer of ownership of such materials. Nothing in this Section 10 shall be construed to diminish the rights of the parties under Sections 7, 8, 9a, 9b and 9c.

10b. Physical materials, including but not limited to clones, cultures or substances, produced by or for the U.S. Government prior to, or independent of this agreement shall remain the property of the U.S. Government. Specifically, if such an HHS derived clone or its product, even if it is not

described as an invention, becomes an integral part of an invention the title to which accrues to [redacted] as a result of this Agreement, HHS will retain unimpaired ability to further develop alternative options with such clone or product for any other purpose and with any other organization. Access to such materials by [redacted] shall be governed by standard Government regulations for disposition of Government property. Any previous agreements that the Government has in place relative to title, possession or use of these materials shall remain in place. NCI agrees to inform [redacted] in advance of any restrictions relating to such materials which would limit [redacted] proposed use of the materials.

11. NCI and [redacted] warrant that they will conduct their respective activities hereunder in strict compliance with this Agreement so that no third party rights in any invention arising hereunder are created except as described herein.

12a. Each party will be responsible for its own compliance with all laws, requirements of Government agencies, and use of due care, and will bear its own expenses in the conduct of experiments hereunder.

12b. NCI's Institutional Review Board for clinical research will review all information related to the safety and efficacy of each product prior to administration of the product to any patient in the course of this Agreement.

12c. At NCI's request, [redacted] will provide NCI with analytical, chemical and other data related to the product provided by [redacted] hereunder. NCI will use this data to determine the safety and efficacy of the product for clinical use. If impurities are present in the product preparation which are caused by the use of Encapsulation Technology and which prevent the use of the product in patients, [redacted] will use its best efforts to remove such impurities. If such removal is not accomplished satisfactorily, the project involved may be discontinued at the option of NCI.

13. This Agreement will be binding upon and inure to the benefit of the successors and assigns of [redacted]. NCI may not assign this Agreement or any of its rights hereunder, or delegate any of its duties hereunder, without the prior written consent of [redacted].

14. This Agreement and the license herein granted to NCI shall remain in effect for one (1) year from the date set forth below and thereafter until either party terminates it by giving the other no less than thirty (30) days' prior written notice of termination. The rights and obligations of the parties with respect to maintaining the confidentiality of [redacted] trade secret information, and with respect to patentable discoveries and physical materials resulting from experiments hereunder commenced prior to termination of this Agreement, will survive such termination; specifically, NCI may complete the testing, preclinical and clinical, of such discoveries and materials, with [redacted] cooperating as necessary in that completion, and NCI's and [redacted] rights to use such discoveries and materials in such preclinical and clinical trials as set forth in this Agreement will not be restricted by such termination.

15. Neither this Agreement nor any term or provision hereof may be waived in whole or in part except by a written instrument signed by one of [redacted] officers and the Director, Division of Cancer Treatment, on behalf of NCI, expressly stating that it is intended to operate as a waiver or modification of this Agreement. If any term or provision of this Agreement shall be invalid or unenforceable to any extent or in any application, then the remainder of this Agreement, and such term or provision, except to such extent or in such application, shall not be affected thereby, and each and every term and provision of this Agreement shall be valid and enforced to the fullest extent and in the broadest application permitted by law.

This Agreement is effective as of _____.

NATIONAL CANCER INSTITUTE [redacted]

_____ _____