# RESEARCH AGREEMENT Clinical Trial

THIS AGREEMENT is made effective as of July 20, 2005 (the "Effective Date") by and among Idenix Pharmaceuticals, Inc., organized under the laws of the state of Delaware, with offices located at 60 Hampshire Street, Cambridge, Massachusetts 02139, (hereinafter "SPONSOR"); San Mateo Medical Center (hereinafter "INSTITUTION") and Joanne Imperial, M.D. (hereinafter "INVESTIGATOR").

# 1. Scope of Work.

- 1.1 INSTITUTION and INVESTIGATOR, acting as independent contractors for SPONSOR, agree to conduct a study entitled: "A Phase IIb Clinical Trial to Evaluate the Combination of Pegylated Interferon Alfa plus Valopicitabine (NM283) in Treatment-Naïve Patients with Chronic Hepatitis C" (the "Study") in accordance with Protocol NV-08A-006, dated July 12, 2005 (the "Protocol"), which has been previously provided to the INSTITUTION and INVESTIGATOR.
- 1.2 INSTITUTION and INVESTIGATOR agree to devote their best efforts to effectively perform the work described under this Agreement. INSTITUTION and INVESTIGATOR shall be responsible for performing the Study, which shall include, but shall not be limited to:
- Supervise any individual performing portions of the Study:
- Exercise independent medical judgment as to the compatibility of each subject with the Study Protocol requirements;
- Obtain from each subject in the Study a signed consent form which has been approved by the Institutional Review Board ("IRB") and SPONSOR in accordance with 21 C.F.R. Part 50;
- Review all Case Report Forms ("CRFs") for accuracy and completeness;
- Submit all data in a timely manner;
- Notify SPONSOR and IRB of any unanticipated or serious adverse reactions to the Study investigational product or control product ("Investigational Products");
- Notify SPONSOR and the IRB of any deviations from the Protocol;
- Maintain adequate records of subject identification, clinical observations, laboratory tests and investigational product receipts and disposition;
- Cooperate with SPONSOR in all of its efforts to monitor the Study;
- Protect Confidential Information, as defined below, from unauthorized use or disclosure in accordance with this Agreement and other agreements that are in effect between SPONSOR and INSTITUTION or INVESTIGATOR for the protection of Confidential Information.

INSTITUTION and INVESTIGATOR shall conduct and perform the Study in conformance with (i) all applicable local, state, and federal laws and regulations, (ii) the Protocol, (iii) instructions provided by SPONSOR, and (iv) generally accepted standards of

Good Clinical Practice. INSTITUTION and INVESTIGATOR shall deliver completed CRFs to SPONSOR and shall resolve all reasonable queries of SPONSOR in a timely manner.

- 1.3 The Protocol and any alteration in or amendment to the Protocol shall be approved by SPONSOR and the IRB for the Study.
- 1.4 INSTITUTION and INVESTIGATOR shall, upon SPONSOR's request, permit FDA's or SPONSOR's representatives, at reasonable times and in a reasonable manner, to visit the facilities for the Study to validate CRFs against the original data in Study subjects' records and monitor work performed. Copies of tests used to determine response evaluation will be provided to SPONSOR if requested. Reasonable costs for duplication and transport of imaging copies will be reimbursed to INSTITUTION and INVESTIGATOR by SPONSOR once estimated amounts are approved by SPONSOR.
- 1.5 Federal regulations require approval (and continuous review) of this Study by an IRB. To the best of INSTITUTION's and INVESTIGATOR's knowledge, the INSTITUTION's IRB is in full compliance with all applicable federal regulations. INVESTIGATOR will not place any subjects on the Protocol until the Study has been submitted to and approved by the IRB.
- 1.6 INVESTIGATOR will obtain a written informed consent given by each subject or such subject's authorized representative. Each signed original informed consent form will remain in the subject's record. The consent should authorize, on a confidential basis, the SPONSORS use of information resulting from or provided in connection with the Study. Clinical progress and laboratory findings will be reported promptly and accurately in a format designed by the SPONSOR. No discrepancies will exist between findings reported to the SPONSOR and the subject's medical records.
- 1.7 INVESTIGATOR agrees to report all adverse events to SPONSOR, as defined and required by the Protocol, including the immediate reporting (no later than within twenty-four hours of knowledge of the event) to SPONSOR's Safety Officer by facsimile of all serious adverse events whether in INVESTIGATOR's judgment related to the investigational product or not.

Reports to SPONSOR shall be sent via facsimile to:

Karin Galil, MD Project Safety Officer Idenix Pharmaceuticals, Inc. 60 Hampshire Street Cambridge, MA 02139 USA Telephone: 1-617-995-9870 Fax: 1-617-995-9940

#### 2. Term.

The term of this Agreement shall commence on the Effective Date and shall continue until the delivery of all services and materials required by this Agreement, unless earlier terminated in accordance with this Agreement. The INSTITUTION represents and warrants that it has adequate staff and resources to complete its obligations under this Agreement according to its terms and the Protocol in a timely manner.

#### 3. Termination.

- 3.1 This Agreement may be terminated by SPONSOR upon fifteen (15) days prior written notice to INSTITUTION and/or INVESTIGATOR.
- 3.2 Immediately upon receipt of a notice of termination, INSTITUTION and/or INVESTIGATOR shall stop entering subjects into the Study and shall cease conducting procedures, to the extent medically permissible, on subjects already entered into the Study. INSTITUTION and INVESTIGATOR shall use their best efforts to conclude and/or transfer all data pertaining to the Study and return all Investigational Products, all materials used in the Study and all Confidential Information, as hereinafter defined, to SPONSOR as expeditiously as possible and in accordance with good clinical practices and all applicable laws and regulations.
- 3.3 In the event of early termination, the sum payable under this Agreement shall be limited to pro-rated fees relating to work actually performed pursuant to the Protocol prior to the effective date of termination. Any funds not due INSTITUTION and/or INVESTIGATOR under this calculation but already advanced to INSTITUTION and/or INVESTIGATOR shall be returned to SPONSOR within thirty (30) days of the notice of termination.
- 3.4 In the event that the work necessary to conclude this Agreement or transfer the Study to SPONSOR or its designee is not completed by the INVESTIGATOR and/or INSTITUTION within the fifteen (15) day notice period set forth in Section 3.1 above, after the expiration of such period, the INVESTIGATOR and/or INSTITUTION will perform only those services as SPONSOR may direct in writing, with payment terms to be mutually agreed upon by the parties. Any payments due to the INVESTIGATOR and/or INSTITUTION pursuant to this Section 3.4 shall be made within thirty (30) days after the completion of such post-termination services.
- 3.5 This Agreement may immediately be terminated by SPONSOR, upon written notice, if any of the following conditions occur and such termination shall be effective as of the date of receipt of such notice by INVESTIGATOR.
  - (a) if the regulatory authorization and approval to perform the Study is withdrawn;
  - (b) if animal, human and/or toxicological test results, in the opinion of SPONSOR, support termination of the Study;

(c) if the emergence of any adverse reaction or side effect with the Investigational Products administered in the Study is of such magnitude or incidence in the opinion of the SPONSOR to support termination.

# 4. Costs and Billing.

4.1 The approved reimbursement for the Study to be conducted by INSTITUTION and INVESTIGATOR is set forth in the Investigator Budget attached hereto as Exhibit A.

4.2 It is agreed that payment of the sums due under this Agreement shall be made payable to:

Name:

San Mateo Medical Center

(the "Payee")

Address:

Clinical Trials and Research Unit 222 W. 39<sup>th</sup> Avenue

San Mateo, CA 94403

Tax ID#

94-6000532

- 4.3 As described in the Protocol, subjects participating in this Study may have as many as seventeen (17) contacts with the INSTITUTION. As set forth in Exhibit A hereto, payments for Study participation will be made five (5) times throughout the Study based on the number of evaluable subjects enrolled into the study. Payments will be made for evaluable subjects only. An evaluable subject means a subject who meets all inclusion/exclusion criteria to enroll in the Study and does not have significant Study Protocol violations that would cause the exclusion of his/her data from analysis. Evaluable subjects not completing the Study will be paid for on a prorated basis according to the number of completed visits. A final payment will be made following (a) the submission of all subject Study documentation to SPONSOR, (b) query resolution and the locking of the database, and (c) the return of unused Study Investigational Products, any materials used in the study and all Confidential Information, as hereinafter defined. Payments will be dependent upon the data as described in the Protocol being submitted to the SPONSOR in a timely and satisfactory manner on the case report form provided. IRB costs will be paid separately within thirty (30) days upon receipt of invoice from the INVESTIGATOR to the SPONSOR.
- 4.4 As many as twenty-four (24) sites may participate in this Study. Study enrollment will terminate when all one-hundred and seventy-five (175) subjects have been fully enrolled, or at the SPONSOR's discretion. Upon notification of the date of enrollment termination, INSTITUTION and/or INVESTIGATOR agree to terminate all activities associated with the screening/enrollment of subjects, unless otherwise directed by SPONSOR.

#### 5. Confidentiality.

In furtherance of the conduct of the Study, it may be necessary or desirable for SPONSOR hereto to disclose proprietary, trade secret and/or other confidential information to

the INSTITUTION, INVESTIGATOR and/or the INSTITUTION's or INVESTIGATOR's employees or agents. For purposes of this Agreement, all results and data, preliminary or final, relating to the Study, the investigator brochure, case report forms, and any other Study-related documents, and all know-how, discoveries, inventions, drawings, samples, Study Investigational Products, materials, models or other information disclosed by SPONSOR to INSTITUTION or INVESTIGATOR will be considered Confidential Information and shall be deemed to be the sole and exclusive confidential property of SPONSOR. Each party hereto agrees that any such Confidential Information shall be used only in connection with the legitimate purposes of this Agreement, shall be disclosed only to those who have a need to know it and are obligated to keep same in confidence. INSTITUTION and INVESTIGATOR agree to ensure that INSTITUTION and INVESTIGATOR and their employees and agents shall maintain such Confidential Information in confidence and not disclose it to any third party or use it for the benefit of the INSTITUTION or INVESTIGATOR, any of the INSTITUTION's or INVESTIGATOR's employees or agents, or any third party, without the prior written consent of SPONSOR and agree to be responsible for any unauthorized disclosure or use of such information by its or his/her employees or agents. At any time upon the request of SPONSOR, all tangible expressions of Confidential Information in written, electronic, tangible or other form shall be delivered to SPONSOR or, at SPONSOR's option, destroyed; provided, however, that INSTITUTION or INVESTIGATOR may retain a single copy of such Confidential Information for regulatory purposes as set forth in Section 13.6 and to demonstrate compliance with this Agreement.

The obligations of this Section shall not extend to:

- (i) information which is publicly available at the time of disclosure or development under this Agreement or which becomes publicly available, except by breach of this Agreement;
- (ii) information which INSTITUTION and/or INVESTIGATOR can demonstrate they possessed prior to this Agreement or developed independently without reference to or reliance upon the Confidential Information;
- (iii) information which becomes available to INSTITUTION and/or INVESTIGATOR from a third party which is not legally prohibited from disclosing such information;
- (iv) information which INSTITUTION and/or INVESTIGATOR is legally required to disclose, provided that SPONSOR is notified as soon as possible of any such requirement to allow SPONSOR to seek a protective order or other modifications to the requirement; or
- (v) a Study subject's specific medical information, as necessary for the appropriate medical care of the subject.

The obligations of the INVESTIGATOR set forth in this Section 5 are in addition to and not in substitution for the obligations arising pursuant to the Confidentiality and Non-Disclosure Agreement between INVESTIGATOR and SPONSOR.

No party hereto shall use the other party's name, symbol, logotype or mark in connection with any advertising, press release or promotion without prior written consent.

Nothing in this Agreement does, is intended to, or shall be construed to create, confer, give effect to or otherwise imply in INVESTIGATOR, INSTITUTION or anyone claiming through INVESTIGATOR or INSTITUTION any license, right or property interest in Confidential Information, SPONSOR patents or patent rights, SPONSOR trademarks or trade names, or other SPONSOR property.

# 6. Intellectual Property.

The respective exisiting inventions, kmow-how and technologies of INSTITUTION, INVESTIGATOR and SPONSOR are their separate property and are not affected by this Agreement. INVESTIGATOR and INSTITUTION agree to promptly and fully disclose to SPONSOR, in writing, any discovery, invention or reduction to practice, whether patentable or not, made by INSTITUTION, INVESTIGATOR, Subinvestigators or other employees or agents of INSTITUTION OR INVESTIGATOR in the performance of the Study, or arising directly or indirectly in whole or in part from the Study Investigational Products and/or the Confidential Information (hereinafter "Inventions"). All such Inventions shall be the sole and exclusive property of the SPONSOR. INVESTIGATOR and such other personnel shall assign all of their rights, title and interest in such Inventions to INSTITUTION, and at the request of SPONSOR, INSTITUTION agrees to execute, without charge to SPONSOR, irrevocable assignments of all such rights, title and interest in and to such Inventions to SPONSOR or its nominee. INSTITUTION and INVESTIGATOR further agree to use reasonable efforts to assist SPONSOR, at SPONSOR's cost and expense, to file patent applications on such Inventions. In addition, SPONSOR shall have an option to a license to make, use or sell any other invention reduced to practice in the performance of the Study by INVESTIGATOR or any other INSTITUTION personnel on reasonable terms and conditions as the parties mutually agree in a subsequent writing.

### 7. Publication.

Any formal presentation or publication of data collected as a direct or indirect result of this Study will be considered as a joint presentation or publication by the Investigators and the SPONSOR. As is customary for multicenter trials, publication by individual Study centers or INVESTIGATOR/INSTITUTION will not be allowed prior to the publication of the principal Study abstract(s) and manuscript(s), without the explicit written permission of SPONSOR. SPONSOR will determine authorship of the principal Study manuscript(s) in conjunction with the Investigators. All Investigators contributing at least one evaluable subject to the Study will be considered as co-authors for the principal Study manuscript(s). For such manuscript(s), masthead roles for Investigators will be determined based on subject enrollment and scientific contributions to the Study.

Subsequent to publication of the principal Study manuscript(s) and abstract(s), INSTITUTION and INVESTIGATOR may, consistent with academic and scientific standards,

publish or present the results of work performed in accordance with the Study, provided that any proposed publication, presentation, abstract, submission or disclosure (collectively hereinafter "Proposed Publication") is first reviewed and commented upon by SPONSOR prior to submission for publication or presentation. INSTITUTION and INVESTIGATOR will submit any Proposed Publication to SPONSOR for review and comment at least sixty (60) days prior to submission to a third party. If SPONSOR believes in good faith that any Proposed Publication contains any proprietary or Confidential Information, SPONSOR shall have the right to remove such references to such Confidential Information. At the request of SPONSOR, each of the INSTITUTION and INVESTIGATOR agree to withhold submission of a Proposed Publication for an additional period of up to sixty (60) days after receipt of SPONSOR's comments, in order to allow filing of patent application(s) relating to an Invention (as defined in this Agreement) or otherwise seek protection of information to be published or otherwise disclosed.

#### 8. Indemnification.

- Indemnification by INSTITUTION/INVESTIGATOR. To the extent permitted 8.1 by law, INSTITUTION and/or INVESTIGATOR, jointly and severally, shall hold harmless, defend and indemnify SPONSOR, its successors in interest, affiliates, shareholders, directors, officers, employees, representatives and agents of any kind (the "SPONSOR Indemnified Parties") for any and all damages, losses, costs, expenses and liabilities of any kind including, without limitation, reasonable attorneys fees incurred in connection with any claim, action or proceeding against any of the SPONSOR Indemnified Parties arising or reasonably expected to arise from the INSTITUTION's and/or INVESTIGATOR's obligations under this Agreement, to the extent such claims result from (i) the negligence, medical malpractice, wrongful acts or omissions, and/or intentional misconduct of INSTITUTION and/or INVESTIGATOR, (ii) a material breach of this Agreement by INSTITUTION and/or INVESTIGATOR, or (iii) the material failure of INSTITUTION and/or INVESTIGATOR to comply with the terms of the Study Protocol, all FDA and other applicable laws, rules and regulations and all other directions. specifications and recommendations furnished by SPONSOR to INVESTIGATOR for the proper use of Investigational Products or the administration of the Study under this Agreement; provided, however, INSTITUTION and/or INVESTIGATOR shall have no obligation hereunder to SPONSOR to the extent that any such claim arises from the negligence, gross negligence, or intentional wrongful acts or omissions of SPONSOR or any of the SPONSOR Indemnified Parties.
- 8.2 Indemnification by SPONSOR. SPONSOR shall hold harmless, defend and indemnify INSTITUTION, its trustees and officers, INVESTIGATOR, and INSTITUTION's or INVESTIGATOR's employees, representatives and agents providing services in accordance with the Agreement under INVESTIGATOR's direct supervision ("INSTITUTION Indemnified Parties") for any and all damages, losses, costs, expenses and liabilities of any kind, including without limitation, reasonable attorneys fees, incurred in connection with any claim, action or proceeding brought by or on behalf of a Study subject against any of the INSTITUTION Indemnified Parties alleging a bodily injury or death resulting from the use of any Investigational Product supplied by SPONSOR for the Study in connection with the Protocol, provided that: (i) the handling, storage and use of such Investigational Products and the conduct of the Study

complied with the terms of the Protocol; (ii) said use of such Investigational Products was in accordance with International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guidelines ("ICH Guidelines"), Good Clinical Practice ("GCP"), all other information, instructions, or warnings furnished by SPONSOR, and applicable state and federal laws and regulations; (iii) IRB approval of the Protocol was obtained where required by law or INSTITUTION procedure; (iv) an Informed Consent form approved by the IRB and the SPONSOR was executed by the claimant; provided, however, that SPONSOR shall have no obligation hereunder to any of the Institution Indemnified Parties to the extent that any such claim arises from the negligence, medical malpractice, gross negligence, or intentional wrongful acts or omissions of INSTITUTION, or any of the INSTITUTION Indemnified Parties.

- 8.3 Procedure for Indemnification. The indemnifying party's obligations hereunder shall be conditioned upon receipt of prompt notification of any claim or loss which may give rise to an indemnification obligation and the reasonable cooperation of the Indemnified Parties in the investigation, defense and settlement of any actual, pending or threatened claim. The indemnifying party shall be entitled at its option to control the defense or settlement of any claim for which it may be liable, provided the indemnifying party shall act reasonably and in good faith with respect to matters relating to the settlement or disposition of a claim as the settlement or disposition relates to the Indemnified Parties. The indemnifying party shall not be liable for any settlement of any indemnifiable claim which settlement is effected without the prior written consent of the indemnifying party, which consent will not be unreasonably withheld.
- Medical Care. If, during the course of the Study, a Study subject requires emergency and/or temporary medical treatment as a direct result of the subject's participation in the Study and use of the Investigational Products in conjunction therewith, the INVESTIGATOR shall, if possible, advise SPONSOR in advance of the need for such treatment or, in the event of an emergency, immediately thereafter. SPONSOR will reimburse the subject for the actual costs of reasonable and necessary medical expenses incurred by the subject directly related to the subject's diagnosis and treatment, to the extent such expenses are not covered by the subject's medical insurance or other third-party coverage. SPONSOR's obligation to reimburse a subject for medical treatment in accordance with this paragraph is subject to the following: (i) the INVESTIGATOR and INSTITUTION have adhered to and complied with all the requirements and specifications of the Protocol, relevant ICH Guidelines and regulations, and GCP; (ii) there is no negligence, medical malpractice or intentional misconduct by INVESTIGATOR or INSTITUTION or their employees, representatives or agents; and (iii) such subject has complied with the requirements of the Study and followed all of the instructions of the INVESTIGATOR or INSTITUTION and their employees, representatives and agents. SPONSOR makes no commitment to pay a subject any compensation beyond that specified herein.
- 8.5 <u>Special Damages</u>. Except in the event of a breach of Sections 5 or 6 herein, neither party shall be liable to the other party for any indirect, consequential, incidental, or exemplary damages, including but not limited to loss of profits, business or goodwill.

# 9. Product Storage and Return of Study Materials.

Investigational Products shall be used by the INSTITUTION and INVESTIGATOR solely for the purpose of completing the Study according to the Protocol. Investigational Products shall be kept in a locked, secured area at all times. INSTITUTION and INVESTIGATOR shall maintain complete, up-to-date records showing receipt, dispensing and returns of all Investigational Products as required by the Protocol and applicable federal, national, state, regional and local laws, regulations and guidelines, including ICH guidelines. Upon completion of the Study, INSTITUTION and INVESTIGATOR will return to SPONSOR or SPONSOR's designee all unused Investigational Products, equipment and related materials and all copies of Confidential Information that were furnished to or generated by the INSTITUTION and INVESTIGATOR; provided however that INSTITUTION and INVESTIGATOR shall be entitled to retain one copy of all documents for archival purposes for use in connection with regulatory requirements and as evidence of INSTITUTION's and INVESTIGATOR's performance of their respective obligations hereunder.

#### 10. Financial Disclosure

If SPONSOR provides financial disclosure forms to the INSTITUTION pursuant to U.S. regulatory requirements, then the INSTITUTION agrees that, for each listed or identified INVESTIGATOR who is directly involved in the treatment or evaluation of research subjects, it shall promptly return to SPONSOR a financial disclosure form that has been completed and signed by such INVESTIGATORS, which shall disclose any applicable interests held by those INVESTIGATORS or their spouses or dependent children. SPONSOR may withhold payments if it does not receive a completed form from each such INVESTIGATOR. The INSTITUTION shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The INSTITUTION agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, and their agents, and the INSTITUTION consents to such review.

#### 11. Electronic Records

If the INSTITUTION uses electronic systems for creating, modifying, maintaining, archiving, retrieving or transmitting any records that are required by, or subject to inspection by, the U.S. Food and Drug Administration ("FDA"), including, but not limited to, CRFs, medical records, informed consent forms, test results, or other source documents, then the INSTITUTION warrants that its systems for such electronic records are in compliance with Section 21 of the United States Code of Federal Regulations, Part 11. The INSTITUTION further warrants that, in order to comply with Part 11, it will not use any electronic signatures on any documents required by, submitted to, or supporting a submission to the FDA unless it has certified to the FDA that it intends such electronic signatures to be the legally binding equivalent of a hand-written signature.

# 12. Shipping of Dangerous Goods and Infectious Materials

The shipment of dangerous goods and infectious materials (including infectious subject specimens) is subject to local, national, and international laws and regulations. The INSTITUTION is responsible for ensuring that each individual who packages or handles any dangerous goods or infectious materials for shipping from the INSTITUTION complies with all applicable laws and regulations (including, but not limited to, U.S. Federal Aviation Administration regulations if the materials will be shipped in the U.S.) and obtains and documents all training required by such laws and regulations. Any information provided by SPONSOR and their agents concerning transportation of dangerous goods or infectious materials is not intended to be, and should not be considered as, training in the packaging or handling of dangerous goods or infectious materials.

#### 13. Miscellaneous.

- Agreement and for a period of not less than three (3) years following the completion of the Study, INSTITUTION and/or INVESTIGATOR and each medical professional performing portions of the Study on behalf of INSTITUTION and/or INVESTIGATOR shall maintain medical professional liability insurance with minimum limits in accordance with generally accepted standards for the applicable medical practice fields. However, under no circumstances will the policy limits be less than \$1,000,000 for each medical incident and \$3,000,000 per medical aggregate (unless prohibited by applicable law). INSTITUTION and/or INVESTIGATOR agree to provide evidence of medical professional liability insurance in writing upon request by SPONSOR.
- been debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a(a) and (b), or disqualified as a clinical investigator under the provisions of 21 C.F.R. § 312.70, and have not come under investigation for such debarment or disqualification and that they will not use in any capacity in connection with the Study the services of any individual or entity which has been debarred or disqualified or has come or is currently under investigation for debarment or disqualification. INSTITUTION shall notify SPONSOR immediately if it, INVESTIGATOR, or any individual or entity providing services in any capacity in connection with the Study on behalf of INSTITUTION and/or INVESTIGATOR is debarred or disqualified or receives notice of an action of debarment or disqualification. Upon receipt of such notice or if INSTITUTION and/or INVESTIGATOR become aware of such debarment or threatened debarment, then SPONSOR shall have the right to immediately terminate the Agreement.
- 13.3 <u>Headings</u>. The headings in this Agreement are intended solely for convenience or reference and will be given no effect in the construction or interpretation of this Agreement.
- 13.4 <u>Independent Contractors</u>. In undertaking to perform professional services for SPONSOR, it is understood that INSTITUTION and INVESTIGATOR are doing so as independent contractors and not as partners, joint venturers or employees of SPONSOR. As independent contractors, INSTITUTION's and INVESTIGATOR's fees will be limited to those

stated in <u>Exhibit A</u>. Neither INSTITUTION, INVESTIGATOR nor any associated staff performing the Study will participate in any SPONSOR employee benefit plans nor receive any other compensation beyond that stated herein.

- 13.5 Taxes. It is understood that payments to INSTITUTION and/or INVESTIGATOR for services rendered under this Agreement shall be made in full at the agreed rate without any deductions for taxes of any kind whatsoever, this being in conformity with non-employee status. It is understood that any taxes that may be due and payable as a result of the payments herein specified by SPONSOR to INSTITUTION and/or INVESTIGATOR ("Recipient") shall be entirely the Recipient's responsibility. It is understood that, as a part of this Agreement, the Recipient undertakes to pay all taxes on such payments for which it may be liable when due.
- 13.6 <u>Compliance</u>. The INVESTIGATOR and/or INSTITUTION represent and warrant that the services at all times shall be performed in compliance with applicable laws and regulations. By execution of this Agreement INVESTIGATOR and/or INSTITUTION acknowledge that (i) the INVESTIGATOR and/or INSTITUTION may be subject to a field audit by regulatory authority inspectors and by representatives from SPONSOR to verify that the Study is conducted in accordance with the requirements of the Protocol, as well as in compliance with the International Conference on Harmonisation ("ICH") guidelines and the FDA regulations and (ii) records and other data resulting from the Study shall be retained for a period of fifteen (15) years following the termination of a study, unless a greater time period is mandated by the appropriate regulatory authority.
- 13.7 <u>Entire Agreement</u>. This Agreement, and the Confidentiality and Non-Disclosure Agreement between the INVESTIGATOR and the SPONSOR, including attached appendices, supersede all prior oral and written communications, if any, and set forth the entire Agreement of the parties with respect to the subject matter hereof. This Agreement may not be altered or amended except in writing, signed by an authorized representative of each party hereto.
- 13.8 <u>Waiver</u>. No waiver of any default, condition, provision or breach of this Agreement will be deemed to imply or constitute a waiver of any other like default, condition, provision or breach of this Agreement.
- 13.9 <u>Surviving Provisions</u>. The obligations of the parties set forth in Sections 3, 5, 6, 7, 8, 9, 10 and this Section 13 of this Agreement shall survive the termination or expiration of this Agreement.
- 13.10 Notices. All notices or other communications required or permitted to be delivered hereunder shall be in writing signed by the party giving notice to the other party or parties and delivered by first class mail, postage prepaid with return receipt requested, by reputable overnight courier, or by confirmed facsimile to the respective address set forth below. Notices sent by mail will be deemed received as of the third business day thereafter. Notices sent by courier or facsimile will be deemed received as of the next subsequent business day.

Clinical Trial Agreement Idenix Pharmaceuticals, Inc

Any party may change the address to which notice to him/her/it shall be delivered by providing written notice of such change to the other parties to this Agreement.

SPONSOR:

Idenix Pharmaceuticals, Inc.

60 Hampshire Street Cambridge, MA 02139 Attn: Kristin Kleber

Manager, Clinical Operations

Phone: 617-995-9807 Fax: 617-995-9817

INSTITITUTION: San Mateo Medical Center

INVESTIGATOR: Joanne Imperial, M.D.

- 13.11 Severability. If any provision of this Agreement shall be found by any court of competent jurisdiction to be invalid or unenforceable, the parties hereby waive such provision to the extent it is found to be invalid or unenforceable, and all other provisions hereof shall continue in full force and effect. The invalid or unenforceable provision shall be deemed replaced by a provision which is valid and enforceable and corresponds most closely to the intent of the parties as evidenced by the original provision.
- 13.12 Execution. This Agreement may be executed in counterparts, all of which together shall constitute one and the same instrument.
- 13.13 Authorized Representative. The Parties hereby represent that each of their respective signatories is duly authorized and that each Party relies upon the authenticity of each signature to be that of a duly authorized representative.
- 13.14 Governing Law. The provisions of this Agreement and any documents delivered pursuant hereto shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (excluding any conflicts of law rule or principle that might refer same to the laws of another jurisdiction).

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be signed by their respective officers duly authorized as of the date and year written.

Notwithstanding the date of the signatures below, this Agreement shall be a binding agreement upon execution by the parties as of the effective date first stated in paragraph 1 of this Agreement.

Name: Date
Title:

FOR INSTITUTION:

Name: Richard S. Gordon
Title: President, Board of Supervisors
Dept.: San Mateo County

FOR INVESTIGATOR:

Joanne Imperial, M.D.

Date

Clinical Trial Agreement Idenix Pharmaceuticals, Inc

Principal Investigator

#### **EXHIBIT A – INVESTIGATOR BUDGET**

- 1. Study budget is XXXX.XX per enrolled, evaluable subject. Evaluable subjects not completing the study will be paid for on a prorated basis according to the number of completed visits.
- 2. Screen Failures will not be reimbursed.
- 3. IRB costs will be reimbursed separately within 30 days upon receipt of invoice with original bills from the IRB attached.
- 4. INVESTIGATOR acknowledges that if INVESTIGATOR is not the Payee, SPONSOR will not pay INVESTIGATOR even if the Payee fails to reimburse INVESTIGATOR.

# Payment Schedule:

- 1. Upon signature of the Agreement, an initial payment of \$2,000 will be made to cover upfront costs. This payment will be refundable to SPONSOR if INVESTIGATOR fails to recruit any eligible subjects.
- 2. SPONSOR will reimburse the site quarterly (March, June, September, December) on a completed visit per patient basis in accordance with the attached budget. SPONSOR will pay 80% of this sum. Payments will be based on the number of subject visits completed and documented by the 15<sup>th</sup> day of the last month of the prior quarter.
- 3. Twenty percent (20%) of the total expected study payment will be withheld and issued as a final payment after the last subject has completed the final follow-up visit and all data clarifications have been resolved and the Close-Out visit has been completed.

In the event the INSTITUTION or INVESTIGATOR disputes any payment made under this Agreement, INSTITUTION or INVESTIGATOR shall provide written notice of such dispute within 60 days of receipt of payment.