

Standard MSKCC Agreement

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT (the "Agreement") is effective on the date last subscribed below (the "Effective Date"), and is by and between

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH and its affiliate corporation **MEMORIAL HOSPITAL FOR CANCER AND ALLIED DISEASES** both having a principal place of business at 1275 York Avenue, New York, New York 10065, membership corporations of the State of New York (hereinafter "SKI/MEMORIAL") and

[], a corporation having its principal place of business at [] (hereinafter "COMPANY").

WITNESSETH

WHEREAS, SKI/MEMORIAL, in accordance with its mission of patient care, teaching and research in pursuit of the advancement of knowledge and the improvement of patient care, desires to participate in clinical studies; and

WHEREAS, COMPANY conducts business in the development, manufacture and sale of health products; and

WHEREAS, the clinical trial is to be funded by COMPANY and carried out by SKI/MEMORIAL, under the terms and conditions specified herein;

NOW, THEREFORE intending to be legally bound and upon the terms, conditions and covenants hereinafter set forth, SKI/MEMORIAL and COMPANY agree as follows:

ARTICLE I - THE STUDY

1.1 SKI/MEMORIAL will perform for COMPANY a clinical trial entitled "_____ " (hereinafter "Study").

1.2 The Study under this Agreement will be conducted under the norms of Form FDA 1572, and using the protocol approved by SKI/MEMORIAL'S Human Subject Institutional Review Board (hereinafter "IRB"), based on the draft protocol by COMPANY [or SKI/MEMORIAL] annexed hereto as Exhibit A (hereinafter "Protocol"). SKI/MEMORIAL shall submit the Protocol for review and approval to the IRB. In the event of a conflict between the text of this Agreement and the text of the final, IRB-approved Protocol, the final Protocol shall control with respect to any matter for which the United States Food and Drug Administration (hereinafter "FDA") has promulgated regulations addressing the requirement set forth in the Protocol; this Agreement shall govern for all other matters.

1.3 COMPANY shall provide SKI/MEMORIAL with pre-clinical or background information that is germane to the Study.

1.4 COMPANY shall provide, without cost to SKI/MEMORIAL, sufficient amounts of its [] ("Study Material") to conduct the Study. SKI/MEMORIAL may not use Study Material in any way other than as specified in the Protocol. COMPANY shall supply Study Material after this Agreement has been executed.

1.5 SKI/MEMORIAL and COMPANY agree that in the performance and documentation of the Study they shall adhere to all applicable government laws, rules, regulations and guidelines, including but without limitation the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its regulations

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and official guidance promulgated thereunder, and those of the FDA, including among others the Generic Drug Enforcement Act of 1992 (21 USC §§ 305,306). Certifications and other documents required by these statutes and regulations, such as those relating to financial conflicts of interest and debarment from performing clinical trials, shall be provided as necessary.

ARTICLE II - SKI/MEMORIAL STAFF AND FACILITIES

2.1 SKI/MEMORIAL shall appoint [] M.D. to oversee the Study (the “Principal Investigator”), and/or such other physicians as it may deem appropriate as investigators. If Dr. [] should become unable to complete the Study, SKI/MEMORIAL shall consult with COMPANY regarding the appointment of a new principal investigator.

2.2 The Study shall be carried out at SKI/MEMORIAL, and SKI/MEMORIAL shall provide the physician, laboratory, statistical, and clinical support staff levels of effort reasonably required to complete the Study.

ARTICLE III - REPORTS

3.1 SKI/MEMORIAL shall prepare and maintain records and case histories with all pertinent data documented as required by the Protocol on case report forms supplied by COMPANY. Such records and case histories shall be the property of SKI/MEMORIAL, but the case report forms (hereinafter “CRFs”) provided to the COMPANY shall be the property of the COMPANY.

3.2 SKI/MEMORIAL shall keep COMPANY advised of the status of the Study via periodic reports. The frequency of reports shall be mutually agreed to by both parties. There shall also be a final report of the Study presented to COMPANY.

3.3 All reports submitted to COMPANY shall become the property of COMPANY and may be used by COMPANY without, however, making any reference to SKI/MEMORIAL unless such reference appears in a communication with the FDA or as otherwise required by law. SKI/MEMORIAL shall have the right to use the reports for its own internal non-commercial research and educational purposes.

3.4 SKI/MEMORIAL shall also promptly notify COMPANY of any adverse reaction, as defined in the Protocol “Adverse Reaction” of which they become aware in the course of the Study. COMPANY agrees to promptly notify SKI/MEMORIAL of any Adverse Reactions of patients enrolled in the study at sites other than SKI/MEMORIAL, and of any material information regarding the safety or advisability of the use of the Study Material in humans.

ARTICLE IV - CONFIDENTIAL INFORMATION

4.1 In order to effectively complete the Study, it may be necessary or desirable for the parties to disclose proprietary, trade secret and/or information relating to patients (hereinafter "Confidential Information") to one another.

4.1.1 All medical records (or other patient information) not transcribed into the case report forms are Confidential Information of SKI/MEMORIAL, and do not need to be marked “Confidential.” There shall be no time limit on the parties’ obligation to maintain the confidentiality of patient identifiable health information, including information whose identifiers may be ascertained by the exercise of reasonable effort through investigation. Patient identifiable health information shall be protected in compliance with all applicable regulations, rules and statutes. COMPANY agrees to refrain from publishing or disclosing any part of such confidential medical records or from using it except as necessary to discuss and analyze the results of the Study, to ensure research integrity, to communicate with the FDA and other regulatory authorities, and otherwise as required by law or specifically permitted by authorizations or consents signed

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by Study subjects, or waivers of authorization granted by an IRB overseeing the Study (“Permitted Activities”). COMPANY also agrees to restrict the use and disclosure of any individually identifiable health information gained through the Permitted Activities to its workforce, contractors, subcontractors, Study collaborators and agents who must have access to that information in order directly to support or facilitate the Permitted Activities, and to use the necessary means to bind those parties to these restrictions and requirements, as though these restrictions and requirements applied to these entities directly.

4.1.2 Any other Confidential Information shall be marked as “Confidential” or, if provided to the other party orally, shall be reduced to writing marked as “Confidential” and sent to the other party within ten (10) days of the oral disclosure, except that this requirement shall not apply to patient information, which is always Confidential Information. Each party agrees that such other Confidential Information of the other party disclosed to it or to its employees or to an independent data management company retained by it, and the CRFs and the reports, which are Confidential Information of Sponsor, shall for three (3) years after disclosure:

- (a) be used only in connection with the legitimate purposes of this Agreement;
- (b) be disclosed only to those who have a need to know it; and
- (c) be safeguarded with the same care normally afforded confidential information in the possession, custody or control of the party holding the Confidential Information.

The foregoing shall not apply when, after and to the extent the Confidential Information disclosed:

- i. can be demonstrated to have been in the public domain prior to the date of the disclosure; or
- ii. enters the public domain through no fault of the receiving party; or
- iii. was already known to the receiving party at the time of disclosure as evidenced by written records in the possession of the receiving party prior to such time; or
- iv. is subsequently received by the receiving party in good faith from a third party without breaching any confidential obligation between the third party and the disclosing party; or
- v. was independently developed, as established by tangible evidence, by the receiving party without reference to information or material provided by the disclosing party; or
- vi. is required to be disclosed for minimal compliance with court orders, statutes or regulations or SKI/MEMORIAL audits for compliance with such regulatory requirements, provided that prior to any such disclosure to the extent reasonably practicable, the party from whom disclosure is sought shall promptly notify the other party and shall afford such other party the opportunity to challenge or otherwise lawfully seek limits upon such disclosure of Confidential Information.

ARTICLE V - PUBLICATION

5.1 Notwithstanding anything contained herein to the contrary including without limitation Articles IV and XI, SKI/MEMORIAL may freely publish the results of its investigative findings hereunder. The authorship and contents (including scientific conclusions and professional judgments) of any paper submitted shall be determined by SKI/MEMORIAL. SKI/MEMORIAL shall provide COMPANY with a copy of the papers prepared for publication prior to their submission to a scientific journal or presentation at scientific meetings. COMPANY shall have thirty (30) days to review the papers; if no response is received within such thirty (30) days, it may be conclusively presumed that the publication or presentation may proceed without delay. COMPANY shall not make any editorial changes in the papers but, within such thirty (30)-day period, may request that SKI/MEMORIAL delete any COMPANY Confidential Information that COMPANY supplied to SKI/MEMORIAL. COMPANY personnel shall be acknowledged with customary scientific practice.

5.2 If this study is part of a multicenter study, SKI/MEMORIAL agrees that the first publication or presentation of the results and data of such Study shall be made in conjunction with the presentation of a

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joint, multicenter publication of the Study results and data with the investigators and the institutions from all appropriate sites contributing data, analyses and comments. However, SKI/MEMORIAL may publish or present the results and data from SKI/MEMORIAL's site individually when SKI/MEMORIAL believes that an SKI/MEMORIAL publication will address a perceived public health risk, or twelve (12) months (i) after conclusion, abandonment or termination of the Study at all sites, or (ii) after COMPANY confirms there will be no multicenter Study publication, whichever occurs first.

5.3 COMPANY shall register the Study in a public trials registry such as www.ClinicalTrials.gov in compliance with registration requirements as specified in Section III.J of the latest update of the "Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication."

ARTICLE VI - COMPENSATION

6.1 In consideration for SKI/MEMORIAL'S participation associated with the Study, COMPANY shall pay SKI/MEMORIAL a total of \$ [] payable as follows:

- a. \$ [] within thirty (30) days after the execution of this Agreement;
- b. \$ [] upon enrollment of one-half of the patients into the Study; and
- c. \$ [] upon COMPANY'S receipt of final case reports on all of the patients enrolled into the Study in accordance with the Protocol.

SKI/MEMORIAL shall enroll up to [] () patients into the Study.

6.2 SKI/MEMORIAL shall discuss, if COMPANY so requests, budgetary matters with COMPANY, but reserves the right to be the final control on budgetary categories and expenditures. SKI/MEMORIAL shall not be obligated to provide expenditure reports, or to submit to audits by COMPANY.

6.3 The checks shall be made payable to Sloan-Kettering Institute for Cancer Research (Sloan-Kettering Institute Tax I.D. No. 13-1624182) and shall be forwarded to:

Memorial Sloan-Kettering Cancer Center
P. O. Box 27718
New York, New York 10087-27718

6.5 COMPANY should note on its check stub or in its transmittal letter that the payment relates to a Clinical Trial Agreement, SK# [], under the direction of Dr. []

ARTICLE VII - TERM AND TERMINATION

7.1 This Agreement shall commence on the Effective Date of this Agreement and shall continue until completion as provided in the Protocol, which is estimated to occur [__] months from the Effective Date hereof.

7.2 This Agreement can be terminated by either SKI/MEMORIAL or COMPANY with or without cause upon thirty (30) days prior written notice without penalty to either party. Notwithstanding any notice period SKI/MEMORIAL may immediately cease provision of services pursuant to the Protocol if either the Principal Investigator or the IRB determines that immediate cessation is appropriate for patient safety.

7.3 In the event that this Agreement is terminated prior to completion of the Study, the amount due to SKI/MEMORIAL from COMPANY shall be \$ [] for each patient who was enrolled in the Study any time between the Effective Date and the date of termination of this Agreement. For purposes of this Agreement enrollment shall mean a patient that has signed the IRB-approved patient Informed Consent Form

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for the Study and successfully passed any pretreatment screening that is required.

7.4 If COMPANY terminates the Agreement prior to completion of the Study, COMPANY shall, if permitted by law and requested by SKI/MEMORIAL, supply SKI/MEMORIAL, free of charge, with sufficient Study Material to allow SKI/MEMORIAL to complete the treatment of those patients participating in the Study on the date of SKI/MEMORIAL'S receipt of COMPANY'S termination notice.

7.5 Sections 1.5, 7.3, and 7.4, and Articles III, IV, V, VIII, IX, X, and XI shall all survive the termination of this Agreement.

ARTICLE VIII - COMPANY WARRANTIES

COMPANY and SKI/MEMORIAL represent and warrant to each other that:

8.1 Neither they nor their employees, agents and subcontractors who provide services in connection with this Agreement have been excluded from participation in, or otherwise sanctioned by Medicare, Medicaid or any other federal, state or local health care program, and will promptly notify the other party if it or any such entity becomes so excluded or sanctioned during the term of this Agreement.

8.2 They have not been found by the FDA or any other state or federal government agency or enforcement body to have violated any relevant federal, state or local laws, rules or regulations relating to clinical investigations. If it is so found during the term of this Agreement, whether in connection with the Study, or in connection with any other clinical investigations or studies, COMPANY will notify SKI/MEMORIAL immediately.

ARTICLE IX - INVENTIONS

9.1 If any patentable inventions or discoveries result from the Study conducted by SKI/MEMORIAL under this Agreement, inventorship shall be determined by applicable patent law; ownership follows inventorship. SKI/MEMORIAL shall extend to COMPANY options to obtain exclusive worldwide licenses to SKI/MEMORIAL'S rights in any pertinent patent applications or patents. The options shall expire three (3) months from the date of the receipt of SKI/MEMORIAL'S disclosure to COMPANY. The parties shall exercise reasonable diligence in negotiating license agreements, but if no agreement to license a patent application or patent is reached within six (6) months after an option is exercised, SKI/MEMORIAL shall be free to grant licenses under such patent application or patent to other parties.

ARTICLE X – INDEMNIFICATION AND INSURANCE

10.1 COMPANY shall indemnify, defend and hold SKI/MEMORIAL, and its affiliate Memorial Sloan-Kettering Cancer Center, and their respective trustees, directors, officers, agents, employees and contractors (each an "Indemnitee") harmless from and against all claims, causes of action, suits, damages and costs arising out of the Study, except to the extent such claims, causes of action, suits, damages and costs arise directly from (i) gross negligence by an Indemnitee, (ii) failure by an Indemnitee to comply with any applicable FDA or other government requirement, or (iii) failure by an Indemnitee to adhere to the terms of the Protocol.

10.2 [For small companies] COMPANY shall obtain and maintain a comprehensive general liability insurance policy, including but not limited to contractual liability, in the minimum amount of two million dollars (\$2,000,000) per occurrence and five million dollars (\$5,000,000) in the aggregate. Such insurance shall name SKI/MEMORIAL as an insured, and provide for SKI/MEMORIAL to obtain prior written notice of any material change in or cancellation of such insurance. COMPANY will provide SKI/MEMORIAL with certificates evidencing such insurance upon reasonable request of SKI/MEMORIAL.

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[For large companies] In support of such indemnification, COMPANY represents that it maintains general and product liability insurance coverage and a self-insurance account.

10.3 In addition to the obligations set forth in Section 10.1 above, COMPANY shall be responsible for reasonable medical expenses not covered by other insurance or government programs, to the extent that the expenses are incurred by any participant in the Study directly arising from his or her participation under the Protocol, unless a diagnostic work-up establishes that the condition giving rise to such expenses was unrelated to the Protocol, in which event the responsibility of COMPANY shall be limited to medical expenses reasonably incurred in connection with the diagnostic work-up.

ARTICLE XI – NON-USE OF NAME

11.1 Except as set forth in Articles IV and V, as required by law and/or as may be required in order to maintain a party's status as an exempt organization under Section 501(c) (3) of the Internal Revenue Code and regulations thereunder, neither SKI/MEMORIAL nor COMPANY shall release any information, publicity, news releases or other public announcement, written or oral, with regard to the Agreement or any amendment thereto or to performance hereunder, to newspapers or any other mass communication media without the prior written approval of the other party. COMPANY shall not use the name of SKI/MEMORIAL or its affiliate, Memorial Sloan-Kettering Cancer Center, or a variant of any of the foregoing in any advertising, packaging or other promotional material in connection with Study Material except as may be required by law.

ARTICLE XII - GENERAL

12.1 Both parties shall, at all times during the performance of this Agreement, remain as independent contractors and the Agreement shall not make the parties partners, joint venturers, or agents of one another. No party to this Agreement shall have the power to bind or obligate the other party.

12.2 No right or license is granted under this Agreement by either party to the other either expressly or by implication, except those specifically set forth herein.

12.3 Nothing contained within this Agreement shall impose an obligation of exclusivity on one party by the other. Both parties reserve the right to enter into and participate in other activities (either alone or with a third party) including, but not limited to, clinical trials and sponsored research projects.

12.4 All matters affecting the interpretation, validity and performance of this Agreement shall be governed by the laws of the State of New York applicable to agreements made and to be performed wholly within the State of New York. This Agreement, including the Protocol, sets forth the entire understanding between the parties herein, and cannot be changed or amended except by written agreement executed by the parties. This Agreement may not be assigned by either party without the prior written consent of the other party.

12.5 All notices to be given by either party to the other shall be made in writing, delivered by any means providing proof of delivery, at the following addresses respectively:

Memorial Sloan-Kettering Cancer Center
1275 York Avenue
New York, New York 10065
(Attention: Director, Office of Industrial Affairs
(Copy: Eric M. Cottington, Ph.D., Vice President, Research Resources Management)

COMPANY

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(Attention: _____)

Any notice shall be effective as of its date of receipt.

IN WITNESS THEREOF, SKI/MEMORIAL and COMPANY have caused this Agreement to be executed in duplicate by their respective duly authorized officers.

COMPANY

By: _____

Date: _____, 2008

**SLOAN-KETTERING INSTITUTE FOR
CANCER RESEARCH, AND
MEMORIAL HOSPITAL FOR CANCER
AND ALLIED DISEASES**

By: _____

Eric M. Cottingham, Ph.D.
Vice President, Research Resources Management

Date: _____, 2008

By: _____

Chairman

Date: _____, 2008

By: _____

Head, Div. of

Date: _____, 2008

By: _____

Principal Investigator

Date: _____, 2008

SK#