**STUDY START-UP AGREEMENT**

The VA Boston Healthcare System (“VA”) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, a corporation (hereinafter “Sponsor”), with offices at , agree that VA anticipates performing for Sponsor a clinical study entitled,

“ ” Protocol # (hereinafter the "Study"). The Boston VA Research Institute, Inc., a non-profit corporation (hereinafter “NPC”), with offices at 150 S. Huntington Avenue, Suite 151B, Boston, MA 02130 will provide administrative and budget management services in support of the Study. Based on this anticipation, Sponsor agrees to pay VA and NPC certain non-refundable start-up costs (“Study Start-Up Activities”).

“Study Start-up Activities” are events identified below that VA and NPC will begin (1) after Sponsor’s notification that the VA Boston site will participate in the Study, and (2) before research activities commence at the Boston VA site . All Study Start-up activities begin after this Agreement is executed by the parties.

VA is entering into this Agreement under the authority of the Federal Technology Transfer Act of 1986, 15 U.S.C. § 3710a.

NON-REFUNDABLE PAYMENT Sponsor shall pay a non-refundable payment of $8,000 for Study Start-Up Activities (inclusive of indirect costs of 30%).

Study Start-Up Activities include, but are not limited to:

* Protocol review and summary report
* Institutional Review Board (IRB) preparation and application
* Study consent forms review and submission
* HIPAA Compliance
* Budget analysis and preparation
* Training of staff and ancillary departments involved in the Study
* Principal Investigator’s time with company representatives regarding the Study
* IRB Review Fee

Payment will be made to the “Boston VA Research Institute, Inc.” The tax identification number is 04-3081524. Checks should reference the Principal Investigator's name. Payment should be sent to:

Janyce E. Sarmaniote

Director of Finance

150 S. Huntington Avenue

151B Room 11B-60

Boston, MA 02130

Either Sponsor or VA may terminate this Agreement upon written notice to the other. Notice by Sponsor via email to the designated Study Investigator, including a communication that Sponsor is cancelling the planned Study, will constitute appropriate notice to VA. In the event the parties are unable to fully execute a final Cooperative Research and Development Agreement (CRADA), or either party terminates this Agreement, Sponsor will pay NPC as described above for completed activities and related fee(s) under this Agreement following receipt of an invoice submitted to Sponsor in accordance with Sponsor instructions. No additional payment will be due to VA or NPC for other work claimed to have been done in connection with the Study or for any lost compensation due to not progressing to a CRADA.

This Agreement does not establish a contract between any VA entity and NPC.

# NOTHING CONTAINED IN THIS AGREEMENT SHALL BE DEEMED TO GRANT EITHER DIRECTLY OR BY IMPLICATION, ESTOPPEL, OR OTHERWISE ANY AUTHORIZATION TO BEGIN THE STUDY. THIS AGREEMENT IS ONLY FOR THE PURPOSE OF SPONSOR PROVIDING PRE-STUDY COSTS.

The below parties signing this Agreement have authority to enter into Agreement for their respective entities.

# Boston VA Research Institute, Inc.

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By: Name: Nancy Watterson-Diorio

Title: CEO

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sponsor**

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

**VA Boston Healthcare System**

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Vincent Ng, Director

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*PRINCIPAL INVESTIGATOR, although not a party, acknowledges his/her responsibilities under the Agreement. Principal Investigator acknowledges that this Agreement does not authorize the conduct of the Study.*

By: Principal Investigator:

Date: