NPC Logo

RE: Study Start-Up Agreement

Sponsor:

Study Title:

Protocol Number:

Principal Investigator:

This Study-Start Up Agreement ("SSUA"), effective as of the last date of signature, is between (enter name of VA) ("VA"), (Enter name of NPC). ("NPC"), and Sponsor (Individually a "Party" and collectively "Parties") for the provision and payment of study start- up services (the "Services") in connection with the above-referenced Study. VA is entering into this SSUA under the authority of the Federal Technology Transfer Act of 1986, 15 U.S.C. § 3710a.

This SSUA will serve as an interim agreement between the Parties to facilitate the undertaking by VA and NPC of the necessary preparations for study start- up services but is not intended to constitute a Cooperative Research and Development Agreement ("CRADA") or to cover the performance of the Study. The Parties will negotiate, in good faith, the terms and conditions of a Cooperative Research and Development Agreement ("CRADA") for the participation of VA and its respective investigator in the Study. Any fees paid under this SSUA are not inclusive of all study start-up costs.

Services

Upon signature of this SSUA by the Parties, VA and NPC will prepare and submit all necessary information to the Institutional Review Board ("IRB") and VA Research and Development Committee for approval. Other Services include, but are not limited to:

- Completion and submission to Sponsor of all regulatory documents pertaining to the Protocol as identified by Sponsor's Study team; and

- Training of VA and NPC staff and ancillary departments involved in the Study; and
- Principal Investigator's time with Sponsor's representatives regarding the Study.

In conducting the Services, each Party agrees that it will comply with all applicable laws and regulations including, without limitation, United States Food and Drug Administration regulations and Good Clinical Practice. Further, the Services will be performed in a manner commensurate with professional standards generally applicable to VA.

No human subject research activities shall begin until the Parties have entered into a CRADA.

Payment

Should the Parties fail to enter into a CRADA, Sponsor, in consideration for the provision of the Services hereunder, agrees to pay NPC non-refundable fees in accordance with the attached Fee Schedule within thirty (30) days of receipt of invoice following execution of this SSUA.

All payments received under this SSUA shall be incorporated into the payment schedule approved for the Study. All payments will be made payable to: Enter NPC Name and Address, Attn: Executive Director and will reference the above Protocol number. NPC's tax identification number is (enter EIN).

Notwithstanding the foregoing, if the Study Site does not perform the services at all, or only does an insubstantial amount of the service for which these fees are being provided, the parties will reasonably work together to negotiate a partial refund of the fees in accordance with fair market value principles. Study Site represents that these fees are uniformly charged to all industry sponsors of clinical trials and that these are non-negotiable to all such sponsors.

Term and Termination

This SSUA will commence when executed by the Parties and shall continue until the execution of the definitive CRADA but not longer than two (2) years after execution of this SSUA. The Parties acknowledge that they shall enter into good faith negotiations to finalize and execute the CRADA at the earliest practicable date. Execution of the definitive CRADA will render this SSUA null and void. In such case, all costs here-in will be included with the final executed CRADA.

Either Party may terminate this SSUA with or without cause at any time upon thirty (30) days prior written notice. 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 and NPC.

PLEASE NOTE:

1. Sponsor's protocol will not be submitted for IRB review until an SSUA is executed and payment is received. Please email your signed copy to the attention of: Executive Director at (enter email address)
2. Payment for these fees is not contingent on the outcome of the IRB review or execution of the CRADA.

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

SIGNATURES ON NEXT PAGE

Sponsor, VA, and NPC each acknowledge acceptance of this SSUA by countersigning below.

NFFRE	NF/SG VHS
By:	By:
Name:	Name:
Title:	Title:

Sponsor

By:

Name:

Title:

READ AND AGREE TO ABIDE BY THE TERMS CONTAINED HEREIN, BUT NOT AS A PARTY HERETO:

Principal Investigator:

By:

Name:

Schedule of Fees includes indirect cost

Service	**NFFRE Fee**
Start-Up Regulatory Support Includes protocol review, regulatory document preparation and submission to IRB of record and VA Research and Development (R&D). R&D includes the following committees: Human Research Protection Program (HRPP), Privacy Officer, Information Systems Security Officer, Safety, and Radiation (if applicable). If more than one study coordinator is required for the protocol (i.e. blinded and unblinded study staff), this amount is subject to change.	$5,000.00
Pharmacy Set-up * Protocol review, prescription setup, pharmacy training, IT, and equipment setup. *Per IP, Blinded/Unblinded studies will incur additional charges.	$3,000.00
Administrative Start-up Includes but is not limited to: CDA and CRADA correspondence, budget negotiation, study coordinator selection, protocol review, IB review, study communication, staff training, Sponsor communication, feasibility and initiation activities/visits, document prep, protocol training for clinicians and study staff, accounting software setup, and electronic binder setup.	$15,500.00
Clinical Trial Center CTMS Admin Includes administrative costs for new study assessment and setup of clinical trial management system.	$5,000.00
Office of General Counsel CDA/CRADA Legal Review Includes review by STAR (VA Office of General Counsel Specialty Team Advising Research), the legal team that works on CDA and CRADA legal reviews and negotiations. This review is mandated by the VA and applies to all projects requiring a CDA, CRADA, including Master CRADAs. No contract can be executed without STAR's review and approval.	$2,000.00