Site Implementation Plan (SIP)
PART I

Principal Investigator: _____ **Department/Division**: _____

Phone number: _____ Fax number: _____

Primary Contact/Study Coordinator: _____

Phone number: _____ Fax number: _____

Protocol Title and Number:

_____
_____
_____
_____
_____

Sponsor: _____

SECTION I: Protocol Assessment/Study Population

1. Regarding the science, is the study valuable? Please explain:

   _____
   _____
   _____
   _____
   _____
   _____

2. Is this study competing with others for the same population, and if so, which one(s)?

   _____

3. Are the inclusion/exclusion criteria reasonable, given your potential research subjects?

   ☐ Yes ☐ No

   a. Number of subjects sponsor is requesting for this study **at our site**: _____

   b. Estimated number of potentially eligible subjects that your Department/Division has the resources to screen: _____

   c. Will you be relying in other Departments to identify potential subjects, if so, which ones and how will you accomplish this? _____

   d. How do you plan to recruit these subjects? (by advertising, brochures, etc.?)

      _____

SECTION II: Site Resources/Staff:

1. Does the PI currently have the time needed to devote to this study? ☐ Yes ☐ No
    a. How many ACTIVE studies does the PI have? _____

2. Is there currently a Study Coordinator who can handle the workload, carry-out study procedures, regulatory submissions, etc. If yes, who: _____
    a. How many studies does the Study Coordinator presently handle? _____

3. If no Study Coordinator is available, will the PI utilize a Study Coordinator from the OCT?

    ☐ Yes ☐ No

    a. If yes, estimate the # of hours per week needed for this project: _____

4. If the answer to 2. and 3. is no, please indicate what personnel resources will be utilized in order to perform study procedures

    _____

5. Where will subjects be seen? (CRC, hospital, clinic, cath lab, ER, Cancer Center, etc.)

    _____

6. Will Stony Brook Hospital/State Nurses be used to perform study procedures?
    a. If yes, indicate which procedures they will be involved with

    _____

    _____

7. Will other Hospital Staff be used to perform study procedures [e.g., Respiratory Therapy, Occupational Therapy, Speech Therapy, and Physical Therapy)?
    a. If yes, indicate which procedures they will be involved with

    _____

    _____

SECTION III: Preliminary Financial Coverage Analysis

Please select one:

☐ Sponsor will reimburse the institution for **ALL** tests, procedures, and interventions associated with the clinical trial (Patient's third party health insurance carrier, including Medicare, **WILL NOT** be billed).

☐ Patient's third party health insurance carrier, including Medicare, **WILL** be billed for routine care associated with this clinical trial. If you select this option you must continue with Part II.

Please **sign and email** this form to silvia.muniz@stonybrookmedicine.edu or faxed it to OCT at 4-1199

_____	_____	_____
Name of person completing form On behalf of Investigator	Signature	Date

SITE IMPLEMENTATIONPLAN
PART 2

SECTION IV: Medicare Coverage Analysis

This section should only be completed for those studies attempting to bill third-party health insurance carriers, including Medicare, for particular items/procedures or services associated with the research study.

The Medicare National Coverage Determination (NCD) on Clinical Trials states that Medicare covers the **routine costs of qualifying** clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in clinical trials.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself,
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g. conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g. administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service – in particular, for the diagnosis or treatment of complications.

A qualifying trial is one that meets the requirements below:

Requirement For Medicare Coverage of Routine Costs	Yes	No	Comments
Does the investigational item/service fall within a Medicare benefit category (e.g. physician's services, durable medical equipment, diagnostic test) and is not excluded from coverage (e.g., cosmetic surgery, hearing aids)?	☐	☐	
The trial must not be designed exclusively to test toxicity or disease pathophysiology. Does the study have therapeutic intent?	☐	☐	
Does the study enroll subjects with diagnosed diseases? Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.	☐	☐	

*Determination of **Deemed Trial***

Deemed Characteristic	Yes	No
Funded by a Federal Agency? (NIH, CDC, AHRQ, CMS, DOD, VA)	☐	☐
Supported by centers or cooperative groups funded by Federal Agencies?	☐	☐
Conducted under an IND/IDE or has an IND exemption?	☐	☐

*Does the Study have the seven **desirable characteristics?***

Desirable Characteristic	Yes	No
Improves patient health outcome?	☐	☐
Supported by medical and clinical info?	☐	☐
Does not unjustifiably duplicate existing studies?	☐	☐
Designed to answer the research question?	☐	☐
Sponsored by credible organization?	☐	☐
Compliant with federal regulations?	☐	☐
Conducted according to scientific standards of integrity?	☐	☐

Is this study a deemed clinical trial? ☐ Yes ☐ No

CERTIFICATION BY PRINCIPAL INVESTIGATOR

☐ I certify that this clinical trial meets the above Medicare criteria for qualifying trials.

☐ I certify that this clinical trial does not meet the above Medicare criteria for qualifying trials.

_____ _____ _____

Principal Investigator's Signature Principal Investigator Printed Name Date

Any person involved with this study must have completed the Human Subjects Training

Please send the completed form to: **silvia.muniz@stonybrookmedicine.edu**
Or Fax to: 4-1199