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? (advertising, brochures, etc.?)

      _____

SECTION II: Site Resources/Staff

1. Does the PI currently have the time needed to devote to this study? ☐ Yes ☐ No
2. How many ACTIVE studies does the PI have? _____
3. Study Coordinator:
   a. Can the assigned Study Coordinator handle the workload, carry out study procedures, regulatory submissions, etc.? ☐ Yes ☐ No
   b. How many studies does the Study Coordinator presently handle? _____
   c. If no Study Coordinator is available, will the PI utilize a Study Coordinator from the OCT?
      ☐ Yes, estimated # of hours/week needed _____ ☐ No
4. If not using a Study Coordinator, 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?

☐ Yes - Indicate below which procedures they will be involved with	☐ No

7. Will other Hospital Staff be used to perform study procedures [e.g., Respiratory Therapy, Occupational Therapy, Speech Therapy, and Physical Therapy)?

☐ Yes - Indicate below which procedures they will be involved with	☐ No

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).	*Sign and submit this form up through Section III
☐	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 2

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

Name of person completing form on behalf of Investigator	Signature	Date

SITE IMPLEMENTATIONPLAN

Device Trials Worksheet – PART 2

REQUIREMENT FOR MEDICARE COVERAGE OF ROUTINE COSTS OF DEVICE TRIALS
Medicare covers routine costs in a device trial with a "covered device"

Section 1 – Device Categories (check one)

☐ 1) PMA – (Approved by FDA through the Pre-Market Approval process) - Device may be billable to Medicare – Request to Fiscal Intermediary (FI) must be sent for determination on coverage of device and/or trial related services

☐ 2) 510K – Device may be billable to Medicare – Request to FI must be sent for determination on coverage of device and/or trial related services

☐ 3) FDA IDE Category A – Device is experimental/investigational (generally not covered by Medicare, but under the Medicare Modernization Act, routine costs may be billable to Medicare – requires approval from Fiscal Intermediary)

☐ 4) FDA IDE Category B – Device may be billable to Medicare – Request to FI must be sent for determination on coverage of device and/or trial related services

☐ 5) IDE Exempt – Device may be billable to Medicare – Request to FI must be sent for determination on coverage of device and/or trial related services

Section 2 –

1) What is the IDE or Pre-Market Approval number assigned? _____
   This information is mandatory and required on all claims.

2) Who will pay for the study device(s)?

   a. ☐ Sponsor will provide device(s) free of charge
   b. ☐ Hospital will purchase device(s) and bill study participants and/or their insurance
   c. ☐ Other, please describe: _____

MEDICARE CERTIFICATION BY PRINCIPAL INVESTIGATOR

☐ I certify that the device used in this study meets the category above checked and that a request for Medicare coverage will be submitted to the Fiscal Intermediary.

☐ I certify that the device used in this study does not meet the category for a "covered device" by Medicare. Sponsor will be responsible for all costs associated with this study.

_____ _____ _____
Principal Investigator's Name Principal Investigator Signature Date

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