

St. Vincent Hospital Research & Regulatory Affairs

Check List for Research Proposal Submission

Research Proposal Title:

Principle Investigator:

Inpatient Study:

Outpatient Study:

YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	IRB/IBC Approval Form
<input type="checkbox"/>	<input type="checkbox"/>	Research Description Form
<input type="checkbox"/>	<input type="checkbox"/>	Signed Original St. Vincent Affiliated/Unaffiliated Investigator Agreement
<input type="checkbox"/>	<input type="checkbox"/>	Protocol (1 Copies)
<input type="checkbox"/>	<input type="checkbox"/>	Study Schema (indicate standard of care/non-standard of care)
<input type="checkbox"/>	<input type="checkbox"/>	Informed Consent Form
<input type="checkbox"/>	<input type="checkbox"/>	Investigator's Brochure/History of Investigational Drug or Device 2 copies
<input type="checkbox"/>	<input type="checkbox"/>	Current Curriculum Vitae of Principle Investigator and Sub-Investigators
<input type="checkbox"/>	<input type="checkbox"/>	Study Budget
<input type="checkbox"/>	<input type="checkbox"/>	Contract or Site Agreement
<input type="checkbox"/>	<input type="checkbox"/>	Copy of Signed Investigator's Agreement
<input type="checkbox"/>	<input type="checkbox"/>	Copy of NIH (National Institutes of Health) Certificate of Completion
<input type="checkbox"/>	<input type="checkbox"/>	Copy of the protocol checklist

FOR DEVICE STUDIES

Device Designation: (one only)

<input type="checkbox"/>	<input type="checkbox"/>	Name of Device Manufacturer	_____
<input type="checkbox"/>	<input type="checkbox"/>	IDE Number	_____
<input type="checkbox"/>	<input type="checkbox"/>	510K Number	_____
<input type="checkbox"/>	<input type="checkbox"/>	Cost of Device	_____
<input type="checkbox"/>	<input type="checkbox"/>	Device Warranty	_____
<input type="checkbox"/>	<input type="checkbox"/>	PMA Number	_____
<input type="checkbox"/>	<input type="checkbox"/>	The name of the device (both trade, common or usual, AND classification name and a detailed narrative description of the device)	
<input type="checkbox"/>	<input type="checkbox"/>	A signed copy of the request for a FDA approval letter	
<input type="checkbox"/>	<input type="checkbox"/>	A signed copy of the FDA approval letter demonstrating Category B, IDE status and approval form the FDA to the participating company or manufacturer.	

- A copy of the protocol you intend to follow when performing the procedure utilizing the Category B, IDE device and a summary of the results of patients who have undergone the procedure(s) described with in the protocol.
- A copy of the agreement between the company or manufacturer and the provider, furnishing the details of provider participation in the study
- Copies of at least two peer-reviewed publications (abstracts are not acceptable) addressing the topic of the study.
- Any product literature illustrating the device and/or the procedure
- A list of any alternative devices, therapies, etc., that may be available to treat the indicated disease
- A copy of the protocol used for obtaining informed consent from beneficiaries for their participation in the study.
- An institutional review board approval letter or a statement form the provider assuring that approval has been obtained from the study institution.

FOR DRUG STUDIES

- Name of Drug _____
- IND Number _____
- Study Phase I II III IV Registry Other
- Copy of signed 1572 Form

COORDINATOR INFORMATION

Contact Name:
 Contact Phone Number: