

RR 402-A

01/01/07

Project Title: _____

IRB Protocol ID #: _____

Type of Study: Drug Device (requires SR/NSR risk determination)

Other

Principal Investigator: _____

To Attend Meeting?

No Yes

Criteria for Approval

1. Risks to subjects are minimized

- Research procedures are consistent with sound research design
- Research procedures do not unnecessarily expose subjects to risk
- Researcher is qualified to conduct study
- Routine or standard procedures to be performed on subjects for the purposes of the study whenever possible
- The research plan makes adequate provision for monitoring the data to ensure the safety of subjects

COMMENTS ON PART 1:

2. Risks to subjects are reasonable in relation to anticipated benefits (if any), and the importance of the knowledge that may be expected to result

- Purpose of study is clear and acceptable
- Results of any related studies are included
- Number of subjects and duration of participation is stated and appropriate
- Duration of the study is clear and appropriate
- Compensation paid to subjects is appropriate.
- Is there a washout period? No Yes
If so, is it appropriate, and are safeguards in place to assure subject will be adequately monitored?
- Is there a placebo / no treatment control? No Yes
If yes, is use of placebo appropriate and does not put subjects at risk?

COMMENTS ON PART 2:

3. Selection of subjects is equitable

- Justification for use of vulnerable groups provided (note: prisoners not allowed at SHS)
- Additional safeguards have been included in the study to protect the rights and welfare of these groups
- Presence of any special community attitudes that may affect subject participation has been addressed where applicable
- Selection of subjects reflects purposes of the research and group that will benefit from research outcome

COMMENTS ON PART 3:

4. Legally effective informed consent is obtained (content checklist in Form IC 701-A)

- Informed consent will be sought from each subject
- Informed consent procedures and documentation appear to be appropriate
- Does the protocol call for Waiver of Informed consent? No Yes
If yes, is Waiver appropriate? No Yes

COMMENTS ON PART 4:

5.	There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
	Separate Hospital HIPAA Use and Disclosure form attached for protected health information, if applicable

COMMENTS ON PART 5:

6.	Review of Required Protocol Elements	
	Note: Protocols for Phase I studies may be less detailed than for Phase II and III studies	
	Required protocol elements	
	Present?	
	Statement of objectives and purpose of study	<input type="checkbox"/> No <input type="checkbox"/> Yes
	Name, address, and statement of qualification (e.g. CV) of each Investigator and Co- or Sub-Investigator	<input type="checkbox"/> No <input type="checkbox"/> Yes
	Name of each research facility to be used	<input type="checkbox"/> No <input type="checkbox"/> Yes
	Verification of Human Subjects Training for Investigator(s) and research team	<input type="checkbox"/> No <input type="checkbox"/> Yes
	Patient selection criteria, exclusion criteria and estimated number to be studied	<input type="checkbox"/> No <input type="checkbox"/> Yes
	Summary of study design, including control(s) and steps to reduce bias risks	<input type="checkbox"/> No <input type="checkbox"/> Yes
	For drug studies: methods to determine dosing, expected maximum dosage, and duration of exposure to drug	<input type="checkbox"/> No <input type="checkbox"/> Yes
	Observations and measurements to be made during the study	<input type="checkbox"/> No <input type="checkbox"/> Yes
	Clinical procedures, laboratory tests and other measures to be taken to monitor the test article's effects and minimize risks to subjects	<input type="checkbox"/> No <input type="checkbox"/> Yes
	Summary of data analysis and statistical methods to be used	<input type="checkbox"/> No <input type="checkbox"/> Yes

COMMENTS ON PART 6:

7.	Criteria for Review Schedule
	Studies that are considered high risk will generally be reviewed at least semiannually.
	Studies may be reviewed semiannually if the IRB believes that the study population is especially vulnerable.
	Studies may be reviewed more frequently if the IRB believes that previous studies indicate high incidence of adverse events.
	Studies may be reviewed more frequently if the IRB believes close monitoring is indicated.
	Note: If the IRB determines that a study that had been approved for an annual review requires closer monitoring, the IRB may make a determination to review that study on a more frequent basis. The reasons for such a determination will be included in the minutes and communicated to the Investigator.

COMMENTS FOR PART 7:

8.	Risk Assessment - criteria checklist in Forms RR 402-B and RR 402-C (Device)
	This study is: <input type="checkbox"/> Low Risk <input type="checkbox"/> Intermediate Risk <input type="checkbox"/> High Risk
	Do you believe the monitoring plan described is adequate for the risk? <input type="checkbox"/> No <input type="checkbox"/> Yes
	Do you believe that this study needs verification from sources other than the Investigator that no material changes have occurred? <input type="checkbox"/> No <input type="checkbox"/> Yes
	Do you believe that this study requires full IRB review more often than annually? <input type="checkbox"/> No <input type="checkbox"/> Yes
	Is an interim report required? <input type="checkbox"/> No <input type="checkbox"/> Yes
	If yes, how often? <input type="checkbox"/> in 3 months <input type="checkbox"/> in 6 months <input type="checkbox"/> other

Bring comments to the IRB meeting for discussion.