

**ST. JOSEPH MEDICAL CENTER
Towson, MD 21204**

**Clinical Trial Approval Form:
Departmental Scientific and Operational Review**

Protocol Title:	
Principal Investigator:	Department:
Contact Name & Phone #:	Sponsor:

The purpose of this form is to ensure that all clinical trials are reviewed and approved by all effected departments prior to initiation. This authorization process will allow for evaluation of the clinical trial for operational and scientific feasibility at SJMC. Additionally, it provides a formal mechanism for addressing any concerns, comments, and financial requirements notes by the departments.

The departments should consider the following questions during evaluation of the clinical trial protocol:

1. Is the science proposed in this study valuable?
2. Do SJMC and the study team have the capacity and expertise to successfully execute the trial?
3. Will the trial adversely effect the operations within the hospital and or department? If so, how should this impact be minimized?
4. Does the department have the required resources (i.e. space, people, expertise) to support the trial?
5. Are there any patient safety or data protection issues that need to be addressed?

The ancillary departments (i.e. pharmacy, laboratory, and radiology) should address the questions above, and if there are budgetary requirements from the department, the budget should be attached to this form and noted on the appropriate signature line below. This ancillary departmental budget will be added to the overall clinical trial budget, and used to reimburse the ancillary department for its services provided.

The form should be signed off in the following order: VPMA, Principal Investigator, ancillary departments (i.e. pharmacy, laboratory, and radiology), Executive Director / Medical Director and Office of Clinical Research. The Office of Clinical Research will obtain VPMA, OR, OCR.

DEPARTMENT APPROVALS

Req'd	Department (as applicable)	Signature for Approval	Date Signed	Info Attached
<input type="checkbox"/>	Vice President Medical Affairs / CMO			<input type="checkbox"/>
<input checked="" type="checkbox"/>	Principal Investigator			<input type="checkbox"/>
<input checked="" type="checkbox"/>	Department Head/Executive Director			<input type="checkbox"/>
<input type="checkbox"/>	Nursing			<input type="checkbox"/>
<input type="checkbox"/>	Pharmacy Lisa Ruppel			<input type="checkbox"/>
<input type="checkbox"/>	Laboratory - Inpatient / Outpatient			<input type="checkbox"/>
<input type="checkbox"/>	Radiology / Pathology			<input type="checkbox"/>
<input type="checkbox"/>	Operating Room			<input type="checkbox"/>
<input type="checkbox"/>	Office of Clinical Research			<input type="checkbox"/>

Sign-off by the department head / manager signifies the department's approval for the execution of the clinical trial, and the department's understanding of the impact of the trial on the operations of the department. Any additional information, including scientific, operational, and/or financial concerns or comments should be attached to this form, and noted by checking the "Info Attached" box.