



CTRMG STUDY ACTIVATION FORM

STUDY INFORMATION

Study Title: _____
Sponsor Name: _____
CRO Name: _____
Study Type (<i>check all that apply</i>): <input type="checkbox"/> Drug <input type="checkbox"/> Device <input type="checkbox"/> Expanded Access <input type="checkbox"/> Compassionate Use <input type="checkbox"/> Registry <input type="checkbox"/> PI-Initiated Proposal (PI is author) <input type="checkbox"/> Other*
*Describe Other _____
Funding Source*: <input type="checkbox"/> Industry <input type="checkbox"/> None (Gift or Department funded) <input type="checkbox"/> Other Funding Source*
<i>*If Other Funding Source, STOP and Request Assistance from a Grant RPM at RMG.</i>

CONTACT INFORMATION

PI Name: _____	Sponsor/CRO Contact Name: _____
Email: _____	
Phone: _____	Email: _____
Department: _____	
Coordinator Name: _____	
Email: _____	
Dept. Financial Contact: _____	
Email: _____	

REQUIRED DOCUMENTS

	For expedited review, the following documents MUST be submitted with this form:
1	Protocol
2	Contract with Payment Schedule
3	Completed Workbook*
4	CTRU Pricing (<i>if applicable</i>)
	<i>*If you need assistance completing the Workbook, check "Budget Development" in the Kickoff Meeting Section below.</i>

KICKOFF MEETING**Type of Kickoff Meeting Requested:**

- Budget Finalization Budget Development None
 In Person By Phone Video Conference

IRB INFORMATION

IRB Filing: Have you filed an IRB application? Yes No

If YES, Meeting Date: _____ **eProtocol #** _____

IRB Type: Single IRB Stanford IRB Expedited Not Required/Exempt*

**Please attach IRB's [Human Subject Research \(HSR\) Determination](#)*

STUDY TIMELINE

Desired Start Date: _____ **Estimated Duration of Trial (# of Years)** _____

Site Initiation Visit Scheduled: Yes No **Date of SIV:** _____

Timeline Issues: Deadline Patients Waiting Rollover/Extension Study Other _____

DEVICE STUDY QUESTIONS (IF APPLICABLE)

Please answer the following questions only if your study involves testing a Device

Click Below to Select Answer

How will Stanford obtain the Device?

Device Classification

IDE Number: _____

BUDGET QUESTIONS

Total Number of Patients _____ **Patients in:** Arm 1 _____ Arm 2 _____ Arm 3 _____

Study Location (check all that apply): Hospital/Clinic Space University Office Space

Non-clinical Laboratory Space Stanford Free Clinics Other _____

Stanford Services (check all that apply): CTRU Lucas Center Stanford Center for Clinical Research

(SCCR) Spectrum Child Health Cancer Center/SRC (CCTO) Translation Services

Interpretation Services

Other Fees to Include in Start-up: None CTRU Review Fees Advertising Investigational Pharmacy Other Fees **IRB Fees and Budget Development Fees are added to all Clinical Trial Budgets.*

SALARIES/STAFFING/EFFORT ESTIMATE

Coordinator: Hours Per Patient Per Study____ - **OR** - % Annual Effort per Study____

PI: Hours Per Patient Per Study____ - **OR** - % Annual Effort per Study____

Resident Fellow? Hours Per Patient Per Study ____ - **OR** - % Annual Effort per Study____

Other Name____: Hours Per Patient Per Study____ - **OR** - % Annual Effort per Study____

Other Name:____: Hours Per Patient Per Study____ - **OR** - % Annual Effort per Study____

PHARMACY INFORMATION **NOT APPLICABLE**

Who will dispense the Study Drug? Pharmacy* Department Other_____

**Please forward email with Pharmacy quote.*

SPONSOR EQUIPMENT

Will the Sponsor Provide Equipment for use on the Study? Yes No

If YES: Describe equipment:_____

If YES: Will equipment be provided without charge to Stanford? Yes No*

**If NO:* How will costs be covered?_____

If equipment is being provided, how will it be used?

In accordance with FDA approval - **OR** - As an experimental component in the Study*

**If experimental, please be sure answer Device Study Questions on page 2.*

SEND FORM & DOCUMENTS TO RMG_CT_INTAKE@STANFORD.EDU

CTRMG USE ONLY

SPO # _____ Date Assigned: _____

CT RPM _____ CT CO _____

Kickoff Scheduled: _____

Documents Received: Protocol Contract Payment Schedule Completed Workbook
 Incomplete Workbook

Review: Expedited Standard