# Clinical Trial Research Management Group
# Study Activation Form

## STUDY INFORMATION

**Study Title:** _____

**Sponsor Name:** _____

**CRO Name:** _____

**Study Type** *(check all that apply):* ☐ Drug ☐ Device ☐ Registry ☐ PI-Initiated (PI is author) ☐ Other*

**Describe Other* _____

**Funding Source*:** ☐ Industry ☐ None (Gift or Department funded) ☐ Other Funding Source*

**IF Other Funding Source, **STOP** and Request Assistance from a Grant RPM at RMG.*

## CONTACT INFORMATION

**PI Name:** _____
**Email:** _____
**Phone:** _____

**Department:** _____

**Coordinator Name:** _____
**Email:** _____
**Dept. Financial Contact:** _____
**Email:** _____

**Sponsor/CRO Contact Name:**

_____

**Email:** _____

## KICKOFF MEETING

**Type of Kickoff Meeting Requested:**

☐ In-Person
☐ Zoom/WebEx
☐ None

**Proposed Availability** ***(Scheduled within 2 weeks of study submission)*:**

**Option Date 1:** _____ **Time:** _____ **to** _____
**Option Date 2:** _____ **Time:** _____ **to** _____
**Option Date 3:** _____ **Time:** _____ **to** _____

## IRB INFORMATION

**IRB Submission: Have you submitted 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 If Yes, **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? | Not Applicable |
| Device Classification | Not Applicable |

**IDE Number:** _____ **FDA Letter Date:**_____

**Please provide a copy of the FDA Letter if available*

## BUDGET QUESTIONS

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

**Study Location** ***(check all that apply)*:** ☐SHC ☐ LPCH ☐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_____ **-OR-** % Annual Effort Per Study _____

**PI:** Hours Per Patient_____ **-OR-** % Annual Effort Per Study _____

**Other Name:** _____ Hours Per Patient _____ **-OR-** % Annual Effort per Study _____

**Other Name:** _____ Hours Per Patient _____ **-OR-** % Annual Effort per Study _____

## PHARMACY INFORMATION ☐ NOT APPLICABLE

**Who will dispense the Study Drug?** ☐SHC ☐LPCH ☐Department ☐Other _____

**Please forward email with Pharmacy quote.*

## SPONSOR EQUIPMENT

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

***If YES:*** Describe equipment:_____

***If YES:*** Will equipment be provided without charge to Stanford? O Yes O 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.*

## REQUIRED DOCUMENTS

| | |
|---|---|
| **1** | Protocol |
| **2** | Contract with Payment Schedule |
| **3** | Completed Workbook*** |
| **4** | CTRU Pricing *(if applicable)* |

******SHC and LPCH workbooks can be downloaded on the SPECTRUM website - Budget & Billing Workbook***

***Please send completed form and required documents to the Clinical Trial Intake Team: rmg_ct_intake@stanford.edu***

## CTRMG USE ONLY

SPO #_____ Date Assigned:_____

CT RPM_____ CT CO _____

**Documents Received:** ☐Protocol ☐Contract ☐Payment Schedule ☐Workbook

**Reviewed as**: ☐Expedited ☐Standard

**Comments:**_____