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* _____

IND/IDE Holder: ☐ Stanford ☐ Sponsor ☐ Third Party ☐ Exempt

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

*Study documents do not need to be submitted to RMG, please work with your study team's Financial Manager

**IF a itemized negotiable per unit budget has not been requested by sponsor, STOP and submit the online Proposal Intake Form (PIF) in SeRA or request assistance from your departmental Grant RPM.

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

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: ☐ 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 _____

Patient Population: ☐ Adult ☐ Pediatric

Study Location ***(check all that apply)*:** ☐SHC ☐ LPCH ☐University Office Space ☐ValleyCare ☐ Non-clinical Laboratory Space ☐Cardinal Free Clinics ☐Other _____

Stanford Services ***(check all that apply)*:** ☐CTRU ☐Lucas Center ☐ Spectrum Child Health ☐Translation Services ☐Interpretation Services ☐Stanford Center for Clinical Research (SCCR)

Other Fees to Include in Start-up: ☐None ☐CTRU Review Fees ☐Advertising ☐Investigational Pharmacy ☐Other Fees

Applicable institutional fees will be applied by the CTRPM.

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 ☐SHC Neuroscience Health Center Pharmacy
☐LPCH ☐Redwood City ☐Department ☐Other/External Pharmacy _____

**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.*

REQUIRED DOCUMENTS

1	Protocol
2	Contract with Payment Schedule
3	CTRU Pricing *(if applicable)*
4	Draft ICF (if available)
5	Workbook(s) for Pediatric Studies*

***Industry sponsored studies with adult populations and services at SHC and/or CTRU will be submitted to Ankura for Coverage Analysis review. No workbook is required to be submitted by study team.**

******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

CT RPM **CT CO**

Reviewed as: ☐ **Expedited** ☐ **Standard** ☐ **Clinical Research** **Review Date:**

Comments:

Similar Studies for Reference - SPO / PI / Sponsor:

One Arm/Workbook ☐
Multiple Arms/Workbooks ☐ **Number of Workbooks**

Complex Procedure - Identify Procedure:

Number of Visits counted on RPS form and included in sponsor's fee calculation:

Other Observations: