Ann & Robert H. Lurie Children's Hospital of Chicago

NUCATS Clinical and Translational Sciences Institute

Clinical Research Unit Submission Form

CRU Use Only	
CRU#	

Instructions: Submit this form to CRU@luriechildrens.org to request a letter of support for your study. Following IRB approval, you will need to provide the CRU with approved regulatory documents and request CRU Activation of your study. Save this form with a new version date, click the second box for Activation and update any information that may have changed since your initial CRU submission. Resubmit this form to CRU@luriechildrens.org to request study activation.

☐ **Request for CRU LOS (Letter of Support)** **Submission Date:**

☐ **Request for CRU Activation (post IRB-approval)**

Activation only: Indicate here if new information has been added or any information has changed since your initial CRU submission

☐ Section A ☐ Section B ☐ Section C ☐ No changes in Sections A-C*

*if no changes, skip to Section D

Section A. General Information

1. **Protocol Title**: *(Must be the same as complete IRB title)*

2. **Study Short Name:** *(Example: QUICK Trial, GDK3702 Study, LL5577)* _____

3. **IRB Protocol#:** **IRB Approval Status:** ☐ Pending ☐ Approved*

must be Approved for CRU Activation

4. **Principal Investigator (PI)**:

Name: _____ Department: _____

Phone: _____ Email: _____

5. **Study Coordinator:**

Name: _____ Title: _____

Phone: _____ Email: _____

6. **Billing Contact:** ☐ Same as Study Coordinator

Name: _____ Title: _____

Phone: _____ Email: _____

Section B. Sponsor and Funding Information

1. **Sponsor:**	☐ Federal Grant or Non PHS *(Example: NIH, PCORI, CF Foundation)*	Sponsor:
	☐ Investigator Initiated (The PI is the primary author of the research plan & responsible for funding this trial)	
	☐ Industry Sponsored *(Example: pharmaceutical company, device company)*	Sponsor:
2. **Lurie Children's Study Fund#:**	☐ Pending* *Fund # must be provided for CRU Activation*	

Section C. CRU Resources and Study Visits

1. Study Timeline:

Length of Study Participation:	*(example: single visit, 15 weeks per subject, 2-3 years per subject)*
Anticipated Date of First Visit in CRU:	
Anticipated Study Life Cycle:	☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **Other:** *(approximately how many years to complete enrollment, for CRU budget estimate)*

2. Subjects and Study Visits:

# of Subjects Approved to be Enrolled	**# Outpatient Visits per Subject**	**# Inpatient Visits per Subject**

3. CRU Services, Supplies and Training: ☐ **NA, Space-Only Request** (Skip to Section D)

A. Will <u>ALL</u> study visits occur in the CRU?	☐ **Yes** ☐ **No*** ***If No**, specify only visits that will occur in the CRU:
B. What services are required from CRU staff?	☐ **Oral and/or Subcutaneous drug administration** ☐ **IV Infusion** ☐ **Phlebotomy** ☐ **PK/PD draw** ☐ **Vital signs** *(Ht/Wt/BP/HR/etc.)* ☐ **Other (specify):** ☐ **ECG**
C. Will laboratory supplies be provided to the CRU? *(Example: sponsor kit, phlebotomy supplies, vacutainers, blood tubes, etc.)*	☐ **Yes*** ☐ **No** ☐ **N/A** ***If Yes**, specify:
D. Will <u>clinical labs</u> be drawn along with research labs?	☐ **Yes*** ☐ **No** ***If Yes**, will clinical lab collection tubes be provided to the CRU? ☐ **Yes** ☐ **No**
E. Will CRU staff require special protocol training for this study? *(Example: IV infusion with blinded/un-blinded staff, equipment management, etc.)*	☐ **Yes*** ☐ **No** ***If Yes**, specify training:

NOTE: Please provide any additional comments on Page 3

Section D. Attachments and Instructions

Attachments required for LOS (Letter of Support):

Please submit the following documents with the completed CRU submission form to CRU@luriechildrens.org.

- ☐ Sponsor Protocol *(if no Sponsor Protocol, submit copy of your Cayuse IRB PDF/Research Plan)*
- ☐ Draft Consent forms *(if available)*

Additional Comments:

Upon review, the Study Team will receive a Draft CRU Budget and Letter of Support.
Standard turnaround for this process is **2 weeks**.

Attachments required for CRU Activation:

Please submit the following documents with the completed CRU submission form to CRU@luriechildrens.org.

- ☐ IRB Approval Letter *(download PDF from Cayuse IRB)*
- ☐ IRB Stamped Consent Forms *(all approved versions)*
- ☐ Sponsor Protocol *(if no Sponsor Protocol, submit copy of your Cayuse IRB PDF/Research Plan)*
- ☐ Investigator Brochure *(if applicable)*

Additional Comments:

Upon review, the Study Team will receive a Final CRU Budget and Letter of Activation.
Standard turnaround for this process is **2-4 weeks**. The PI must sign and return the Final CRU Budget to complete study activation in the CRU.

Publication Disclosure Information: Please help us continue our support for clinical and translations research by citing our grant number in relevant publications: **UL1TR001422.** The following manuscript citation is suggested: ***"Supported in part by UL1TR001422 from the National Center for Advancing Translational Sciences (NCATS) and National Institutes of Health".***