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| **Clinical Research Office (CRO)**  **New Protocol Submission Form**  676 N. St. Clair, Suite 1200| Chicago, IL 60611  **Scientific Review Committee Coordinator:** [**SRC.CCSG@northwestern.edu**](mailto:SRC.CCSG@northwestern.edu) |
| **All new protocol submissions MUST be submitted electronically and include the following documents or the project will not be reviewed and will be returned to the Principal Investigator:**  **Completed New Protocol Submission Form**  **Final Protocol (electronic copy)**  **Consent form, electronic copy of Word or modifiable text (if applicable)\***  **Standard of Care vs. Research Determination - signed & dated by PI (see section 7D)\***  **Grant (if applicable)\***  **Investigational Drug Brochure (investigational drugs ONLY)**  **Please submit all materials to the Scientific Review Coordinator:**  [**SRC.CCSG@northwestern.edu**](mailto:SRC.CCSG@northwestern.edu)  *\*If unsure whether this is required for the project, please contact the study*  *start-up lead for the associated disease team.*  **Disease team endorsement is REQUIRED prior to submitting the new protocol submission packet**  **for all interventional studies.** |

**\*\*IMPORTANT:** The accrual projections provided by the pi will be used to enforce the accrual policy. the projections provided in section 4 will govern whether or not a study remains open. Please review the accrual policy for more information.\*\*

* *Section 1: Project*
* *Section 2: Conflict of Interest and Financial Responsibility*
* *Section 3 Study Classification*
* *Section 4 Accrual and Locations*
* *Section 5 ICF and Drug Risk Profile*
* *Section 6 Drug/Device Source*
* *Section 7: Funding*
* *Section 8: Facilities Used*

**Section 1: Project**

**A) Project Title and PI:**

* Title:
* Principal Investigator:

**B) Type of study (select one)**

Industry sponsored  NCTN (cooperative group)  Federally funded  Consortium

Investigator-initiated (NU or LCH)  Investigator-initiated; external institution

Will this be a multi-institutional study?  Yes  No

If yes, will NU or Lurie Children’s be the lead site:  Yes  No

**C) Contact Information** Please provide **at least one** contact for the sponsor or Contract Research Organization.

Name:

E-mail:

Phone:

**Section 2: Conflict of Interest and Financial Responsibility (LCH investigators may skip this section)**

1. Have you completed an annual and/or research related COI disclosure through your school or FASIS in the last 12 months?

Yes  No

1. Please provide any additional information that may impact this study. :

**Section 3 Study Classification**

**Clinical Trials:**

First in human/phase 0  I  I/II \*  II

III  IV Pilot/Feasibility

**Non-Clinical Trials:**

Retrospective Chart Review  Prospective Chart Review

Questionnaire/survey study/ interview  Data registry  Biorepository or biobank

Other (please provide details):

**Section 4 Accrual and Locations \*REQUIRED for all submissions\***

**\*\*IMPORTANT:** The accrual projections provided by the pi will be used to enforce the accrual policy. the projections provided in section 4 will govern whether or not a study remains open. Please review the accrual policy for more information.

**Note: Ranges are not acceptable for accrual OR duration.***\*If a phase I/II study, both phase sections must be completed.*

* NU or Lurie Children’s Investigator-Initiated studies – Non-clinical trial

      Total accrual **for entire study**       Total accrual **NU/Lurie Children’s**

      Annual accrual **NU/Lurie Children’s**      Annual accrual **for all institutions (for multi-institutional studies ONLY)**

      Expected time (**in months**) to reach total accrual

* + NU or Lurie Children’s Investigator-Initiated studies, Phase 0 & I:

      Total accrual **for entire study**       Total accrual **NU/Lurie Children’s**

      Annual accrual **NU/Lurie Children’s**      Annual accrual **for all institutions (for multi-institutional studies ONLY)**

      Expected time (**in months**) to reach total accrual

* + NU or Lurie Children’s Investigator-Initiated studies, Phase II:

      Total accrual **for entire study**       Total accrual **NU/Lurie Children’s**

      Annual accrual **NU/Lurie Children’s**      Annual accrual **for all institutions (for multi-institutional studies ONLY)**

      Expected time (**in months**) to reach total accrual

* NU or Lurie Children’s Investigator-Initiated studies, Phase III:

      Total accrual **for entire study**       Total accrual **NU/Lurie Children’s**

      Annual accrual **NU/Lurie Children’s**      Annual accrual **for all institutions (for multi-institutional studies ONLY)**

      Expected time (**in months**) to reach total accrual

* Externally Sponsored (Industry Sponsored, NCTN {cooperative group}, Federally funded, Consortium, Investigator-initiated; external institution)
* Phase I

      Total accrual **NU/Lurie Children’s**

      Annual accrual **NU/Lurie Children’s**

      Expected time (**in months**) to reach total accrual

* Phase II

      Total accrual **NU/Lurie Children’s**

      Annual accrual **NU/Lurie Children’s**

      Expected time (**in months**) to reach total accrual

* Phase III

      Total accrual **NU/Lurie Children’s**

      Annual accrual **NU/Lurie Children’s**

      Expected time (**in months**) to reach total accrual

**Section 5 ICF and Drug Risk Profile**   
The study PI must ensure the risk section in the ICF is accurate.

1. Investigational drugs/devices:

The PI has confirmed that risks outlined in the IB are reflected in the ICF.

1. FDA approved drugs:

The PI has confirmed that risks, including REMS®, and Black Box Warnings listed in the Package Insert are reflected in the ICF.

**If risks are missing, please add these to the ICF template using track-changes prior to submitting the NPSF Packet for processing.**

**Section 6 Drug/Device Source (skip this section if drug/device/or biologic is not being used)**

Specify ALL drug(s)/ device(s)/biologic(s) that will be used in this research project. Provide details for all.

1. **FDA Approved, Approved Use**

List Agent(s):

Supplied by Sponsor?  Yes  No Please list supplied agents:

1. **FDA Approved, Unapproved Use**

List Agent(s):

Supplied by Sponsor?  Yes  No Please list supplied agents:

1. **Non-FDA Approved**

List Agent(s):

Supplied by Sponsor?  Yes  No Please list supplied agents:

1. Is there an IND/IDE number?  Yes  No

Industry Sponsor holds IND IND/IDE number required:

NU investigator has filed IND/IDE number required:

NU investigator intends to file

IND Exempt

Other

**Section 7: Funding**

* 1. **Project Funding Status** Funded Unfunded  Funding Pending

* 1. **Project Funding Mechanism** (Please check all that apply.)

RHLCC FSM Industry Sponsor  Federal Grant Philanthropy

Other, please specify:

* 1. **Funding source name:**
  2. **Standard of Care (SOC) vs. Research Determination:**

For all interventional studies supported by the CRO, a **PI signed and dated** determination of SOC vs. Research is required. Please print a copy of the study parameter table and lab breakdown and CIRCLE those items that **are RESEARCH** (including footnotes) and should be billed to the sponsor.

1. **Please provide the following additional information for budget development:** How long will a typical study participant be on treatment?        
    How long will a typical study participant be followed for survival follow-up?
2. **Complete this section for all grants and federal contracts. Grant documents MUST be attached.**

Grant Type:       Grant Number:       Department administering grant:

Research Administrator handling grant (include email address):

**Section 8: Facilities Used – ALL FIELDS MUST BE COMPLETED**

1. **Clinical Research Office (CRO) Services to be used:** *Financial Support Services, including:*

Budget Preparation  Yes  No

Contract Preparation  Yes  No

Study Account Administration  Yes  No

(e.g., paying bills, invoicing sponsors)

Study Coordination  Yes  No

Data Management  Yes  No

Regulatory Services  Yes  No

(e.g., IRB submissions, clinicaltrials.gov and FDA submissions) ***Note:*** *the CRO does not provide support for medical record review studies.*

Other department or institution will be used (specify):

1. **Pathology Core Facility - Clinical Trial Unit Services to be used. Please choose ONE.**

Specimen Procurement/Correlative Studies (e.g., plasma, whole blood, fresh or archived tissue, etc.)

Not Applicable. No pathology or specimen processing services are required for this project.

Not applicable. Other department or institution will be used (specify):

1. **Pathology Specimens and NMH**

Will pathology specimens be obtained at or requested from Northwestern Memorial Hospital (NMH) for shipment to study facility or the Pathology Core Facility?  Yes  No

1. Does the study drug involve recombinant DNA that may require review by the Institutional Biosafety Committee**?**

Yes  No

1. Preferred locations for study is to be conducted (check all that apply):

LCH  NMDTI  Jesse Brown VA  RIC  Galter 21  Prentice 4  NMH Inpatient

CRU  Lake Forest  HOA  other hospital:

other NMG clinic:      

1. Associated Clinical Services (check all that apply):

Quantitative Imaging Lab (QIL)  Ophthalmology  Pulmonology  Transplant

Interventional Radiology  Rube Walker Blood Center  Other

**CRO Administrative Use Only - PI does not complete**

***Clinical Services***

* Please list which disease teams to refer to for authorized personnel.   
  Names:         
  Other:

Other: