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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** |
| **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***\*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: