# Letter of Intent (LOI) Template

A letter of intent (LOI) may be submitted to the respective Disease Team (DT) for endorsement to satisfy the requirement for the first stage of scientific review of an investigator-initiated trial (IIT). Once endorsement is obtained from the respective DT, a Northwestern Medicine or Lurie Children's Hospital Investigator may proceed with submitting a final protocol to the Scientific Review Committee (SRC).

The Lurie Cancer Center Clinical Trials Office (CTO) employs a protocol development team that can assist with the development of an LOI and/or draft protocol.

1. **Principal Investigator:**

2. **Multi-Center Trial:** ☐ **Yes** ☐ **No**

   **Anticipated Participating Sites (please list all):**

| **3. CONCEPT INFORMATION** | |
|---|---|
| **Concept Title:** | |
| **Primary Objective:** | |
| **Secondary Objective(s):** | |
| **Study Phase:** | ☐ I ☐ I/II ☐ II ☐ III ☐ IV ☐ Other<br>Is this a pilot study? Yes☐ No☐ |

| **4. CONCEPT DESIGN AND RATIONALE** | |
|---|---|
| **a)** | ***Background Information on disease state and treatment rationale***<br>*Include supporting preliminary data, either multicenter experience or correlative science studies integral to the study. Include limitations of existing therapeutic options.* |

| | |
|---|---|
| | |
| **b)** | ***Type of study design***<br><br>***Allocation:***<br>☐ **Randomized** ☐ **Non Randomized** ☐ **N/A: Single-arm study**<br><br>***Intervention Model*:**<br>☐ **Single Group:** single arm study<br>☐ **Parallel:** participants are assigned to one or two or more groups in parallel for the duration of the study<br>☐ **Cross-over:** participants receive one of two alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study<br>☐ **Factorial:** two or more interventions, each alone and in combination, are evaluated in parallel against a control group<br>☐ **Sequential:** groups of participants are assigned to receive interventions based on prior milestones being reached in the study, such as in some dose escalation and adaptive design studies |
| **c)** | ***Scientific rationale for dosing schema*** *(For all drugs in regimen, if dose is not by product/package insert, provide rationale below.)* |

| **5. STUDY POPULATION** | |
|---|---|
| **a) Diagnosis or disease being Studied:** | |
| **b) Key inclusion criteria:** | **1.**<br>**2.**<br>**3.**<br>**4.**<br>**5.** |

| | |
|---|---|
| **c) Key exclusion criteria:** | **1.**<br>**2.**<br>**3.**<br>**4.**<br>**5.** |

| **6. CORRELATIVE STUDIES (For example, Pharmacogenomics, biomarkers, ctDNA etc.)**<br>**Please include any known or anticipated information** | |
|---|---|
| Correlative studies to be performed: | |
| Where will correlative studies be completed by study subjects? | ☐ NU only ☐ All sites ☐ Other, specify: |
| List the time points of sample collection and the estimated total number of samples: | |
| How will samples be processed? | ☐ PCF ☐ Another NU Shared Resource ☐ Sponsor ☐ Other, specify: |
| Time Period | Do you anticipate samples will be collected over more than an 8-hour time period?<br>☐ Yes ☐ No ☐ TBD<br>If yes, Clinical Research Unit (CRU) services may need to be used for the study. |

| **7. TREATMENT DETAILS**<br>**If using arms or cohorts etc., please modify the table accordingly (or use free text)** | | | | |
|---|---|---|---|---|
| **Treatment:** | | | | |
| ***DRUG*** | ***DOSE*** | ***FREQUENCY*** | ***# OF CYCLES*** | ***ROUTE OF ADMINISTRATION*** |

| | | | | |
|---|---|---|---|---|
| Arm/Cohort 1: | | | | |
| Arm/Cohort 2: | | | | |
| Arm/Cohort 3: | | | | |
| Arm/Cohort 4: | | | | |

| **8. STATISTICS** | |
|---|---|
| Statistical Considerations: | |
| Proposed sample size: | |

| **9. TYPE OF SUPPORT** | |
|---|---|
| **Type of Support provided by the sponsoring company, if applicable:** | ☐ Drug will be provided ☐ Financial support will be provided |
| **Will other support be provided by other Pharm/Biotech Companies:** | ☐ No ☐ Yes (*specify)* |

**10. IND DETERMINATION**

**Will this study require filing for an IND (US studies only):** ☐ Yes ☐ No

**Study meets the below criteria for IND exemption status (21CFR 312.2 (b)(1)(l)-(v):** *(for US studies only)*

☐ Yes ☐ No

I. The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use, nor intended to be used to support any other significant change in the labeling for the drug;

II. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;

III. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increased the risk (or decreases the acceptability of the risks) associated with the use of the drug product;

IV. The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in Part 50; and

V. The investigation is conducted in compliance with the requirements of § 312.7.

| **11. PUBLICATION PLAN** | |
|---|---|
| All cancer relevant studies conducted at NU are expected to follow clinicaltrials.gov registration laws as specified by US Public Law 110-85, Title VIII, Section 801 (https://clinicaltrials.gov/ct2/manage-recs/fdaaa)<br><br>Studies utilizing CTO regulatory services will follow ICMJE requirements (http://www.icmje.org) for disclosure of protocol and results information to www.clinicaltrials.gov. | |
| Target Abstract Submission(s) | |
| Target Venue: *(specify meeting, journal):* | |
| Target Venue Date *(mm/dd/yyyy):* | |
| Intend to submit final manuscript to a peer-reviewed journal | ☐ Yes ☐ No |