**Investigational Drug Study Registry Form**

**Department of Pharmaceutical & Nutrition Care**

**Nebraska Medicine**

**University of Nebraska Medical Center**

To maintain compliance with The Nebraska Medical Center Department of Pharmaceutical & Nutrition Care policy 1.380, the Pharmacy and Therapeutics Committee of the Medical Staff requires that this registry form be completed for any drug study protocol involving human subjects (volunteers or patients) at The Nebraska Medical Center/UNMC/UNMC-P. The Pharmacy and Therapeutics Committee will review this form along with the study protocol and then make recommendations to the Quality Assurance Committee, the Institutional Review Board (IRB) and the Medical Staff Executive Committee.

**Please Type All Applicable Information (Type N/A if Not Applicable)**

*IRB #:*

 *Name of Medication:*

**(One form per medication)**

**Study Title:** Click here to enter text.

**Principal Investigator:**

Please choose the appropriate box(es):

 [ ] This medication is provided to this institution from the sponsor

 [ ] Not an FDA approved medication (investigational drug)— ***Please*** ***complete sections 1 and 3***

[ ] An FDA approved medication, but supplied by sponsor at no charge to patient—***Please*** ***complete sections 1 and 2***

[ ] This is an FDA approved medication which is available commercially (utilizing hospital supply)—***Please complete sections 1 and 2***

**SECTION #1—GENERAL INFORMATION**

1. Nature or Purpose of Study (briefly describe): Click here to enter text.
2. Drug name:
3. Other drug names (i.e. Trade or Generic):
4. Study dosage form; include strength, concentration, and volume if applicable (i.e. 100 mg/5 mL vial or 500 mg caps/100 per bottle):
5. Dose and treatment regimen:
6. Route of Administration:[ ] IV
[ ] Oral
[ ] SQ
[ ] IM
[ ] ID
[ ] Other, please specify: Click here to enter text.
7. Personnel Approved to Administer Drug:
[ ] Licensed provider
[ ] Patient (Self-Administration)
[ ] Other, please Specify: Click here to enter text.
8. Where will the investigational drug be administered:
[ ] Hospitalized inpatients, please specify (i.e. Onc/Hem, ED, ICU, OR): Click here to enter text.
[ ] Clinic outpatients, please specify clinic (i.e. CRC, Internal Med, Peds): Click here to enter text.
[ ] Lied, Village Pointe, or Bellevue Infusion Center
[ ] Other, please specify:
9. Source of drug supply:
[ ] Sponsor, please specify: Click here to enter text.
[ ] Other, please specify: Click here to enter text.

**SECTION #2—GENERAL INFORMATION ABOUT FDA APPROVED MEDICATION**

*Lexicomp drug insert can be attached as a reference in lieu of completing questions below.*

1. Approved therapeutic indications:

1. Special precautions/warnings:

**Section #3—ADDITIONAL INFORMATION FOR INVESTIGATIONAL NON-FDA APPROVED MEDICATIONS***IB or protocol version and page number can be referenced when completing the questions below (i.e.- IB version 1.2, page 13-14). If information is not found in IB or protocol, please state so.*

1. Clinical lab tests indicated before administration:
2. Defined Drug-Drug and Drug-Lab interactions:
3. Defined Side Effects/Toxicities:
4. Use in pregnancy:
5. Pediatric use: