FORM B: REGISTRATION FOR INVESTIGATIONAL DRUG STUDIES NOT STORED IN PHARMACY

Any clinical research project performed at Hennepin County Medical Center (Hennepin Healthcare) involving the use of an investigational drug will require involvement of the Pharmacy Department. It is encouraged that all investigational drug supplies are stored and dispensed from the pharmacy. All studies involving investigational drugs must be registered with the HCMC Investigational Drug Services.

For questions, please contact the Investigational Pharmacist, 612-873-3213.

Instructions:

1. Complete the Study Information sections of this form and submit it, along with study information, to Investigational Drug Services, ms.idspharmacy@hcmed.org. *Study Information includes a Protocol or Project Summary.*
2. Attach a copy of the label and any auxiliary labels that you are going to use in the study. (For an example of a study label, please contact the Investigational Pharmacist.)
3. After review is complete and signature from Investigational Drug Services has been provided, attach the signed form in the Cayuse smartform (as prompted on the Site Info page).

STUDY INFORMATION (to be completed by the study team)	
Study Title:	
Cayuse ID (if known):	Principal Investigator:
Additional Authorized Prescribers:	
Research Coordinator:	
Number of participants to be enrolled:	
Start Date:	End Date:
Is patient enrollment in the study randomized? Yes ◯ No ◯	
Is it blinded? Yes ◯ No ◯ (*Skip the following questions if not blinded.)* If *yes*, summarize the randomization procedure and include the randomization and blinding procedure: Who has access to the blinding information? _____ Where will the blind be stored? _____ How will the blind be accessed in an emergency? _____	
Description of the study drug/placebo, including picture or diagram of drug supplies packaging and dosage form?	
Are there special drug handling considerations? Yes ◯ No ◯ *(Hazardous to Handle, chemotherapy, biological, controlled substance)* If selecting *Yes*, please describe here: _____	

Will the study drug be added to EPIC and Willow to allow addition to the patient's medication list? Yes ◯ No ◯	Will study medications be provided free of charge to participants? Yes ◯ No ◯
Has this process been initiated? Yes ◯ No ◯	Are there additional medications that are provided by the study with no cost to the participant? Yes ◯ No ◯

DRUG STORAGE INFORMATION (to be completed by the study team)

Where will the drug be stored?

Who will have access to the drug and storage area?

Name: Contact Info:

Who will have the ability to dispense the drug?

Name: Contact Info:

Describe required temperature monitoring:

Who will provide a second check of appropriateness of study drug dispensing?

Name: Contact Info:

Describe the procedure for the second check:

Are there any special storage requirements for the drug inventory? Yes ◯ No ◯
(*Controlled substance, Hazardous to Handle, caustic, flammable*)

If selecting *Yes*, please describe here: _____

Does the product require temperature control beyond room temperature? Yes ◯ No ◯

If selecting *Yes*, please describe here: _____

Will there be any excessive quantity or bulk that will be stored elsewhere? Yes ◯ No ◯

If selecting *Yes*, please describe here: _____

LABELING INFORMATION (to be completed by the study team)

Practitioner prescribing the medication:

Address:

Phone:	Pager:	Email:

Labels MUST include:

- Name, address, and telephone number of principal investigator
- Subject name
- Name of ordering provider
- Title of study
- Directions for use
- Unique prescription number
- Name of manufacturer or distributor of the finished dosage form of the drug
- Auxiliary labels as needed
- Date of original issue or renewal

- Generic or trade name of drug and strength, or study name to identify drug, except when specified by prescriber to the contrary.

- In the case of combining pre-manufactured drug products, the names of the products, or a category of use name shall suffice.
- In the case of compounding basic pharmaceutical ingredients, the common pharmaceutical name (if such exists), the names and strengths of the principal active ingredients or a category of use shall suffice (Minnesota Rule 6800.3400 and 6800.9953).

For "Investigational Use Only" or "Caution: New Drug Limited by Federal (or United States) law to Investigational Use."

Signature: _____ Date: _____

☐ I have read and agree to abide by the Investigational Medications Policy and Procedures (policy #005361).

Investigational Drug Services Signature: _____ Date: _____