UPH-DSM Institutional Review Board

For pediatric oncology studies, please return the signed form to Katy Juhl at Katy.Juhl@unitypoint.org
For all other studies, please return the signed from to Joan Pruisner at Joan.Pruisner@unitypoint.org
Note: it may take up to one month for the Pharmacy Department to evaluate and return this form.

Utilization of Pharmacy Department

In addition to requiring Institutional Review Board (IRB) approval for a clinical investigation to be conducted at UnityPoint Health—Des Moines, utilization of pharmacy services must be approved in advance by the service line director.

For protocols involving an investigational drug (IND), include the Pharmacy Manual and Investigator Brochure (IB) when available.

Note: In the event the protocol has changes that significantly affect the conduct of the study, the department managers may re-evaluate the utilization of their department's services for this protocol.

Protocol Title:
Principal Investigator Name:
Telephone:

Study to be conducted at (check all that apply)**:** ☐ IMMC ☐ ILH ☐ MWH ☐ BCH ☐ Blank or UP clinic(s) ☐ Other site (describe)

Will medications be stored in the pharmacy department? ☐ Yes ☐ No

Will medications be dispensed by the pharmacy department? ☐ Yes ☐ No

Will study medications be entered into and/or documented within Epic, the electronic medical record (EMR) at UnityPoint? ☐ Yes ☐ No

Date of planned study initiation:

Expected number of enrollments (aka study participants) at your site:

Expected duration of study:

Where will study be conducted (check all that apply)**:** ☐ Inpatient ☐ Hospital Outpatient department (HOD) ☐ Ambulatory clinic

Time of day patients are expected to be enrolled: ☐ 24 hours a day ☐ Day-shift only
☐ Weekdays only ☐ Other (describe)

Pharmacy Department

If you are unable to answer any of the following questions, please provide a contact name/number for the study sponsor or contract research organization so the pharmacy department can contact them for more information.

Contact Name:
Company:
Telephone Number:
E-mail:

1.	Will pharmacy randomize?	☐ Yes ☐ No
2.	What medications will be dispensed by pharmacy (specify commercial vs. IND supply, and the route of administration for each medication)? Attach separate form if necessary	
3.	Is there a time limit on any drug preparation (e.g. short stability/sterility or special/labor intensive mixing requirements, time-dependent administration, etc)?	☐ Yes ☐ No
	3.a. If yes, please explain what the time limit is for each applicable drug?	
4.	For each study participant, how often would medications be dispensed by the pharmacy?	
5.	For each study participant, what is the length of treatment during which the above medications will be given?	
6.	What time of the day will most participants receive medications? ☐ 24 hours a day ☐ Day-shift only ☐ Weekdays only	
7.	If enrollment begins inpatient, is there a possibility of transferring to home health or a non-UP entity?	☐ Yes ☐ No
8.	Will pharmacy participate in monitoring visits?	☐ Yes ☐ No
9.	Does pharmacy need to submit a general service request (GSR) through ServiceNow to create a new ERX for any medication included in the study?	☐ Yes ☐ No
10.	Does pharmacy management need to update the EFY (i.e. Epic formulary) to include a previously built ERX that has not yet been added to the local dispense list?	☐ Yes ☐ No
11.	Does pharmacy need to submit an enhancement request (ENH) to the department's informaticist(s) to create a Treatment or Therapy Plan?	☐ Yes ☐ No

☐ The utilization of pharmacy services for this protocol is approved (see below for any restrictions or concerns)

☐ The utilization of pharmacy services for this protocol is not feasible (see below for explanation)

Restrictions or concerns:

Executive Director of Pharmacy signature	Date