Department of Pharmaceutical Care
University of Iowa Hospitals and Clinics

Section	Research
Related Policy	None
Operating procedure	**RES-NP008**

REQUEST FOR WAIVER OF UNIVERSITY OF IOWA HOSPITALS AND CLINICS (UIHC) INVESTIGATIONAL DRUG SERVICE STANDARD OPERATING PROCEDURES

General Procedures:

A. A waiver process is in place for any UIHC Investigational Drug Service (IDS) procedures deemed unacceptable by the sponsor. These requests should only be made when patient safety, research or IP integrity will be compromised by adherence to the UIHC IDS policies.

B. Supporting documentation, including sponsor SOPs, International Council for Harmonization (ICH) or GCP (Good Clinical Practice) may be requested by the IDS pharmacy as justification for waiver requests.

C. Waivers must be submitted prior to the study opening date or within 2 weeks of being provided with the IDS pharmacy SOPs and may incur an additional charge. Completing a waiver request does not guarantee approval.

D. IDS personnel will review all waivers and work with the sponsor to reach a mutually agreeable resolution. In some cases, waivers may be reviewed and approved/denied by pharmacy and/or hospital leadership. The primary investigator or study team may be consulted to aide in determining a resolution. IDS pharmacy review may take up to 2 weeks for completion.

E. All waivers and budget adjustments should be addressed and completed prior to the study opening. In the event no waiver is requested, the SOPs will be deemed acceptable to the sponsor.

F. Amendments may require a waiver. In those cases, IDS personnel will assume responsibility for identifying that a waiver is required. Additional charges may be incurred.

Approved by the Pharmacy Administrative Staff: 7/2023.
Revised:
Reviewed:

University of Iowa Hospitals and Clinics

Investigational Drug Service

Request for Waiver of IDS Standard Operating Procedure (SOP)

IDS will provide an email to a sponsor representative regarding availability of SOPs on the IDS website. For any procedures deemed unacceptable by the sponsor, there must be a waiver of policies requested in writing prior to the study opening date or within two weeks of being provided the SOPs. These requests should only be made when patient safety, research or IP integrity will be compromised by adherence to the UIHC IDS SOPs. Supporting documentation should be submitted along with this request as justification. IDS personnel with review all waivers and work with the sponsor personnel to reach a mutually agreeable resolution. In some cases, waivers may be reviewed and approved/denied by Pharmacy and/or hospital leadership. Waiver requests may incur additional fees not included in the original budget. Please allow 2 weeks for review and approval. In the event that no waiver of policies is requested prior to study opening or within two weeks of being provided SOPs, it will be assumed that all policies are acceptable to the sponsor.

Section 1 (To be completed by sponsor personnel)	
Sponsor Protocol # and/or HawkIRB #:	PI:
Submitted by:	Title/Role:
Phone:	Email:
Signature:	

Section 2 (To be completed by sponsor personnel)		
Specific SOP being requested for Waiver (e.g., SUP-002-02)	Reason for request	Additional documentation provided

Section 3 (To be completed by IDS, Pharmacy or hospital leadership)		
UIHC IDS Decision	Additional Fees Required	Signature/Date