

Penn Investigational Drug Service (IDS) Pharmacy Exemption (Waiver) Request Form

Note: A copy of the current study protocol(s), investigator brochure(s), and all other pertinent document(s) should be provided with the completed and signed form.

Part 1. Completely fill in all entry fields, sign form and submit to Penn IDS (pennids@pennmedicine.upenn.edu)

Primary Investigator	Name: Email: _____ Phone Number: _____
Protocol	Title: Protocol Number: _____ IRB Number: _____ IND: <input type="checkbox"/> Yes (IND Number: _____) <input type="checkbox"/> No
Study Team Members	List names and roles of study team members (You may attach a list or submit DOA or 1572 if available)
Drug Management	Drug Classification: <input type="checkbox"/> Gene therapy <input type="checkbox"/> Controlled Substance <input type="checkbox"/> Hazardous <input type="checkbox"/> Other: Procurement (Supplier) <input type="checkbox"/> Sponsor (Brief description- including name of supplier) <input type="checkbox"/> Non-Sponsor (Brief description – including the name of purchaser/vendor) Drug Storage location (Please describe security and access to the storage area)

	<p>Temperature monitoring (Please describe temperature monitoring and documentation)</p> <p>Preparation and dispensation (Please list location, name, and roles of study team members involved in preparation)</p>
Protocol Monitoring	<input type="checkbox"/> Regulatory Sponsor' designated study monitor will conduct quality control activities <input type="checkbox"/> No sponsor-appointed monitor, the PI and study team conduct all quality activities <input type="checkbox"/> Other:
Purpose/Justification for Exception Request	
Other information, if applicable	
PI's Attestation	<input type="checkbox"/> I attest to all the information noted above
PI's Signature	
Date Completed	

Part 2. Exception – Decision/Approval (Penn IDS Use Only)

Decision	<input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Rejected <input type="checkbox"/> Not Approved
Conditions	
Remarks	
IDS Director Signature	
Date Signed	