

UW Health Department of Pharmacy – Pharmaceutical Research Center FAQ 3-19-20

Can additional investigational products (IP) or supplies be sent to the PRC?

PRC is not accepting requests to empirically increase the inventory of investigational products (IP) or supplies. Storage space is extremely limited, and proper storage conditions for the additional IP over established par values cannot be guaranteed.

Can monitor visits or other sponsor-associated visits be conducted?

Monitoring visits must be cancelled. Requests for documents or information will not be honored at this time; exceptions may be granted on a case by case basis after review by the Manager of the PRC.

Site qualification visits will not be scheduled at this time

Site initiation visits may proceed only if performed in a virtual manner; in person visits will not be scheduled

Information regarding potential drug shortages

The UW Health Department of Pharmacy consistently monitors medications impacted by shortages and potential alternatives. The PRC will follow Departmental recommendations, and will contact study teams or sponsors if, in the event of shortage, appropriate alternatives cannot be identified or obtained.

How does this impact campus research purchase of pharmaceuticals?

Many of our campus research colleagues have accounts set up with UW Health Department of Pharmacy, to facilitate purchase of required pharmaceuticals for research projects. The COVID-19 pandemic requires us to make changes to this process in an effort to conserve resources required for our caregivers and our patients. We are therefore providing updated guidance on this process and notifying you of changes that will take place, effective immediately.

- Current accounts, with developed pick lists will still be honored. Pharmaceuticals may continue to be ordered via our current process (completion of the pick list, scanning and emailing to our pharmacy purchasing team)
- Edits to current pick lists may be requested. Only items currently available from our pharmacy wholesaler may be added to pick lists
- No new accounts to purchase pharmaceuticals via this process will be opened.

Finally please note that specific pharmaceuticals that are required for clinical care and are under shortage conditions, will be allocated toward clinical needs and not provided for a research trial. Exceptions may be made for human therapeutic trials; with active/enrolled subjects on a case by case basis.

Shipments of study medication

Study team responsibilities

- Study teams are responsible for obtaining all necessary approvals from the PI and the sponsor to ship product to the subject; they are also responsible for ensuring that this information is provided to the PRC.
- Study team is responsible for allowing the maximum time possible to ensure that study treatment windows are met. This may mean communication with sponsor for advance medication assignment within the IWRS
- Study teams are responsible for contacting the subject to ensure that product has been received and documentation accordingly
- When a shipment need is identified
 - Study team must notify PRC in a timely manner (minimum 48 hours) that a shipment of IP is necessary
 - Study team must provide (in addition to ordering within Health Link or Direct order to PRC):
 - Permission from sponsor and PI
 - Patient address (no P.O. Boxes)
 - Patient contact phone number
 - UPS or FED Ex billing label (must be billed to the study team or sponsor)
 - Anything that needs to be included in the package including diaries
 - Study team is responsible for contacting the subject and:
 - Confirming and documenting drug receipt
 - Providing instructions for use

Procedure for Mail out

- PRC will not accept sponsor provided shipping containers and temperature monitoring devices for shipping of product. All requested shipments will be made utilizing the UW Health Mail Order Pharmacy
- Pursuant to the study prescription (Health Link or Fax)
 - PRC will obtain medication, label and document

- All shipping will be handled by the UW Health Department of Pharmacy Mail Order Service
- Shipments will be made utilizing the existing procedures and qualified shippers in the UW Health Mail Order Pharmacy
- Turnaround time for ship leaving the mail order pharmacy is targeted at 24 hours but may be as long as 48

Every effort will be made to maintain compliance and timeliness in delivery of study medication to a subject; however unexpected situations may arise that require documentation and flexibility.

Is PRC still working on new protocol activations?

Please note that during this time our focus is on our currently enrolled subjects, thus protocol development activities may need to be delayed. It is also possible that the PRC pharmacists will be deployed to provide clinical pharmacist coverage. If you have questions about protocols currently in the activation phase, please contact the PRC. Your understanding during this time, and later when systems are back in place is appreciated

How and when to contact PRC

With more research staff working remotely, email volume will be driven up. Please do not expect a response to your email until a minimum of 24 hours has passed. Urgent needs (please use extreme discretion) may be addressed by paging the PRC Pharmacist on call – UW Pager ID# 2717

Additional questions?

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