

Investigational Drug Service Guidance for COVID-19 Pandemic
March 13, 2020

The following information provides guidance for the Investigational Drug Service (IDS) operations during the COVID-19 pandemic. As situations evolve this information may require updates. The safety and well-being of our patients and their families, our students, visitors, staff members and communities is our top priority.

***Please check the IRB website daily for updates:**

https://www.hopkinsmedicine.org/institutional_review_board/news/letters_dean/archive/2020_covid19.html

1. Investigational Products (IP) and Other Supplies

- a. What would happen if IP supply shipments are affected?
 - i. IDS staff is monitoring the inventory of the IPs. In some cases, the sponsors have requested to send additional IP supply while others have remained silent on the issue. The IP supply is being evaluated by IDS staff based on participant enrollment volumes. In addition, the quantities of IP supply sent to JHH are dependent upon supply availability from sponsors, NCI, etc.
- b. Our research participants may also be affected by the availability of commercial drug supply. What is being done to track these drugs?
 - i. The Department of Pharmacy Drug Shortages Committee is tracking commercial drug supply. Drug shortages are tracked continuously and a weekly report is provided to communicate new shortage items, out-of-stock items and drug shortages that have been resolved.
- c. Do Interactive Response Systems (IRT) impact the ordering of investigational products?
 - i. IRT systems track inventory distribution, dispensing, expiration dates, lot numbers and other protocol specific information for the clinical trial. Participant enrollment is also tracked in the systems, so one would believe that IRT systems would not impact the ordering of extra IP. However, without knowing technical operations of the systems the impact cannot be determined.

2. Dispensing of IP to Study Participants

- a. If participants are unable to come in-person for follow up visits, how will we operate?
 - i. In this case, IDS will work with research teams to determine the best means of providing continued services to our study participants.
 - ii. Examples of requests include:
 1. Prepare and send drug to Green Spring Station as an alternative to having patients visit the hospital.
 2. Increase days supply of IP to assure that participants have adequate IP supply.
- b. Can IP be shipped to participants if they are unable to come on-site?
 - i. Most clinical trial protocols or sponsors prohibit the shipping of IP to participants. Written authorization will need to be obtained from the sponsor to ship drugs to participants, and the FDA and IRB protocols must be amended to reflect this change.
 - ii. According to the Code of Federal Regulations, IDS can ship IND drugs across state lines, where permitted by protocol.

- iii. At this time, the FDA has not issued any emergency orders that would permit shipping of drugs for research purposes where the drugs are not covered by an IND across state lines. Additional information is being obtained for this specific issue and investigators should consult the sponsor of the study about plans for non-IND studies.
- iv. For subjects who are out of the country, please consult the sponsor about what arrangements they are making to permit international shipment of IP.
- c. Does IDS have a SOP to ship IP to participants?
 - i. No, a SOP does not exist at this time since this is not standard practice. However, a draft SOP is being developed assuming IDS will need to ship IP to participants.
 - ii. Information that would be needed from the sponsor to ship IP includes:
 - 1. Written authorization from sponsor to ship drug
 - 2. Acceptable methods to ship IP (FedEx, UPS, direct courier, etc.)
 - 3. Special procedures for shipping
- d. What happens if FedEx, UPS, etc. are impacted and cannot provide services?
 - i. These couriers transport the majority of the IP shipments and interruptions in service would drastically impact the supply of IP. In most cases, IDS shipments are delivered directly to the pharmacy. If service is restricted to the loading dock, IDS will work with the appropriate individuals in-house to obtain the shipments.
 - ii. As of March 11, 2020, IDS was not required to provide a signature at the time of IP delivery to the FedEx courier.

3. Personnel and Travel Considerations

- a. What policies are in place regarding travel and in-person meetings?
 - i. IDS will follow [Johns Hopkins Medicine Incident Control Center policies](#) for travel and meetings. The Senior Vice President of Human Resources and her team are closely monitoring the situation as well as human resources concerns.
 - ii. Broad travel considerations for all personnel were developed to protect our workforce and are detailed in the linked document stated above.
- b. If telecommuting is necessary, what are the roles and responsibilities of on-site vs. telecommuting staff?
 - i. Preliminary stages of brainstorming how to operationalize working remotely are being evaluated by pharmacy – what can be done from home, what needs to be done on site, what equipment is needed to support these efforts, etc.

4. Visitor/Monitor Information

- a. How is IDS managing monitor site visit requests?
 - i. IDS will support remote monitoring visits utilizing Vestigo® (software used to support investigational drug operations) at this time
 - ii. The remote monitoring is limited to functionality and documentation that is currently available in Vestigo®. Staff are unable to accommodate phone and video conferencing with a site monitor.

For additional information or inquiries, please contact the Investigational Drug Service pharmacies or contact Janet Mighty jmighty1@jhmi.edu.