[Update] Investigational Drug Service Guidance for COVID-19 Pandemic
October 15, 2021

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 are our top priority.

Please check IRB website daily for updates:
https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/index.html

FAQ: Shipping of investigational drugs IND and non-IND

1. What investigational drugs may be shipped and to what locations?

a. Investigational drugs with an Investigational New Drug (IND) may be shipped to any location within the U.S.A.
b. Investigational drugs without an IND (non-IND) cannot be shipped across state lines (outside of Maryland).
c. Investigational drugs (with or without an IND) cannot be shipped internationally.

2. Why can INDs be shipped to any state in the U.S.A. but non-INDs cannot be shipped across state lines (outside of Maryland)?

a. 21 CFR 312.1 states "An investigational new drug for which an IND is in effect in accordance with this part is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug."

3. The FDA *Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency* provides additional guidance for Industry, Investigators, and Institutional Review Boards. Does language in this document allow for non-IND shipping across state lines?

a. The FDA recognizes that the COVID-19 pandemic may impact the conduct of clinical trials of medical products. The guidance document does not imply that current regulations can be disregarded. The document outlines considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity.

4. Do the shipping restrictions mentioned above only apply to investigators, does it apply to JHM Investigational Drug Service (IDS) pharmacies as well?

a. The shipping restrictions mentioned in questions 1-3 apply to both investigators and JHM IDS pharmacies.

5. What alternatives are available to investigators to supply non-INDs to participants living out of state?

a. Since an IND or EUA (Emergency Use Authorization) is needed to ship across state lines, the investigator should consult with the sponsor or the FDA.

6. I am a site investigator on a CTEP study. Are there any special considerations for CTEP studies?

a. Yes, multiple memorandums have been distributed by the CTEP Pharmaceutical Management Branch. You should consult the most recent memorandum from April 30, 2021. Previous memorandums should also be reviewed and they are available on the CTEP website: https://ctep.cancer.gov/investigatorResources/corona_virus_guidance.htm.

7. At clinic visits, the study teams collect any used, unused, or empty drug containers (patient returns) from the study participants. How should these "patient returns" be returned to IDS?

a. The study team may drop off any "patient returns" at any of the IDS pharmacy windows in Osler, Weinberg, or Viragh. Please do not ship or mail any "patient returns" to the IDS pharmacy.

FAQ: Monitoring Visits

1. **Are study monitors allowed to visit the JHM IDS pharmacies?**
   a. At this time, it is preferred to conduct monitoring visits remotely using Vestigo®. Due to lack of space and physical distancing requirements, the IDS pharmacy may not be able to accommodate any in-person visits at this time.
      a. Please refer to the JHM IRB website for frequently asked questions regarding monitoring visits during the pandemic:
         i. https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/covid19_faqs.html
   b. All in-person JHH visitors must comply with current JHM visitor restrictions.
      a. https://www.hopkinsmedicine.org/coronavirus/visitor-guidelines.html

2. **How much advance notice do I need to provide to JHM IDS pharmacies?**
   a. Please contact IDS at least 10-14 days in advance to allow pharmacy staff time to prepare for the visits. Requests for appointments within 3 days will likely be denied.

3. **How can I set up a remote monitoring visit?**
   a. Study teams or monitors may email the contact for the appropriate IDS pharmacy to request a remote monitoring visit using Vestigo®. The IDS pharmacy staff will provide the next available dates and times, and set up the appointment accordingly.
   b. For monitoring visits with the Weinberg Oncology IDS Pharmacy, email oncpharmacy@jhmi.edu.
   c. For monitoring visits with the JHH Central IDS Pharmacy or Bayview IDS, email the lead pharmacist for the study.
   d. The subject line of the email should read as follows: Monitoring Visit (External Review) Request: Hopkins Protocol # and PI Name
      a. The body of the email should include the possible dates of the visit and the preferred time, and what information is requested for review.

4. **What information is available remotely through Vestigo® for the monitors to review?**
   a. Through Vestigo®, monitors will be able to review drug accountability logs, participant returns, receipt records, and temperature monitoring documentation. Monitors will also be able to authorize drug destruction.

5. **Is it possible to set up an assisted remote monitoring visit through telephone or video conference?**
   a. No, the IDS pharmacy is not able to accommodate any assisted remote monitoring visits through telephone or video conference.