



Monday Morning Practice Pearls #82

I have an international patient who is eligible for an oral drug IND study. Can the pharmacy ship investigational drug(s) overseas?

Yes. To ship investigational drug(s) internationally, the outpatient pharmacy must be provided with the following documentation from the research team:

- CRIS order for the investigational drug(s)
- Sponsor approval
- Approval of the Ministry of Health of the country where the investigational drug(s) is being shipped
- Two shipping forms ([Request for Shipment](#) and [Commercial Invoice](#)), which both must indicate that the medication is an investigational drug.

Please contact the pharmacist working with your research team for any questions regarding the documentation above. The pharmacy will coordinate with the shipping department and courier regarding shipment logistics and contact the research team if any additional information or documentation is needed.

Alternately, can we dispense investigational drug(s) to those patients while they are in the United States, such as during a NIH visit?

It may be possible to supply enough investigational drug(s) while the patient is in the United States to last until their next protocol visit, if the IRB approved protocol allows for ordering and dispensing of multiple cycles of investigational drug. In addition, the patient must be counseled on how to store the extra investigational drug(s) in accordance with the Pharmaceutical and Investigational Device Information section of the protocol (e.g., controlled room temperature (20°C-25°C). Investigational drug must be properly accounted for per CCR SOP PM-8 *Conducting and Documenting Drug Accountability for Oral Investigational Products that are Self-Administered by Research Participants*.

Please remember the research team will need to make arrangements with the patient/family to have any remaining investigational drug(s) returned if the patient unexpectedly comes off treatment or off study and is unable to return to the NIH.

Resources

- [NIH-1884 Request for Shipment](#) and [NIH-1884-1 Commercial Invoice](#) forms
- [Pharmacy Department Policies](#)
 - Investigational Drug Dispensing (4007.1)
- [CCR SOP PM-8 Conducting and Documenting Drug Accountability for Oral Investigational Products that are Self-Administered by Research Participants](#)