Department of Pharmaceutical Care
University of Iowa Hospitals and Clinics

Section	Research
Related Policy	None
Operating procedure	**RES-NP007**

INVESTIGATIONAL DRUG SERVICE SPONSOR PERSONNEL EXPECTATIONS

Definitions:

Study Monitor: An organization, individual, or group responsible for the oversight and monitoring of the conduct of a clinical study.

Vestigo: A web-based platform used by the University of Iowa Investigational Drug Service to manage investigational drug products used in studies conducted at the University of Iowa Hospitals and Clinics. It allows tracking of details such as trial status, study team members, patient enrollment, drug dispensing, temperature monitoring etc.

Purpose:

To outline and reinforce a standardized process for clinical trial monitor visits with the Investigational Drug Service at the University of Iowa Hospitals and Clinics.

General Procedures:

1. In order to balance patient care needs and ensure successful pharmacy operations, the following will be required of sponsor/study team personnel.

    A. Prior to study opening

    - The monitor and/or other sponsor personnel should be well versed with the protocol and have a thorough understanding of the study-related pharmacy requirements.
    - If the monitor and/or sponsor personnel cannot readily address a question or issue, they are expected to acquire needed information and respond to IDS (Investigational Drug Service) in a timely manner before the initiation of the study. Failure to respond in a timely manner may result in IDS escalating the question or issue further. Contact information for an alternative responsible person, as well as the immediate supervisor for the study monitor, shall be available to IDS prior to study initiation and IDS will be informed in a timely manner regarding changes to the aforementioned responsible personnel.
    - IDS will provide the sponsor with the University of Iowa Investigational Drug Service Standard Operating Procedures (SOP) only once at the time of initiation and only later if an update occurs. Monitoring personnel are expected to share these documents with the sponsor and any monitors that are assigned to the University of Iowa.
    - The IDS pharmacy will keep a copy of email sent to study sponsor personnel that provides information on how to obtain our policies from the IDS website.

- For any procedures deemed unacceptable by the sponsor, a request for Waiver of University of Iowa IDS SOPs form must be submitted in writing prior to the study opening date or within 2 weeks of being provided with SOPs (if no response is received, SOPs are deemed acceptable). These requests should only be made when patient safety, research or IP integrity will be compromised by adherence to the University of Iowa IDS SOPs. If a waiver of policies is not requested during the allowable time period, it will be assumed that all policies are acceptable to the sponsor.
- At the time of qualification visit or site initiation visit, IDS expects sponsor representatives or monitors to schedule a time to provide information regarding study and to answer any IDS questions.

B. Scheduling an Onsite Monitor Visit

- Pharmacy monitoring visits will be scheduled separately from the study team via a request submitted through the University of Iowa IDS pharmacy website. All appointments and Vestigo access are in the Central Time Zone. One monitor is allowed per study visit unless approved by the IDS pharmacy staff. Due to the high volume of requests, it is strongly recommended to schedule 2-4 weeks in advance. All visits are subject to approval by IDS. In instances where the study requires an immediate visit after the first patient is enrolled, the monitor should reach out to Pharmacy via email if an appointment is not available. The monitor is expected to inform IDS as soon as possible for these initial visits that are required to be within a certain time frame.
- IDS staff spend a significant amount of time preparing for a monitoring visit. Therefore, the monitor shall respect the schedule of other study monitors and IDS staff and will arrive on time for their appointment.
- Cancelling or rescheduling a visit should be done directly with IDS staff (not other site staff) at least 24 hours prior to the visit. Rescheduling of the visit is done at the discretion and availability of IDS staff.
- A monitor arriving late to an appointment will not be guaranteed IDS availability beyond the time initially scheduled. If the monitor is running more than 20 minutes late for a scheduled appointment, the monitor shall call or email IDS. Same-day rescheduling of the visit or increase in time allowance is done at the discretion and availability of IDS staff.
- Each onsite monitor visit will be scheduled for no more than 3 hours though Vestigo access will always be open for the duration of the business day if the study is in Vestigo. Monitors are responsible for verifying their access prior to visits.
- If more time is needed, the monitor may request three-hour visits on two subsequent days. Extending the time allowance for a visit is left to the availability and discretion of IDS staff.

C. During the Monitor Visit (Accountability and Temperature)

- During the visit, the monitor will be assisted by IDS technicians. A pharmacist will be available for any questions and issues. If any significant issues are identified during the visit, then a pharmacist must be notified prior to the monitor leaving the pharmacy.
- Every effort should be made to rectify any issues prior to the end of the visit.
- Due to narrow temperature requirements for some sponsor's IP and the potential for an excursion, medications in the -70 freezer will not be available for accountability for onsite monitoring visits.

- All temperature logs will be done monthly and added to Vestigo. Studies that are not in Vestigo will also be provided with monthly temperature reports. Requests for any other time period will not be honored. Specific temperature logs will only be provided monthly as noted above and not for the overall length of the study.
- Temperature logs will not be signed and dated or contain the hospital name.
- No photos are allowed during onsite visits.

For any studies in Vestigo:

- It is recommended that monitors review electronic accountability records remotely prior to the onsite visit to allow for efficient use of their time.
- Paper copies of accountability records will not be provided. Documents are provided in a pdf format within Vestigo so that the monitor can save the file, print at a later time and share with other sponsor personnel.

For any studies not in Vestigo:

- The monitor may not remove any documents from the study binder or folder to make copies of items if they have not been deidentified of patient information.
- The study binder/folder and any of its documents may not be removed from the pharmacy.
- It is expected that the monitor will make copies of any documents that do not require deidentifying during their visit to provide to the sponsor.

Study Regulatory Documents

- Many regulatory items are maintained in the study team's regulatory binders. Copies of these items are not maintained in the pharmacy binder. (Items maintained by regulatory may include Delegation of Authority logs, training logs, IDS staff CV's, GCP and Human Subjects training, licensure, protocols, amendments and Investigational Brochures, etc.)
- Regulatory binders can be viewed by setting up a time with the study team. IDS will not have regulatory binders present during the pharmacy monitor visit.

D. **After the Monitor Visit**

- The monitor is expected to provide IDS with a monitoring report within 30 days of the visit that includes a summary of the items reviewed and the monitor's statements concerning significant findings/facts, deviations and deficiencies, conclusions, actions taken or not taken and/or actions recommended.
- IDS will address all findings, deviations and deficiencies presented by the monitor with a specified timeline that is acceptable to the sponsor and the investigational site. All corrective actions will be documented and filed appropriately.

E. **Remote Monitor Visits**

- The use of Vestigo also provides the capacity to offer remote monitor visits. These requests should still be scheduled following the procedures in Section B above, with the exception that it should be noted that the visit is remote.
- IDS will only provide information that is reviewable in Vestigo. This means the monitor will have access to drug accountability records (showing

current IP quantities, locations, patient returns, and quarantined IP), IP shipping receipts and temperature logs.

- Note, temperature logs are provided on a monthly basis at the beginning of each month. Other documents will not be provided through Vestigo or email and an onsite visit will be required to collect any other documents.
- Photos will not be provided of IP.
- For any studies that are not in Vestigo, drug accountability logs and temperature logs will be provided. Any other documents can be obtained at the next on-site visit.

F. **Close Out Visit**

- Upon notification of the last patient completing treatment or of study closing, IDS will contact the monitor to schedule a pharmacy close out visit within 60 days of said notification. At this point IDS will notify a monitor to request drug destruction or return, if applicable. It is expected that the monitor will request all needed documents and information prior to or during the close out visit. Requests occurring after the close out visit for additional copies or data will be subject to additional charges.

- All IP will be returned or destroyed based on the sponsor's requirements. Expired IP or IP remaining after a study is closed will be retained for 60 days to allow the monitor to schedule the pharmacy close out visit. At the end of the 60 days, IP will be destroyed if no visit has been scheduled, unless a prior agreement is reached with IDS. A monitor can follow up with IDS personnel to have IP destroyed if review of the product is not needed during a visit, or a visit is not required. IP destruction will be documented in per our SOP.

- Any study medication that is received onsite after a trial is closed to accrual and there are no active patients will be destroyed immediately and will result in a fee for the disposal.

- IDS records will be stored onsite for three years after study closing; thereafter, they will be stored at the following location:

The Advantage Companies
1035 33rd Avenue SW
Cedar Rapids, IA 52404

G. **Other Expectations**

- Monitor noncompliance may be reported to the monitor's manager or study personnel. Continued failure to comply with requirements may result in denial of visit requests.

- IDS will be notified when a change in monitor occurs. IDS expects sufficient handoff occurs between the outgoing and the incoming monitor such that all agreed upon procedures will continue and will not require review or revision. All documents provided to the previous monitor will be passed to the new monitor and all documents provided to the previous monitor will be filed in the Trial Master File (TMF) such that they will be available to future monitors.

- The monitor is expected to ensure that inventory on site is sufficient and inventory on hand is accurate. This is extremely important for automatically supplied IP since IDS is not actively involved in managing the inventory.

- The monitor shall ensure that IDS has the most up-to-date version of the pharmacy manual.
- IDS expects the new monitor to be up to date on the protocol and past events with the protocol such that IDS will not be required to re-educate new monitors.
- Requests for records previously provided will incur an extra charge.
- Documents requested after the close out visit will incur an extra charge.