Investigational Drug Service
Huntsman Cancer Hospital
1950 Circle of Hope, Suite N2545
Salt Lake City, Utah 84112

STANDARD OPERATIONAL PROCEDURE (SOP)
AUDITOR AND MONITOR VISITS

Purpose

The purpose of this standard operational procedure is to outline and enforce a standardized process for clinical trial monitor visits within the Investigational Drug Service (IDS) at University of Utah Health (UUH).

Definitions

A. **Auditor or Monitor**: an individual who observes each trial site to ensure that the standardized operation procedures for the trial are being followed, reporting and managing any deviations from the investigation plan as they occur. An auditor/monitor may work directly with the sponsor company of a clinical trial, as an independent freelancer or for a contract research organization. Auditors/monitors may also do the following functions related to clinical research studies; ensure compliance with the clinical trial protocol, check clinical site activities, make on-site or remote monitoring visits, review case report forms and communicate with clinical research coordinators.
B. **Investigational drug**: A new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part. Any drug which has not received FDA approval for use in humans. Also refers to any drug, which is FDA approved and is being used under protocol for human research, possibly outside of FDA approved labeling.
C. **Investigational drug service**: A function of the Department of Pharmacy and provides support to ensure the safety and efficiency of trials at University of Utah Health that use investigational product(s)/investigational drug(s). Pharmacy personnel that perform investigational drug accountability at UUH satellite locations approved for conducting research protocols are considered an extension of the IDS.
D. **Investigational product (IP)**: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
E. **Vestigo®**: A 21 CFR Part 11 compliant electronic accountability software application designed specifically for investigational pharmacy use and utilized by University of Utah Heath IDS. Refer to www.mccreadiegroup.com/vestigo/ for additional information.

Description

A. Scheduling a visit for an audit
    1. Auditor visits are to be scheduled by either the monitor or the study coordinator by using the appointment calendar on external IDS webpage. The webpage collects the information needed to schedule the auditor prior to their visit and notifies IDS pharmacy personnel once the appointment has been scheduled by the auditor. The auditor is also responsible for notifying the research team of their intended visit to the IDS pharmacy.
    2. It is the responsibility of the auditor or the research coordinator to schedule an auditor visit using the IDS auditor scheduling webpage. Auditor visits must be scheduled a minimum of 8 weeks in advance. Shorter notice may be allowed if approved by the IDS manager prior to scheduling.
    3. Visits are to be limited to a maximum of 2 business days; however, visits can be extended if the IDS can accommodate, with prior approval at time of scheduling.
    4. Frequency and number of auditor visits per study is specific to each protocol (no defined maximum per year per the IDS).
    5. Visits must be completed during regular IDS business hours
    6. Only unblinded auditors are allowed to schedule visits with the IDS
    7. Auditor visits may need to be scheduled in an off-site location to accommodate the time and space needed by the auditor in conjunction with other IDS activities. The IDS will coordinate this with the research team to ensure that research documents are kept in the appropriate chain of custody at all times during the audit visit.
B. Remote and On-Site Monitoring
    1. The IDS supports remote monitoring for research protocols.
    2. Remote monitoring visits must be scheduled using the scheduling webpage as described below (Section C.).
C. An additional fee for special monitoring requests (eg, Vestigo® access or accountability logs outside of a scheduled appointment) may be charged per the amount provided in the IDS pharmacy estimate.
D. Scheduling a Monitor Appointment
    1. Remote monitor visits are to be scheduled by either the monitor or the study coordinator by using the appointment calendar on external IDS webpage. The webpage collects the information needed to schedule the monitor prior to their visit and notifies IDS pharmacy personnel once the appointment has been scheduled by the auditor. The monitor is also responsible for notifying the research team of their intended remote visit to the IDS pharmacy.
    2. It is the responsibility of the monitor or the research coordinator to schedule a monitor visit using the IDS monitor scheduling webpage. Monitor visits must be scheduled a minimum of 4 weeks in advance. Shorter notice may be allowed if approved by the IDS manager prior to scheduling. Resources are limited within IDS and shorter notice may not be feasible.
    3. Remote visit access to Vestigo is open from 1700 MTS the evening prior to the scheduled visit and closes at 1600 MST the day of the visit. The remote visit is limited to a maximum of 1 hour with scheduled staff for a phone call if needed. Visits can be extended if the IDS can accommodate, with prior approval at time of scheduling
    4. The IDS can accommodate no more than 1 monitor (1 remote) during any given time frame, and no more than 8 hours of monitor visits per business day.

5. Frequency and number of monitor visits per study is specific to each protocol (no defined maximum per year per the IDS).
6. Remote visits must be completed during regular IDS business hours
7. Monitors are not permitted to enter the IDS pharmacy, which is located within the central pharmacy of the Huntsman Cancer Hospital.
    a. Restrictions to visualizing and/or handling investigational product and related items may apply.
8. Only unblinded monitors are allowed to schedule monitoring visits with the IDS pharmacy.

E. Preparation for Monitor Visit completed by the IDS
    1. After a monitor visit has been confirmed using the IDS monitor scheduling webpage, IDS personnel will send a standardized e-mail to the monitor, including the monitor SOP and Vestigo® access information.
    2. Confirm that Vestigo® is complete and up-to-date for the specific studied being monitored.
    3. Address and resolve any outstanding issues or data queries from prior monitoring visits.
    4. Provide Vestigo® access day of the scheduled visit. Vestigo® access will expire by 1600 on the day of the visit.

F. Monitor Expectations
    1. For remote monitoring visits, monitors are required to enter a visit summary note within Vestigo®. This will document that the remote visit occurred.
    2. Vestigo® access will be provided by the site.
    3. All monitors will utilize and document within Vestigo® to perform drug returns/destruction, and perform all accountability. No additional drug accountability forms or documents provided by the monitor will be used for drug accountability.
    4. Monitors must mark "returns" to be destroyed or to be sent back to the sponsor during the visit within Vestigo®. No additional drug accountability forms or documents provided by the monitor will be used for drug accountability.
        a. It is the responsibility of the monitor to send a packing box to the IDS pharmacy prior to the visit, provide a shipping label, count inventory. The drug will be packaged before the end of the visit.
    5. Monitors will provide a summary of their review and findings at the conclusion of the monitoring visit within Vestigo®. Any additional reviews that are provided post-monitor visit will be filed electronically within Vestigo®.

G. Access to Study Information
    1. Copies of study information may be provided to monitors in the following ways:
        a. Monitors may generate accountability logs (or any other electronic documents made available to them in Vestigo®)
            i. Emailed accountability logs will be provided with an additional charge of special monitor fees to the study.
            ii. The monitor must not send accountability records via personal e-mail in any circumstance due to noncompliance with HIPPA.
            iii. Research records must only be sent to a sponsor e-mail address. It is the responsibility of the monitor to ensure the correct e-mail address is being used. If an inappropriate e-mail is used for sending research documents from Vestigo® then future monitoring visits may be revoked or refused.

b. Temperature monitoring reports will provide a graphical representation of temperatures and are ONLY available while access to Vestigo® is open. Emailed temperature monitoring logs will be provided with an additional charge of special monitor fees to the study.
c. All study documents and materials provided to the auditor/monitor for review must be secured at all times with pharmacy personnel or a member of the research team present (auditors or monitors may not be left alone with research documents).

H. Viewing Study Drug
1. The IDS pharmacy is located in the central pharmacy of Huntsman Cancer Hospital.
2. Monitors and auditors are not permitted in the central pharmacy per Utah state pharmacy law and senior pharmacy leadership except in the rare circumstance related to a for-cause situation.
    a. A request to access the pharmacy will be submitted to the Chief Pharmacy Officer who will review the request and decide if access is required.
    b. If approved, the monitor or auditor shall be accompanied 100% of the time by a member of the IDS staff while in the pharmacy.
    c. IDS staff will track these requests.
3. Virtual viewing of investigational product stored under refrigeration, in the freezer, or at ambient temperature is available.
    a. IDS is able to take time/date stamped photos of investigational product or participate in video calling service (eg: Microsoft Teams/Zoom) so the monitor may visualize the product. These services are offered on select days and must be scheduled accordingly.
    b. IDS is open to other ideas to visualize investigational product.
        i. Additional options will need to be approved by the IDS pharmacy manager.
        ii. The monitor should describe the option via e-mail to the IDS pharmacy at least one week prior to the scheduled visit.
4. Current inventory on-hand can also be accounted for within Vestigo® without direct visualization per monitor discretion.

I. Monitor/Audit Visit Follow-Up
1. All communication between monitor and IDS will be done through Vestigo® for items to be destroyed or returned.
2. All communication between monitor and IDS will be done through e-mail for any additional document procurement requested by the monitor post-monitor visit
3. Communicate to the project pharmacist and IDS manager any issues that were discussed during the monitor visit.
    a. Ensure any issues or follow-up discussed during the visit are followed up on and/or completed that day or passed along to another technician/pharmacist.
4. Any potential issues identified at a monitoring visit or audit (including temperature excursions) should be provided to the PI, primary CRC, and the associated program manager.

J. Technician Responsibilities Related to Monitor/Audit Visit
1. Prepare for monitor/audit visit (see above).
2. Facilitate monitor visit.
    a. Refer the monitor or auditor to the virtual IDS pharmacy tour at first visit and upon request.

b. Virtually escort the monitor throughout the pharmacy when needed (eg, to view IP when stored in fridge or freezer).

K. Pharmacist Responsibilities Related to Monitor/Audit Visit
   1. Mitigate any issues during the monitor/audit visit as identified by technician.
   2. Follow up on any outstanding issues prior to and after the monitoring/auditing visit as identified by technician.

Owner: IDS Manager

Last updated: 06/04/2021

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Related Foundational Standard(s): 21 CFR Part 312 Subpart D: Responsibilities of Sponsors and Investigators; ICH Guidance for Industry E6: Good Clinical Practice; FDA Guidance for Industry – Investigator Responsibilities