



STANDARD OPERATING PROCEDURE (SOP): Pharmacy Appointments

Policy: Investigational Drug Services (IDS) is responsible for establishing standard procedures for the appropriate control of investigational drugs and biologics used in human subject research. These procedures include but are not limited to: establishment of a drug accountability system, record retention, procurement and shipping, temperature monitoring, dispensing, labeling, and destruction of investigational drugs and biologics within the hospital, affiliated clinics and participating satellite pharmacies, where applicable.

Background: The investigational pharmacy provides service for drug-related research protocols and is responsible for assisting in opening trials and maintaining drug accountability until trial closure. Pharmacy appointments, including site qualifying visits (SQV), site initiation visits (SIV), monitoring visits (MV), telephone monitoring visits (TMV) and closeout visits (COV), are required for opening and maintaining trials until closure. The investigational pharmacy will accommodate these visits as the schedule permits.

Procedure:

- A. The study coordinator or study monitor will schedule site visits with IDS as needed.
- B. Appointments can be made by emailing IDS. The following information is expected:
 - a. Type of visit
 - b. Date and timeslot requested
 - c. Name and contact information of person calling or coming to site
- C. Appointments should be made at least two weeks in advance if possible.
- D. Appointments may not be allowed with less than 3 business days advanced notice.
- E. Requested appointment times are not guaranteed if the schedule is full on the day requested.
- F. There will be no more than three appointments in one day per each IDS pharmacy.
- G. Appointments will be scheduled for a one hour block unless otherwise requested. Longer appointment times will be considered on a case-by-case basis
- H. Study coordinators or monitors should contact IDS for appointment changes or cancellations as soon as possible, and no less than 24 hours. IDS staff will reschedule the appointment as needed, but cannot guarantee availability.
- I. IDS will grant monitors Vestigo access no later than the day prior to their visit.

Implemented: 5/26/2016

Revised: 3/2019