Investigational Drug Service
Emory University School of Medicine

Site Blinding Plan

BACKGROUND

The Investigational Drug Service (IDS) is an integral part of the research process at Emory University. IDS staff have extensive experience with blinded studies in which IDS pharmacists serve as the unblinded third party. IDS has processes in place to insure that the integrity of the blind is maintained.

DEFINITIONS

- Blinded Site Personnel**:** All study personnel who administer study treatment, evaluate the subject, collect clinical, safety and efficacy data, and/or make decisions about the subject's care. This includes principal investigator, co-investigators, research coordinator (primary and backups) and blinded nursing staff. Blinded personnel must remain blinded to the subjects' treatment at all times.

- Unblinded Pharmacists: All unblinded pharmacists fully understand the importance of maintaining the blind and not disclosing any information that will reveal the subject's treatment to the subject, blinded site personnel, or sponsor personnel. Unblinded pharmacists do not have any subject care responsibilities or perform clinical or safety assessments.

FACILITY

The IDS is located in Emory University Clinic Building A, and the location is separate from blinded research staff. Access to the IDS Pharmacy is limited to IDS personnel. All drug storage and dose preparation occur in the Pharmacy and study personnel are not allowed to access the area. A fax machine is located in IDS and is accessible to unblinded personnel only.

UNBLINDED PHARMACISTS

Sy Tran, sy.quoc.tran@emory.edu, 404 712-7485
Esther Park, esther.sue.park@emory.edu, 404 727-0028
Jianguo Xu, jxu5@emory.edu, 404 727-0036
Rebecca Gonzalez, rebecca.feng@emory.edu, 404 778-0672
Vy Ngo, tuong-vy.ngo@emory.edu, 404 778-0672
Rebecca Foster, rebecca.ryan.foster@emory.edu, 404 778-0674
Christine Cook, christine.ann.cook@emory.edu, 404 727-0028
Jessica Patel, jessica.bharat.patel@emory.edu, 404 727-0028

PHARMACIST TRAINING

- IDS pharmacists are trained in blinding procedures and are responsible for dose preparation
- Pharmacists are also trained on each study in IDS at the beginning of the study. Training documentation is maintained electronically in Vestigo.

IP RECEIPT

- All IP is shipped to IDS at the following address:

  Investigational Drug Service
  Emory University Clinic
  Building A, Suite AT111
  1365 Clifton Road, NE
  Atlanta, GA 30322
  FAX #: 404-727-0265

- IP is received by unblinded staff in IDS, a secure location with limited access. Blinded study personnel do not have access to this area.

IP STORAGE

- IP is stored in IDS, a secure location with limited access. Blinded study personnel do not have access to this area
- IP is stored per study protocol requirements at ambient temperature, refrigerated, - 20C freezer or -80C freezer
- Hazardous drugs are stored in a negative pressure room that is separate from non-hazardous drugs
- The storage areas are equipped with a continuous temperature monitoring device
- The temperature monitoring logs are maintained electronically in Vestigo for monitor review

IP ACCOUNTABILITY

- IDS uses Vestigo for protocol management and drug accountability
- Master IP and Subject IP Logs are maintained in Vestigo by unblinded staff only
- Logs are maintained electronically via Vestigo and are available to unblinded monitors as needed

PHYSICIAN ORDER

- IDS pharmacists create study-specific blinded orders which allow the physician to order study doses in a blinded manner. The order is created by one IDS pharmacist and double-checked by a second pharmacist. It is saved as a pdf and emailed to the study team/PI for approval. Blinded staff then use the orderset to obtain blinded investigational drug doses by faxing the signed order to IDS. Once the order is processed and the dose prepared, the IDS pharmacist uploads the order to Vestigo along with any supporting documentation.

RANDOMIZATION/IXRS PROCEDURES

- Randomization may be done manually by an unblinded pharmacist, or electronically via IXRS
- If an IXRS system is used, each unblinded pharmacist should have access
- IDS pharmacists access IXRS notifications in the IDS location only

DOSE PREPARATION

- Dose preparation and dispensing instructions are maintained in Vestigo
- Unblinded staff are available for the full treatment period
- IP is prepared only in IDS which is accessed only by unblinded staff
- Blinded doses are prepared according to the protocol and, in order to maintain the blinding, all blinded doses are prepared to look alike

DOSE LABELLING

- Each prepared dose is labelled by an unblinded pharmacist
- The label includes both or all study treatments to maintain the blinding
- The label is the same for each treatment arm to maintain the blinding

IP DISPOSAL

- Empty, used IP infusion bags are disposed of by trained study personnel per local policy
- Hazardous IP empty bags are disposed per policy
- Prepared but unused IP doses are disposed of by blinded study personnel via appropriate local policy
- Blinding remains intact as no unblinded information will appear on the label
- Vials used to prepare doses are held for monitor inspection, unless the study drug is hazardous

MONITOR VISITS

- Unblinded monitors are given access to Vestigo where all study-specific records are maintained. Access is granted at the time of a remote or onsite visit. If onsite, monitors review Vestigo and can review study IP on request. Only unblinded monitors will be allowed to access study records.

UNBLINDING EVENT

- In the case that an unblinding event occurs, IDS will immediately implement corrective measures to prevent further unblinding events and report as described in study protocol
- In the event a blinded study personnel becomes inadvertently unblinded to a subject's treatment, he/she will be excluded from performing any further protocol assessments for the unblinded subject

UNBLINDED STUDY DOCUMENTS

- All unblinded study documents will be available to unblinded staff only and will be maintained in Vestigo
- Unblinded study documents sent by mail will be opened only by unblinded staff

Signed: Sy Tran, Pharm.D., MPH, Director IDS Date:

Signed: Esther Park, Pharm.D., Backup Pharmacist Date:

Signed: Principal Investigator Date: