SUBJECT/TITLE: INVESTIGATIONAL DRUG SERVICES TRAINING FOR PHARMACY STAFF

POLICY:

University of Iowa Department of Pharmaceutical Care staff will receive training and education for the appropriate handling of investigational drug studies within the organization.

A. All Ancillary Pharmacy Department staff are trained in the proper dispensing of investigational drugs as it relates to their role.

B. The IDS pharmacists will prepare study-specific UIHC dispensing summaries to be used as guidelines when dispensing investigational drugs.

C. The IDS pharmacists shall provide investigational study drug information and training to Ancillary Pharmacy Staff as needed. The information provided in the UIHC dispensing summary will explain protocol-specific information.

D. IDS Pharmacy staff complete human subjects research and GCP training through the University of Iowa Collaborative Institutional Training Initiative (CITI) Program. Study specific GCP or human subjects research protections training will not be honored or completed.

E. Ancillary Pharmacy staff practicing under their general scope of practice will not complete human subjects research and GCP training.

DEFINITIONS:

A. **Investigational drug service (IDS) Staff** are pharmacy personnel who have specific tasks delegated to them by the Principal Investigator (PI) related to the management of investigational drugs used in clinical research studies.

B. **Ancillary Pharmacy Staff** are pharmacy personnel not listed on the delegation of authority (DOA) log and considered "ancillary staff". These individuals are deemed ancillary, as they perform duties within their scope of practice and under the supervision

and authority of the IDS staff. These individuals perform the same role regardless of the patient's status as research or standard of care.

C. **UIHC Dispensing Summary**: Study-specific information (written or contained in the EMR) that is prepared and maintained by the IDS staff using information from, including but not limited to: the study protocol, pharmacy manual, site initiation meeting, etc. The dispensing summary will provide protocol-specific information that the pharmacy must perform for adherence to the protocol.

Approval History
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