

Rotation Name: Investigational Drug Studies (Elective)

Rotation Preceptors: Rajiv Sharma, PharmD, Melissa Johnson, PharmD, BCOP, Winter Chan, PharmD

Site Description: University Hospital, Huntsman Cancer Hospital

Rotation Description: Residents who elect a 1 week rotation are involved in all the activities of the service and assist the program coordinator with dispensing drug, recordkeeping, and preparing study notebooks. Residents become familiar with the applicable regulations surrounding investigational drugs. Residents who elect 2 - 4 week rotations are able to prepare several study notebooks, meet with the investigators to coordinate and plan the study and attend an IRB meeting.

RLS Goals

Goal E4.1 Manage the use of study drugs according to established protocols and the organization's policies and procedures.

OBJ E4.1.1 Utilize appropriate procedures in storing study drugs.

OBJ E4.1.2 Utilize appropriate procedures in dispensing study drugs.

OBJ E4.1.3 Utilize appropriate procedures in documenting actions taken with study drugs.

OBJ E4.1.4 Utilize appropriate procedures for initiation of a drug study.

OBJ E4.1.5 Critique a protocol and patient consent according to conventions established by the organization's institutional review board.

OBJ E4.1.6 Explain the process for reporting adverse drug events that occur during a drug study.

Activities Evaluated:

Rotation Activity	RLS Goal	Teaching Methods
Assist with dispensing investigational agents	E4.1	Modeling Coaching Facilitation
Counsel patients / providers regarding investigational agents	E4.1	Modeling Coaching Facilitation
Meet with study monitors	E4.1	Modeling
Prepare and update study materials (notebooks) as required	E4.1	Modeling Coaching Facilitation
Attend IDS-related meetings	E4.1	Modeling

Readings and Preparatory Work:

To be determined

Evaluations: Evaluations will be documented in Resitrak™. At the end of each rotation, the resident will self-evaluate, the preceptor will evaluate the resident, and the resident will evaluate both the preceptor and the learning experience.

