	Procedure Name	Investigational Drug Pharmacy
		Staff Training Checklist
WWVU Medicine	SOP #02	WVU IDS Pharmacy SOP-02
V V V O IVICAIOII IC.	Date this Version is	01 January 2024
	Effective	
	Responsible for Content	IDS Pharmacy Manager

I. Description

The Investigational Drug Services (IDS) team is comprised of pharmacists and pharmacy technicians. This SOP overviews the different training experiences IDS pharmacists and technicians should complete during their onboarding period.

II. Rationale

The purpose of this SOP is to create a standardized training checklist for all newly onboarded IDS pharmacists and technicians.

III. Procedures

- Upon hire all pharmacists and technicians will follow a standardized training program focusing
 on activities related to the WVU Medicine organization, Department of Pharmacy operations,
 and Investigational Drug Services practices.
 - i. Internal hires may be exempt from shadowing experiences if they have appropriate previous training in those areas.
- 2. Pharmacists and technicians that handle investigational products (IP) at satellite facilities will also complete the IDS specific training.
- 3. Completed training records will be uploaded to Work Day.

IV. Original Procedure Date and Revisions

16 March 2022, 12 July 2023, 01 January 2024

Name: Start Date:

Training Task	Date Completed	Employee's Initials	Orientation/Training Signoff	
O:	rganization Spec		9.30.00	
WVU Medicine				
New Employee Orientation				
EPIC Training				
BEACON Training				
Computer Based Learning (CBL)				
Modules				
	Shadowing Exp	periences		
D-Central Operations Pharmacist				
E-Central Operations Pharmacist				
D-IVR-1 Pharmacist				
D-IVR-2 Pharmacist				
D-Pediatric Operations Pharmacist				
E-IVR Pharmacist				
D-Pharmacy Technician Training				
□ Triage Technician				
□ Controlled Substances				
Technician				
 Central Operations Technician 				
□ D-Unit-5				
□ D-Unit-6				
□ D-Unit-7				
□ D-Unit-8				
D-Unit-9				
□ D-Unit-10				
☐ D-Unit 8SE/3SE				
D-Pharmacist Hospitalist Shadowing				
□ D-CG-Med 1				
□ D-CG-Med 2				
□ D-CG-Med/Surg				
E-Med/Surg Pharmacist				
E-Med Pharmacist				
E-Med/Onc Pharmacist				
D-CC-1				
D-CC-2				
D-CC-Swing				
IDS Pharmacist				
IDS Technician				
Oncology Specialist Clinic (Solid				
Tumor)				
Oncology Specialist Clinic (Heme)				
	ings with Pharm	acy Leadership	•	
Supply Chain Manager				

Medication Use Director			
Revenue Cycle Manager			
Compliance Manager			
Adult Clinical Managers			
Inpatient Operations Managers			
	l tings with Clinica	al Dharmacists	
Peds-NICU		ai i iiaiiiiacists	
Peds-PICU			
Cardiology-CVICU			
Cardiology-Outpatient Heart Failure			
Periop-Op			
Emergency Department			
Internal Medicine			
Intensive Care Units			
Medication Safety			
Oncology			
	onal Drug Servic	ces Specific Training	
General Overview of Protocols:			
☐ Cooperative Group			
☐ Industry Sponsored			
☐ Investigator Initiated			
Review WVU Medicine Policies and			
Standard Operating Procedures			
□ WVU Hospitals			
Pharmaceutical Services Policy			
VII.01			
□ WVU IDS Pharmacy SOP-01			
□ WVU IDS Pharmacy SOP-02			
□ WVU IDS Pharmacy SOP-03			
□ WVU IDS Pharmacy SOP-04			
□ WVU IDS Pharmacy SOP-05			
□ WVU IDS Pharmacy SOP-06			
□ WVU IDS Pharmacy SOP-07			
, , , , , , , , , , , , , , , , , , ,			
CITI Training			
9			
 Human Subjects Protection Training (Human Subjects 			
Research Investigators)			
☐ Conflict of Interest Training			
0 1011 1 10 1 (0.00)			
Protocol and Operations Review			
□ Pharmacy Tour			
☐ Pharmacy Procedures			
☐ Investigational Product (IP)			
Ordering			
☐ IP Receiving			
☐ IP Storage			
□ IP Dispensing			

	Documenting		
	returns/destruction		
	Protocol Correspondence to		
Vestigo	be filed Platform		
v esuge	Vestigo Overview		
	Vestigo Login information		
	Transaction Documents		
	Temperature Documents		
	Protocol Documents		
	Notes to File (NTF Template)		
	IRT (Interactive Response		
	Technology)		
	Vestigo Verify		
	re Platform		
	Protocol Status		
	Staff		
	Accrual		
	Documents/Info		
Advarr	a eREG		
	Protocol Search		
	Sign Document Task		
Billing			
	Fee sheets		
	Review WVU IDS Pharmacy		
	SOP-05		
NCI PI	MB Training Videos		
	DARF Basics		
	DARF Header		
	Oral DARF		
	Agent Receipt		
	Pt-Specific DARFs		
	Agent Transfers		
	Agent Returns		
	Local Destruction		
NCTN			
	Obtain CTEP ID		
	Register for CTEP I-AM		
	account		
	Activity: Verify a CTEP ID		
	Activity: Verify a CTSU		
	Delegation Log		
	Added to Cooperative Group		
	Rosters Subscribe to PMB Newsroom		
	Listsery		
	Reviewed CTSU Website		
	Reviewed C130 Website Reviewed PMB Online Agent		
	Order Processing (OAOP)		

Appendix B: Enterprise Pharmacist Training Checklist

*Enterprise pharmacy teams may complete site specific training rather than the below requirements

Name:			Start Date:	

Training Task	Date Completed	Employee's Initials	Orientation/Training Signoff
C	Organization Spec	ific Training	
WVU Medicine			
New Employee Orientation			
EPIC Training			
Computer Based Learning (CBL)			
Modules			
	Shadowing Exp	periences	
Central Operations Pharmacist			
IV Sterile Compounding Pharmacist			
Technician Operations Training			
Clinical Pharmacist Shadowing			
(If applicable)			
IDS pharmacist (if applicable)			
IDS technician (if applicable)			
Oncology Specialist Clinic-Solid			
Tumor (if applicable) Oncology Specialist Clinic-			
Hematology (if applicable)			
	ional Drug Service	tes Specific Training	
General Overview of Protocols:	Ionai Diug Scivic	l specific Training	
☐ Cooperative Group			
☐ Industry Sponsored			
☐ Investigator Initiated			
Review WVU Medicine Policies and			
Standard Operating Procedures			
□ WVU Hospitals			
Pharmaceutical Services			
Policy VII.01			
□ WVU IDS Pharmacy SOP-01			
□ WVU IDS Pharmacy SOP-02			
□ WVU IDS Pharmacy SOP-03			
□ WVU IDS Pharmacy SOP-04			
•			
□ WVU IDS Pharmacy SOP-05			
□ WVU IDS Pharmacy SOP-06			
□ WVU IDS Pharmacy SOP-07			
□ WVU IDS Pharmacy SOP-08			
CITI Training			
☐ Human Subjects Protection			
Training (Human Subjects			
Research Investigators)			
☐ Conflict of Interest Training			
☐ Good Clinical Practice (GCP)			
2 300d Chinear Fractice (3CF)		l	

			•
Protoco	ol and Operations Review		
	Pharmacy Tour		
	Pharmacy Procedures		
	Investigational Product (IP)		
	Ordering		
	IP Receiving		
	IP Storage		
	IP Dispensing		
	Documenting		
	returns/destruction		
	Protocol Correspondence to		
	be filed		
Vestigo	Platform		
	Vestigo Overview		
	Vestigo Login information		
	Transaction Documents		
	Temperature Documents		
	Protocol Documents		
	Notes to File (NTF		
	Template)		
	IRT (Interactive Response		
_	Technology)		
	Vestigo Verify		
	re Platform		
	Protocol Status		
	Staff		
	Accrual		
	Documents/Info		
	a eREG		
	Protocol Search		
	Sign Document Task		
Billing	oigh Document Task		
	Fee sheets		
	Review WVU IDS Pharmacy		
	SOP-05 (if applicable to		
	individual institution)		
NCI PI	MB Training Videos		
	DARF Basics		
	DARF Header		
	Oral DARF		
	Agent Receipt		
	Pt-Specific DARFs		
	Agent Transfers		
	© .		
	Agent Returns Local Destruction		
NCTN			
	Obtain CTEP ID		
	Register for CTEP I-AM		

Activity: Verify a CTEP ID		
Activity: Verify a CTSU		
Delegation Log		
Added to Cooperative Group		
Rosters		
Subscribe to PMB Newsroom		
Listserv		
Reviewed CTSU Website		
Reviewed PMB Online Agent		
Order Processing (OAOP)		

Name:	Start Date:

WVU Medicine	Completed ganization Speci	Initials fic Training	Signoff
WVU Medicine	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
New Employee Orientation			
EPIC Training			
Computer Based Learning (CBL)			
Modules			
	Shadowing Exp	eriences	
D-Central Operations Technician			
E-Central Operations Technician			
D-IVR STAT Technician			
D-IVR-1 Technician			
D-IVR-2 Technician			
D-Pediatric Operations Technician			
D-Triage Technician Training			
D-Controlled Substances Technician			
E-Controlled Substances Technician			
D-Unit-5 Technician			
D-Unit-6 Technician			
D-Unit-7 Technician			
D-Unit-8 Technician			
D-Unit-9 Technician			
D-Unit-10 Technician			
D-Unit 8SE/3SE Technician			
CC-1 Technician			
CC-2 Technician			
CC-3 Technician			
CC-4 Technician			
CC-5 Technician			
CC-6 Technician			
IDS Pharmacist			
IDS Technician			
Receiving Technician			
Purchasing Technician			
	onal Drug Servic	es Specific Training	
General Overview of Protocols:			
□ Cooperative Group			
☐ Industry Sponsored			
☐ Investigator Initiated.			
Review WVU Medicine Policies and			
Standard Operating Procedures			
□ WVU Hospitals			
Pharmaceutical Services			
Policy VII.01			

	WVU IDS Pharmacy SOP-01			
	WVU IDS Pharmacy SOP-02			
	WVU IDS Pharmacy SOP-03			
	WVU IDS Pharmacy SOP-04			
	WVU IDS Pharmacy SOP-05			
	WVU IDS Pharmacy SOP-06			
	WVU IDS Pharmacy SOP-07			
	WVU IDS Pharmacy SOP-08			
CITI T	raining			
	Human Subjects Protection			
	Training (Human Subjects			
	Research Investigators)			
	Conflict of Interest Training			
	Good Clinical Practice (GCP)			
	ol and Operations Review			
	Pharmacy Tour			
	Pharmacy Procedures			
	Investigational Product (IP)			
	Ordering			
	IP Receiving			
	IP Storage			
	IP Dispensing			
	Documenting			
	returns/destruction Protocol Documents			
Vestigo	Platform			
	Vestigo Overview			
	Vestigo Login information			
	Transaction Documents			
	Temperature Documents			
	Monitoring Visit Reports			
	Notes to File (NTF			
	Template)			
	IRT (Interactive Response			
	Technology)			
	Vestigo Verify			
OnCor	e Platform			
	Protocol Status			
	Staff			
	Accrual			
	Documents/Info			
Advarra	a eREG			
	Protocol Search			
	Sign Document Task			
Billing				
	Fee sheets			
	Review WVU IDS Pharmacy			
l	SOP-05	1	l	

NCI PI	MB Training Videos		
	DARF Basics		
	DARF Header		
	Oral DARF		
	Agent Receipt		
	Pt-Specific DARFs		
	Agent Transfers		
	Agent Returns		
	Local Destruction		
NCTN	Sites:		
	Obtain CTEP ID		
	Register for CTEP I-AM		
	account		
	Activity: Verify a CTEP ID		
	Activity: Verify a CTSU		
	Delegation Log		
	Added to Cooperative Group		
	Rosters		
	Subscribe to PMB Newsroom		
	Listserv		
	Reviewed CTSU Website		
	Reviewed PMB Online Agent		
	Order Processing (OAOP)		

Appendix D: Enterprise Technician Training Checklist

*Enterprise pharmacy teams may complete site specific training rather than the below requirements

Name:			Start Date:	

Training Task	Date	Employee's	Orientation/Training	
Training Task	Completed	Initials	Signoff	
Organization Specific Training				
WVU Medicine				
New Employee Orientation				
EPIC Training				
Computer Based Learning (CBL) Modules				
Wodules	Shadowing Exp	l Deriences		
Central Operations Technician				
Sterile Products Technician				
IDS Pharmacist				
IDS Technician				
Any required site-specific training				
Investiga	tional Drug Servi	ces Specific Training		
General Overview of Protocols:				
□ Cooperative Group				
□ Industry Sponsored				
☐ Investigator Initiated				
Review WVU Medicine Policies and				
Standard Operating Procedures				
□ WVU Hospitals				
Pharmaceutical Services				
Policy VII.01				
□ WVU IDS Pharmacy SOP-01				
□ WVU IDS Pharmacy SOP-02				
□ WVU IDS Pharmacy SOP-03				
□ WVU IDS Pharmacy SOP-04				
□ WVU IDS Pharmacy SOP-05				
□ WVU IDS Pharmacy SOP-06				
□ WVU IDS Pharmacy SOP-07				
□ WVU IDS Pharmacy SOP-08				
CITI Training				
☐ Human Subjects Protection				
Training (Human Subjects				
Research Investigators)				
☐ Conflict of Interest Training				
☐ Good Clinical Practice (GCP)				
Protocol and Operations Review				
□ Pharmacy Tour				
☐ Pharmacy Procedures				
☐ Investigational Product (IP)				
Ordering				
□ IP Receiving				

	IP Storage		
	IP Dispensing		
	Documenting		
	returns/destruction		
	Protocol Documents		
Vestigo	o Platform		
	Vestigo Overview		
	Vestigo Login information		
	Transaction Documents		
	Temperature Documents		
	Monitoring Visit Reports		
	Notes to File (NTF		
	Template)		
	IRT (Interactive Response		
	Technology)		
	Vestigo Verify		
OnCor	e Platform		
	Protocol Status		
	Staff		
	Accrual		
	Documents/Info		
Billing			
	Fee sheets		
	Review WVU IDS Pharmacy		
	SOP-05		
NCI PI	MB Training Videos		
	DARF Basics		
	DARF Header		
	Oral DARF		
	Agent Receipt		
	Pt-Specific DARFs		
	Agent Transfers		
	Agent Returns		
	Local Destruction		
NCTN	Sites:		
	Obtain CTEP ID		
	Register for CTEP I-AM		
	account		
	Activity: Verify a CTEP ID		
	Activity: Verify a CTSU		
	Delegation Log		
	Added to Cooperative Group		
	Rosters		
	Subscribe to PMB Newsroom		
	Listserv		
	Reviewed CTSU Website		
	Reviewed PMB Online Agent		
1	Order Processing (OAOP)	1	

Appendix E: WVUH Resident/Student Learning Checklist

Name:	Start Date:
-------	-------------

Training Task	Date	Employee's	Orientation/Training
- C	Completed	Initials	Signoff
MDDCC IVD Shadawing	Shadowing Exp	beriences	
MBRCC IVR Shadowing IDS IVR Shadowing			
IDS Pharmacist			
IDS Pharmacist IDS Technician			
	ional Dena Coeria	tes Specific Training	
General Overview of Protocols:	Toliai Diug Servic	l specific Training	
☐ Cooperative Group			
☐ Industry Sponsored			
☐ Investigator Initiated			
Review WVU Medicine Policies and			
Standard Operating Procedures			
□ WVU Hospitals			
Pharmaceutical Services			
Policy VII.01			
□ WVU IDS Pharmacy SOP-01			
□ WVU IDS Pharmacy SOP-02			
□ WVU IDS Pharmacy SOP-03			
WWW.T.TDO.DI			
_			
□ WVU IDS Pharmacy SOP-05			
□ WVU IDS Pharmacy SOP-06			
□ WVU IDS Pharmacy SOP-07			
□ WVU IDS Pharmacy SOP-08			
CITI Training			
☐ Human Subjects Protection			
Training (Human Subjects			
Research Investigators)			
☐ Conflict of Interest Training			
☐ Good Clinical Practice (GCP)			
Protocol and Operations Review			
□ Pharmacy Tour			
□ Pharmacy Procedures			
☐ Investigational Product (IP)			
Ordering			
□ IP Receiving			
□ IP Storage			
□ IP Dispensing			
□ Documenting			
returns/destruction			
□ Protocol Documents			
Vestigo Platform			
□ Vestigo Overview			

	Vestigo Login information		
	Transaction Documents		
	Temperature Documents		
	Monitoring Visit Reports		
	Notes to File (NTF		
	Template)		
	IRT (Interactive Response		
	Technology)		
	Vestigo Verify		
OnCor	re Platform		
	Protocol Status		
	Staff		
	Accrual		
	Documents/Info		
Advarr	a eREG		
	Protocol Search		
	Sign Document Task		
IDS To	opic Discussions		
	NCCN IDS Consensus		
	Recommendation		
	Single-Patient Expanded		
	Access		
	Human Subjects Research		
Protocol Review (For Resident			
Learne	rs)		
	Oncology Protocol		
	Non-oncology Protocol		

Appendix F: External Site IDS Checklist for WVUH Consulting

Name:	Start Date:
-------	-------------

	Training Task	Date Completed and Employee Initials	Training Signoff	Additional Notes
	Investigat	ional Drug Servic	es Specific Training	
Genera	l Overview of Protocols:			
	Cooperative Group			
	Industry Sponsored			
	Investigator Initiated			
Review	WVU Medicine Policies and			
Standa	rd Operating Procedures			
	WVU Hospitals			
	Pharmaceutical Services			
	Policy VII.01			
	WVU IDS Pharmacy SOP-01			
	WVU IDS Pharmacy SOP-02			
	WVU IDS Pharmacy SOP-03			
	WVU IDS Pharmacy SOP-04			
	WVU IDS Pharmacy SOP-05			
	WVU IDS Pharmacy SOP-06			
	WVU IDS Pharmacy SOP-07			
	WVU IDS Pharmacy SOP-08			
CITI T	raining			
	Human Subjects Protection			
	Training (Human Subjects			
	Research Investigators)			
	Conflict of Interest Training			
	Good Clinical Practice (GCP)			
Protoc	ol and Operations Review			
	Pharmacy Tour			
	Pharmacy Procedures			
	Investigational Product (IP)			
	Ordering			
	IP Receiving			
	IP Storage			
	IP Dispensing			
	Documenting			
	returns/destruction			
	Protocol Documents			
_	Platform			
	Vestigo Overview			
	Vestigo Login information			
	Transaction Documents			
	Temperature Documents			

	Monitoring Visit Reports		
	Notes to File (NTF		
	Template)		
	IRT (Interactive Response		
	Technology)		
	Vestigo Verify		
OnCor	re Platform		
	Protocol Status		
	Staff		
	Accrual		
	Documents/Info		
Advarr	ra eREG		
	Protocol Search		
	Sign Document Task		
Billing			
	Fee Sheets (IDS SOP-05)		
	MB Training Videos		
	gational Drug Accountability		
	ng Videos Pharmaceutical		
_	ement Branch (PMB) CTEP		
(cancer	0 /		
	DARF Basics		
	DARF Header Oral DARF		
	Agent Receipt		
	Agent Dispensing		
	Patient-Specific DARFs		
	Agent Transfers		
	Agent Returns		
NCTN	Local Destruction		
	Obtain CTEP ID		
	Register for CTEP I-AM		
	Account		
	Activity: Verify a CTEP ID		
	Activity: Verify a CTSU		
	Delegation Log		
	Verify addition to CTSU		
	Organization Roster		
	Subscribe to PMB Newsroom		
	Listserv		
	Review CTSU Website		
	Review PMB Online Agent		
	Order		
	Processing (OAOP/Aurora)		