

	Procedure Name	Investigational Drug Pharmacy Staff Training Checklist
	SOP #02	WVU IDS Pharmacy SOP-02
	Date this Version is Effective	16 March 2022
	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

1. 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 stored in each employee specific folder maintained by the Department of Pharmaceutical Services.

IV. Original Procedure Date and Revisions

16 March 2022, 12 July 2023

Appendix A: Pharmacist Training Checklist

Name:	Start Date:
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Training Task	Date Completed	Employee's Initials	Orientation/Training Signoff
Organization Specific Training			
WVU Medicine New Employee Orientation			
EPIC Training			
BEACON Training			
Computer Based Learning (CBL) Modules			
Shadowing Experiences			
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 <ul style="list-style-type: none"> <input type="checkbox"/> Triage Technician <input type="checkbox"/> Controlled Substances Technician <input type="checkbox"/> Central Operations Technician <input type="checkbox"/> D-Unit-5 <input type="checkbox"/> D-Unit-6 <input type="checkbox"/> D-Unit-7 <input type="checkbox"/> D-Unit-8 <input type="checkbox"/> D-Unit-9 <input type="checkbox"/> D-Unit-10 <input type="checkbox"/> D-Unit 8SE/3SE 			
D-Pharmacist Hospitalist Shadowing <ul style="list-style-type: none"> <input type="checkbox"/> D-CG-Med 1 <input type="checkbox"/> D-CG-Med 2 <input type="checkbox"/> 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)			
Meetings with Pharmacy Leadership			
Supply Chain Manager			

Medication Use Director			
Revenue Cycle Manager			
Compliance Manager			
Adult Clinical Managers			
Inpatient Operations Managers			
Meetings with Clinical Pharmacists			
Peds-NICU			
Peds-PICU			
Cardiology-CVICU			
Cardiology-Outpatient Heart Failure			
Periop-Op			
Emergency Department			
Internal Medicine			
Intensive Care Units			
Medication Safety			
Oncology			
Investigational Drug Services Specific Training			
General Overview of Protocols: <input type="checkbox"/> Cooperative Group <input type="checkbox"/> Industry Sponsored <input type="checkbox"/> Investigator Initiated			
Review WVU Medicine Policies and Standard Operating Procedures <input type="checkbox"/> WVU Hospitals Pharmaceutical Services Policy VII.01 <input type="checkbox"/> WVU IDS Pharmacy SOP-01 <input type="checkbox"/> WVU IDS Pharmacy SOP-02 <input type="checkbox"/> WVU IDS Pharmacy SOP-03 <input type="checkbox"/> WVU IDS Pharmacy SOP-04 <input type="checkbox"/> WVU IDS Pharmacy SOP-05 <input type="checkbox"/> WVU IDS Pharmacy SOP-06 <input type="checkbox"/> WVU IDS Pharmacy SOP-07 <input type="checkbox"/> WVU IDS Pharmacy SOP-08			
CITI Training <input type="checkbox"/> Human Subjects Protection Training (Human Subjects Research Investigators) <input type="checkbox"/> Conflict of Interest Training <input type="checkbox"/> Good Clinical Practice (GCP)			
Protocol and Operations Review <input type="checkbox"/> Pharmacy Tour <input type="checkbox"/> Pharmacy Procedures <input type="checkbox"/> Investigational Product (IP) Ordering <input type="checkbox"/> IP Receiving <input type="checkbox"/> IP Storage <input type="checkbox"/> IP Dispensing			

<ul style="list-style-type: none"> <input type="checkbox"/> Documenting returns/destruction <input type="checkbox"/> Protocol Correspondence to be filed 			
<p>Vestigo Platform</p> <ul style="list-style-type: none"> <input type="checkbox"/> Vestigo Overview <input type="checkbox"/> Vestigo Login information <input type="checkbox"/> Transaction Documents <input type="checkbox"/> Temperature Documents <input type="checkbox"/> Protocol Documents <input type="checkbox"/> Notes to File (NTF Template) <input type="checkbox"/> IRT (Interactive Response Technology) <input type="checkbox"/> Vestigo Verify 			
<p>OnCore Platform</p> <ul style="list-style-type: none"> <input type="checkbox"/> Protocol Status <input type="checkbox"/> Staff <input type="checkbox"/> Accrual <input type="checkbox"/> Documents/Info 			
<p>Billing</p> <ul style="list-style-type: none"> <input type="checkbox"/> Fee sheets <input type="checkbox"/> Review WVU IDS Pharmacy SOP-05 			
<p>NCI PMB Training Videos</p> <ul style="list-style-type: none"> <input type="checkbox"/> DARF Basics <input type="checkbox"/> DARF Header <input type="checkbox"/> Oral DARF <input type="checkbox"/> Agent Receipt <input type="checkbox"/> Pt-Specific DARFs <input type="checkbox"/> Agent Transfers <input type="checkbox"/> Agent Returns <input type="checkbox"/> Local Destruction 			
<p>NCTN Sites:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Obtain CTEP ID <input type="checkbox"/> Register for CTEP I-AM account <input type="checkbox"/> Activity: Verify a CTEP ID <input type="checkbox"/> Activity: Verify a CTSU Delegation Log <input type="checkbox"/> Added to Cooperative Group Rosters <input type="checkbox"/> Subscribe to PMB Newsroom Listserv <input type="checkbox"/> Reviewed CTSU Website <input type="checkbox"/> Reviewed PMB Online Agent Order Processing (OAOP) 			

Appendix B: Enterprise Pharmacist Training Checklist

Name:	Start Date:
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Training Task	Date Completed	Employee's Initials	Orientation/Training Signoff
Organization Specific Training			
WVU Medicine New Employee Orientation			
EPIC Training			
Computer Based Learning (CBL) Modules			
Shadowing Experiences			
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)			
Investigational Drug Services Specific Training			
General Overview of Protocols: <ul style="list-style-type: none"> <input type="checkbox"/> Cooperative Group <input type="checkbox"/> Industry Sponsored <input type="checkbox"/> Investigator Initiated 			
Review WVU Medicine Policies and Standard Operating Procedures <ul style="list-style-type: none"> <input type="checkbox"/> WVU Hospitals Pharmaceutical Services Policy VII.01 <input type="checkbox"/> WVU IDS Pharmacy SOP-01 <input type="checkbox"/> WVU IDS Pharmacy SOP-02 <input type="checkbox"/> WVU IDS Pharmacy SOP-03 <input type="checkbox"/> WVU IDS Pharmacy SOP-04 <input type="checkbox"/> WVU IDS Pharmacy SOP-05 <input type="checkbox"/> WVU IDS Pharmacy SOP-06 <input type="checkbox"/> WVU IDS Pharmacy SOP-07 <input type="checkbox"/> WVU IDS Pharmacy SOP-08 			
CITI Training <ul style="list-style-type: none"> <input type="checkbox"/> Human Subjects Protection Training (Human Subjects Research Investigators) <input type="checkbox"/> Conflict of Interest Training <input type="checkbox"/> Good Clinical Practice (GCP) 			

<p>Protocol and Operations Review</p> <ul style="list-style-type: none"> <input type="checkbox"/> Pharmacy Tour <input type="checkbox"/> Pharmacy Procedures <input type="checkbox"/> Investigational Product (IP) Ordering <input type="checkbox"/> IP Receiving <input type="checkbox"/> IP Storage <input type="checkbox"/> IP Dispensing <input type="checkbox"/> Documenting returns/destruction <input type="checkbox"/> Protocol Correspondence to be filed 			
<p>Vestigo Platform</p> <ul style="list-style-type: none"> <input type="checkbox"/> Vestigo Overview <input type="checkbox"/> Vestigo Login information <input type="checkbox"/> Transaction Documents <input type="checkbox"/> Temperature Documents <input type="checkbox"/> Protocol Documents <input type="checkbox"/> Notes to File (NTF Template) <input type="checkbox"/> IRT (Interactive Response Technology) <input type="checkbox"/> Vestigo Verify 			
<p>OnCore Platform</p> <ul style="list-style-type: none"> <input type="checkbox"/> Protocol Status <input type="checkbox"/> Staff <input type="checkbox"/> Accrual <input type="checkbox"/> Documents/Info 			
<p>Billing</p> <ul style="list-style-type: none"> <input type="checkbox"/> Fee sheets <input type="checkbox"/> Review WVU IDS Pharmacy SOP-05 (if applicable to individual institution) 			
<p>NCI PMB Training Videos</p> <ul style="list-style-type: none"> <input type="checkbox"/> DARF Basics <input type="checkbox"/> DARF Header <input type="checkbox"/> Oral DARF <input type="checkbox"/> Agent Receipt <input type="checkbox"/> Pt-Specific DARFs <input type="checkbox"/> Agent Transfers <input type="checkbox"/> Agent Returns <input type="checkbox"/> Local Destruction 			
<p>NCTN Sites:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Obtain CTEP ID <input type="checkbox"/> Register for CTEP I-AM account <input type="checkbox"/> Activity: Verify a CTEP ID <input type="checkbox"/> Activity: Verify a CTSU Delegation Log 			

<ul style="list-style-type: none"><input type="checkbox"/> Added to Cooperative Group Rosters<input type="checkbox"/> Subscribe to PMB Newsroom Listserv<input type="checkbox"/> Reviewed CTSU Website<input type="checkbox"/> Reviewed PMB Online Agent Order Processing (OAOP)			
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Appendix C: Technician Training Checklist

Name:	Start Date:
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Training Task	Date Completed	Employee's Initials	Orientation/Training Signoff
Organization Specific Training			
WVU Medicine New Employee Orientation			
EPIC Training			
Computer Based Learning (CBL) Modules			
Shadowing Experiences			
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			
Investigational Drug Services Specific Training			
General Overview of Protocols: <input type="checkbox"/> Cooperative Group <input type="checkbox"/> Industry Sponsored <input type="checkbox"/> Investigator Initiated.			
Review WVU Medicine Policies and Standard Operating Procedures <input type="checkbox"/> WVU Hospitals Pharmaceutical Services Policy VII.01			

<ul style="list-style-type: none"> <input type="checkbox"/> WVU IDS Pharmacy SOP-01 <input type="checkbox"/> WVU IDS Pharmacy SOP-02 <input type="checkbox"/> WVU IDS Pharmacy SOP-03 <input type="checkbox"/> WVU IDS Pharmacy SOP-04 <input type="checkbox"/> WVU IDS Pharmacy SOP-05 <input type="checkbox"/> WVU IDS Pharmacy SOP-06 <input type="checkbox"/> WVU IDS Pharmacy SOP-07 <input type="checkbox"/> WVU IDS Pharmacy SOP-08 			
<p>CITI Training</p> <ul style="list-style-type: none"> <input type="checkbox"/> Human Subjects Protection Training (Human Subjects Research Investigators) <input type="checkbox"/> Conflict of Interest Training <input type="checkbox"/> Good Clinical Practice (GCP) 			
<p>Protocol and Operations Review</p> <ul style="list-style-type: none"> <input type="checkbox"/> Pharmacy Tour <input type="checkbox"/> Pharmacy Procedures <input type="checkbox"/> Investigational Product (IP) Ordering <input type="checkbox"/> IP Receiving <input type="checkbox"/> IP Storage <input type="checkbox"/> IP Dispensing <input type="checkbox"/> Documenting returns/destruction <input type="checkbox"/> Protocol Documents 			
<p>Vestigo Platform</p> <ul style="list-style-type: none"> <input type="checkbox"/> Vestigo Overview <input type="checkbox"/> Vestigo Login information <input type="checkbox"/> Transaction Documents <input type="checkbox"/> Temperature Documents <input type="checkbox"/> Monitoring Visit Reports <input type="checkbox"/> Notes to File (NTF Template) <input type="checkbox"/> IRT (Interactive Response Technology) <input type="checkbox"/> Vestigo Verify 			
<p>OnCore Platform</p> <ul style="list-style-type: none"> <input type="checkbox"/> Protocol Status <input type="checkbox"/> Staff <input type="checkbox"/> Accrual <input type="checkbox"/> Documents/Info 			
<p>Billing</p> <ul style="list-style-type: none"> <input type="checkbox"/> Fee sheets <input type="checkbox"/> Review WVU IDS Pharmacy SOP-05 			
<p>NCI PMB Training Videos</p> <ul style="list-style-type: none"> <input type="checkbox"/> DARF Basics <input type="checkbox"/> DARF Header 			

<ul style="list-style-type: none"> <input type="checkbox"/> Oral DARF <input type="checkbox"/> Agent Receipt <input type="checkbox"/> Pt-Specific DARFs <input type="checkbox"/> Agent Transfers <input type="checkbox"/> Agent Returns <input type="checkbox"/> Local Destruction 			
<p>NCTN Sites:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Obtain CTEP ID <input type="checkbox"/> Register for CTEP I-AM account <input type="checkbox"/> Activity: Verify a CTEP ID <input type="checkbox"/> Activity: Verify a CTSU Delegation Log <input type="checkbox"/> Added to Cooperative Group Rosters <input type="checkbox"/> Subscribe to PMB Newsroom Listserv <input type="checkbox"/> Reviewed CTSU Website <input type="checkbox"/> Reviewed PMB Online Agent Order Processing (OAOP) 			

Appendix D: Enterprise Technician Training Checklist

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

<ul style="list-style-type: none"> <input type="checkbox"/> IP Storage <input type="checkbox"/> IP Dispensing <input type="checkbox"/> Documenting returns/destruction <input type="checkbox"/> Protocol Documents 			
<p>Vestigo Platform</p> <ul style="list-style-type: none"> <input type="checkbox"/> Vestigo Overview <input type="checkbox"/> Vestigo Login information <input type="checkbox"/> Transaction Documents <input type="checkbox"/> Temperature Documents <input type="checkbox"/> Monitoring Visit Reports <input type="checkbox"/> Notes to File (NTF Template) <input type="checkbox"/> IRT (Interactive Response Technology) <input type="checkbox"/> Vestigo Verify 			
<p>OnCore Platform</p> <ul style="list-style-type: none"> <input type="checkbox"/> Protocol Status <input type="checkbox"/> Staff <input type="checkbox"/> Accrual <input type="checkbox"/> Documents/Info 			
<p>Billing</p> <ul style="list-style-type: none"> <input type="checkbox"/> Fee sheets <input type="checkbox"/> Review WVU IDS Pharmacy SOP-05 			
<p>NCI PMB Training Videos</p> <ul style="list-style-type: none"> <input type="checkbox"/> DARF Basics <input type="checkbox"/> DARF Header <input type="checkbox"/> Oral DARF <input type="checkbox"/> Agent Receipt <input type="checkbox"/> Pt-Specific DARFs <input type="checkbox"/> Agent Transfers <input type="checkbox"/> Agent Returns <input type="checkbox"/> Local Destruction 			
<p>NCTN Sites:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Obtain CTEP ID <input type="checkbox"/> Register for CTEP I-AM account <input type="checkbox"/> Activity: Verify a CTEP ID <input type="checkbox"/> Activity: Verify a CTSU Delegation Log <input type="checkbox"/> Added to Cooperative Group Rosters <input type="checkbox"/> Subscribe to PMB Newsroom Listserv <input type="checkbox"/> Reviewed CTSU Website <input type="checkbox"/> Reviewed PMB Online Agent Order Processing (OAOP) 			

Appendix E: WVUH Resident/Student Learning Checklist

Name:	Start Date:
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Training Task	Date Completed	Employee's Initials	Orientation/Training Signoff
Shadowing Experiences			
MBRCC IVR Shadowing			
IDS IVR Shadowing			
IDS Pharmacist			
IDS Technician			
Investigational Drug Services Specific Training			
General Overview of Protocols: <ul style="list-style-type: none"> <input type="checkbox"/> Cooperative Group <input type="checkbox"/> Industry Sponsored 			
Review WVU Medicine Policies and Standard Operating Procedures <ul style="list-style-type: none"> <input type="checkbox"/> WVU Hospitals Pharmaceutical Services Policy VII.01 <input type="checkbox"/> WVU IDS Pharmacy SOP-01 <input type="checkbox"/> WVU IDS Pharmacy SOP-02 <input type="checkbox"/> WVU IDS Pharmacy SOP-03 <input type="checkbox"/> WVU IDS Pharmacy SOP-04 <input type="checkbox"/> WVU IDS Pharmacy SOP-05 <input type="checkbox"/> WVU IDS Pharmacy SOP-06 <input type="checkbox"/> WVU IDS Pharmacy SOP-07 <input type="checkbox"/> WVU IDS Pharmacy SOP-08 			
CITI Training <ul style="list-style-type: none"> <input type="checkbox"/> Human Subjects Protection Training (Human Subjects Research Investigators) <input type="checkbox"/> Conflict of Interest Training <input type="checkbox"/> Good Clinical Practice (GCP) 			
Protocol and Operations Review <ul style="list-style-type: none"> <input type="checkbox"/> Pharmacy Tour <input type="checkbox"/> Pharmacy Procedures <input type="checkbox"/> Investigational Product (IP) Ordering <input type="checkbox"/> IP Receiving <input type="checkbox"/> IP Storage <input type="checkbox"/> IP Dispensing <input type="checkbox"/> Documenting returns/destruction <input type="checkbox"/> Protocol Documents 			
Vestigo Platform <ul style="list-style-type: none"> <input type="checkbox"/> Vestigo Overview <input type="checkbox"/> Vestigo Login information 			

<ul style="list-style-type: none"> <input type="checkbox"/> Transaction Documents <input type="checkbox"/> Temperature Documents <input type="checkbox"/> Monitoring Visit Reports <input type="checkbox"/> Notes to File (NTF Template) <input type="checkbox"/> IRT (Interactive Response Technology) <input type="checkbox"/> Vestigo Verify 			
<p>OnCore Platform</p> <ul style="list-style-type: none"> <input type="checkbox"/> Protocol Status <input type="checkbox"/> Staff <input type="checkbox"/> Accrual <input type="checkbox"/> Documents/Info 			
<p>IDS Topic Discussions</p> <ul style="list-style-type: none"> <input type="checkbox"/> NCCN IDS Consensus Recommendation <input type="checkbox"/> Single-Patient Expanded Access <input type="checkbox"/> Human Subjects Research 			
<p>Protocol Review (For Resident Learners)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Oncology Protocol <input type="checkbox"/> Non-oncology Protocol 			