Standard Operating Procedure		
Closed System Transfer Device (CSTD) Policy for Preparing Investigational Agents		
Scope: ☒Dept./Unit/Clinic: Pharmacy ☐Service Line _____ ☐Institutional	**Patient Population:** ☐Neonatal ☐Pediatric ☒Adult ☐Sub-population: _____	**Patient Level of Care:** ☒Ambulatory ☒Acute ☐Intermediate ☐Critical Care ☐Emergency Dept ☐Labor and Delivery ☐Diagnostic/Procedural ☐Peri-operative ☐Other_____
Purpose: To ensure the safety of our staff when preparing investigational agents		

Investigational Drug Services (IDS) supports all clinical drug-related research conducted by investigators at the University of Virginia Health System. IDS provides the support needed to assure safe and efficient conduct of clinical drug trials including compliance with federal, state, and Joint Commission requirements regarding investigational drugs.

Background/ Rationale: Per USP800, CSTDs should be used when compounding hazardous drugs (HDs). CSTDs must be used when administering antineoplastic HDs. CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD.

Per Medical Center Policy NO. 0268, A closed system transfer device shall be used during the preparation and administration of all injectable Hazardous Medications.

The UVA IDS will treat all investigational agents with an unknown hazardous designation as a HD until otherwise notified.

Equipment/Supplies: CCIDS maintains a separate list of current CSTDs utilized in practice, which is available upon request.

Procedure:

Closed System Transfer Device (CSTD) Policy for Preparing Investigational Agents

#	Step
1	The IDS pharmacist will access hazardous designation of all investigational products (IP) using the provided sponsor documents.
2	If deemed hazardous based on provided documents, or hazardous designation is unknown or has not been tested, IDS pharmacy will proceed with treating the IP as a HD.
3	A CSTD will be used when compounding injectable HD unless proven incompatible.
4	A CSTD will be used when administering injectable HD unless proven incompatible.
5	If compatibility testing has not been completed, the sponsor is responsible for completing such testing before IDS can prepare the IP

Expected Outcomes	Unexpected Outcomes (Escalate)
• CSTD will be used for compounding and administering all injectable IP deemed hazardous or unknown hazardous unless the IP has been proven incompatible with the CSTD.	• Sponsor has not tested compatibility with a CSTD and is not allowing the use of a CSTD for drug preparation. Sponsor must test compatibility. UVA IDS will not grant waivers.

Related Documents: *(if applicable: policy, guideline)*

- Medical Center Policy NO. 0268

External References: *(if applicable: regulation, law, certifying body, specialty organization)*

- USP 800

REVISION HISTORY				
Version	Reason (new, cyclical, external)	Relevant Reviewers	Approved By	Date of Approval
08/2020	New	IDS Pharmacists	IDS Pharmacists	08/2020
08/2022	As Needed	IDS Pharmacists	Michael Neace	7 OCT 2022