Content Owner:
Kyle Luedtke, PharmD, BCPS
Pharmacist – Investigational Drug Services

Revised Date:
10/12/2020

Standard Operating Procedure		
PROTOCOL VIOLATIONS BY STUDY PERSONNEL		
Scope: ☒Dept./Unit/Clinic: Investigational Drug Services, 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: *The investigational pharmacy staff is to utilize a standard procedure for handling and reporting protocol violations by study personnel, in accordance with applicable federal and state regulations, as well as good clinical practice guidelines.*		

Background/ Rationale: *The investigational pharmacy provides service for drug-related research protocols and is responsible for establishing standard procedures for the appropriate control of investigational drugs and biologics used in human subject research.*

Equipment/Supplies: n/a

Procedure:

#	Step	Rationale*	Special Considerations*
1	In the event of a potential violation/deviation of an HSR/IRB-approved protocol, the IDS pharmacist will report the concern to the study team/sponsor as appropriate.		The blind will be maintained as necessary.
2	A description of the issue and its resolution will be documented and kept on file.		
3	All documentation will be forwarded to persons/entities as appropriate.		
4	If deemed necessary, the IDS pharmacist will contact the HSR/IRB to ensure proper documentation and resolution of the issue. Once the issue is resolved, it will be reviewed during the IDS Pharmacist weekly meeting to discuss the issue and resolution and decide if study procedures or general SOPs need to be implemented or revised.		

**if applicable*

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Expected Outcomes	Unexpected Outcomes (Escalate)
• Protocol violations are reported	• Protocol violations are not reported

Related Documents: *n/a*

External References:

Joint Commission Standard MM.06.01.05
21 CFR 312.50 – General responsibilities of sponsors.
21 CFR 312.60 – General responsibilities of investigators.
21 CFR 312.66 – Assurance of IRB review.

REVISION HISTORY				
Version	Reason (new, cyclical, external)	Relevant Reviewers	Approved By (Area leadership & PCC)	Date of Approval
1.0	New		IDS Pharmacists	10/2004
2.0			IDS Pharmacists	09/2012
3.0			IDS Pharmacists	06/2017
4.0	Cyclical	IDS Pharmacists	Matt Jenkins	10/2020