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

Revised Date:
10/11/2024

| ***Standard Operating Procedure*** | | |
|---|---|---|
| *PROTOCOL VIOLATIONS BY STUDY PERSONNEL* | | |
| **Scope:**<br>☒Dept./Unit/Clinic: Investigational Drug Services, Pharmacy<br>☐Service Line _____<br>☐Institutional | **Patient Population:**<br>☒Neonatal<br>☒Pediatric<br>☒Adult<br>☐Sub-population: _____ | **Patient Level of Care:**<br>☒Ambulatory<br>☒Acute<br>☒Intermediate<br>☒Critical Care<br>☒Emergency Dept<br>☒Labor and Delivery<br>☒Diagnostic/Procedural<br>☒Peri-operative<br>☐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 |
| 5.0 | Cyclical | IDS Pharmacists | Joeseph Aloi | 10/2024 |