QUICK GUIDANCE

Investigational Product Dispensing Errors

What to do when the wrong investigational product, dose, or quantity is dispensed

WHAT IS IT?

> **IP Dispensing Error:**
>
> The wrong investigational product, incorrect dose, wrong formulation, or incorrect quantity is dispensed to a subject — or IP is dispensed to the wrong subject or at the wrong time.

WHEN DOES THIS APPLY?

- A subject receives the wrong dose, formulation, or kit number of investigational product
- IP is dispensed to the wrong subject
- A subject receives IP outside the protocol-specified dosing window
- An incorrect quantity of IP is dispensed or returned
- IP accountability records do not reconcile with dispensing records

PROCESS AT A GLANCE

1. Identify the Dispensing Error

- Review the IP accountability log, dispensing records, and subject visit notes to confirm the error
- Identify: what was dispensed, to whom, when, and what should have been dispensed
- Do not administer any additional IP until the error is assessed

2. Ensure Subject Safety

- Notify the PI immediately
- The PI must assess whether the dispensing error poses any risk to the subject (e.g., overdose, underdose, wrong product)
- Arrange any necessary medical evaluation or monitoring and document the PI's safety assessment

3. Notify the Sponsor / Medical Monitor

- Contact the sponsor per protocol reporting requirements
- The medical monitor will provide guidance on continued dosing and subject management
- Document all sponsor communications

4. Quarantine and Secure the Affected IP

- If the wrong product was dispensed and can be retrieved, quarantine it separately from study drug supplies
- Do not destroy or discard any IP involved in the error
- Label the quarantined IP clearly and document its disposition

5. Update IP Accountability Records

- Correct the IP accountability log transparently: document the error, the actual dispense amount or activity, and any adjustments
- Do not erase or obscure original entries — add corrections with date, initials, and reason
- Reconcile all IP records to ensure accurate inventory

6. Complete a Protocol Deviation Report

- Initiate a Protocol Deviation form documenting the dispensing error
- Include: subject ID, IP kit number, error description, date, safety impact, and Corrective Action
- Submit to the IRB and sponsor as required

7. Implement Preventive Actions

- Review IP dispensing procedures with all staff who handle study drug
- Implement a double-check system: two staff members verify IP dispense before administration
- Ensure all dispensing staff are properly trained and listed on the delegation log

KEEP IN MIND

x Avoid: Do not discard or alter IP involved in a dispensing error. Do not continue IP administration without PI and sponsor guidance after an error is identified.

✓ **Best practice:** Prioritize subject safety first. Notify the PI and sponsor immediately. Document the error and all corrective actions completely and transparently.

REFERENCES

- ICH E6(R2) Good Clinical Practice Guidelines
- Applicable Study Protocol — IP Management Section