

Investigational Product Accountability Log Discrepancies

What to do when IP inventory records don't reconcile

WHAT IS IT?

IP Accountability Log Discrepancy:

The recorded receipt, dispensing, return, and destruction records for investigational product do not reconcile — meaning the quantities on hand do not match what would be expected based on the log entries.

WHEN DOES THIS APPLY?

- A physical IP inventory count does not match the accountability log
- A dispensing or return entry is missing from the log
- A sponsor monitor identifies reconciliation errors during a monitoring visit
- IP is found that is not recorded in the accountability log
- A destruction or return shipment does not match expected quantities

PROCESS AT A GLANCE

1. Identify the Discrepancy

- Conduct a full physical inventory of all IP on hand, including all kits, vials, or units
- Compare the physical count against the accountability log entries for receipt, dispensing, return, and destruction
- Identify the specific discrepancy: missing entries, incorrect quantities, or unaccounted IP

2. Notify the PI and Pharmacist (if applicable)

- Inform the PI and pharmacist (if IP is pharmacy-managed) of the discrepancy immediately
- Document PI notification and any guidance provided
- Do not attempt to correct the log without PI authorization

3. Investigate the Root Cause

- Review all dispensing records, visit notes, and subject diaries for undocumented dispenses or returns
- Check for transcription errors, missed entries, or calculation mistakes
- Consult with all staff who have handled IP to identify where the discrepancy originated

4. Correct the Accountability Log

- Correct identified transcription or calculation errors using GCP-compliant correction methods (single line, initials, date, reason)
- For missing entries: add with the actual date of the activity , current date of entry, and a note explaining the late addition. The distinction must be clear and transparent.
- Have the PI review and countersign significant corrections

5. Notify the Sponsor

- Report the discrepancy to the sponsor per protocol requirements
- Provide a full explanation, investigation findings, and corrective actions taken
- Retain all sponsor communications in the regulatory file

6. Complete a Protocol Deviation Report (if applicable)

- If the discrepancy reflects a significant accountability failure, initiate a Protocol Deviation report
- Include root cause analysis and CAPA
- Submit to the IRB and sponsor as required

7. Implement Preventive Actions

- Complete accountability log entries in real time — at the moment of dispense, receipt, or return
- Conduct monthly reconciliation checks of the IP accountability log
- Ensure all staff who handle IP are trained on proper accountability procedures

KEEP IN MIND

x Avoid: Do not alter original accountability log entries to force reconciliation. Do not destroy or discard unaccounted IP without sponsor authorization.

✓ Best practice: Conduct a thorough investigation before making any corrections. Correct transparently. Notify the sponsor promptly and implement robust preventive measures.

REFERENCES

- ICH E6(R2) Good Clinical Practice Guidelines
- 21 CFR Part 312.62 — Investigator Recordkeeping
- Applicable Study Protocol — IP Accountability Section
- Sponsor IP Management Manual
- Reportable New Information <https://research.arizona.edu/sites/default/files/2025-08/Reportable-New-Information-v2025-07.pdf>
- [Corrective and Preventative Action Plans v2025-06](#)