

# Delegation Log Errors & Gaps

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*What to do when study tasks are performed by staff not properly listed on the delegation log*

## WHAT IS IT?

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### Delegation of Authority Log:

A document that records the study tasks delegated by the PI to each study team member, along with their qualifications and the dates of their authorization.

### Delegation Log Error:

Missing signatures, missing staff entries, missing end dates, undated authorizations, tasks performed outside the delegation period, or tasks assigned to unqualified personnel. Incomplete or illegible documentation, outdated information, unclear delegation of responsibilities, retroactive delegation.

## WHEN DOES THIS APPLY?

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- A new staff member begins performing study tasks before being added to the delegation log
- A staff member performs a task not listed under their delegation
- A staff member's delegation period has lapsed due to expired training or departure
- A monitor or auditor identifies a discrepancy between study activities and the delegation log
- A staff member leaves the study and is not properly removed from the log

## PROCESS AT A GLANCE

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### 1. Identify the Gap or Error

- Review the delegation log against study staff CVs, training records, and visit source documents
- Confirm the specific error: missing staff member, incorrect dates, unauthorized task, or gap in coverage
- Determine the timeframe during which the error existed

## 2. Notify the PI

- Inform the PI immediately — the PI is responsible for all delegations and must authorize any corrections
- Document PI notification and guidance

## 3. Correct the Delegation Log

- For missing staff: add the staff member with accurate start dates reflecting when they actually began study tasks
- For expired delegations: update end dates and re-authorize if the staff member is still active
- Do not backdate entries — add a note-to-file explaining the late addition
- Ensure the PI signs all new or corrected delegation entries

## 4. Review Supporting Qualifications

- Confirm CVs and training records on file support the tasks delegated
- Update the regulatory binder with current CVs and training certificates as needed
- Ensure medical licensure is current for any staff performing tasks requiring licensure

## 5. Create a Note to File

- Document the gap, when it was identified, why it occurred, and what corrective action was taken
- File the note-to-file in the regulatory binder and have the PI sign it

## 6. Report as a Protocol Deviation if Required

- If study tasks were performed by an unauthorized person, initiate a Protocol Deviation report
- Submit to the IRB and sponsor as required
- Assess whether any data collected by unauthorized staff is affected

## 7. Implement Preventive Actions

- Add new staff to the delegation log before they begin any study tasks
- Conduct regular delegation log reviews (e.g., quarterly) against study activity records
- Assign a designated staff member to maintain regulatory binder completeness

## KEEP IN MIND

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**x Avoid:** Do not backdate delegation log entries. Do not allow staff to perform study tasks without PI authorization.

**✓ Best practice:** Add staff to the delegation log before they begin study tasks. Review the log regularly. Maintain current CVs and training records for all delegated staff.

## REFERENCES

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- ICH E6(R2) Good Clinical Practice Guidelines
- Reportable New Information <https://research.arizona.edu/sites/default/files/2025-08/Reportable-New-Information-v2025-07.pdf>