QUICK GUIDANCE

Prohibited & Concomitant Medication Errors

THE UNIVERSITY OF ARIZONA Research & Partnerships

What to do when a subject takes a prohibited medication or medications are not properly documented

WHAT IS IT?

Prohibited Medication Error:

A subject takes a medication that is explicitly prohibited by the study protocol.

Concomitant Medication Documentation Error:

Medications taken during the study are not recorded in source documents and the EDC as required by the protocol.

WHEN DOES THIS APPLY?

- A subject discloses use of a medication that is on the protocol prohibited medications list
- Concomitant medications are not documented at a visit as required by the protocol
- A medication interaction is identified that may affect subject safety or study endpoints
- A monitor or auditor identifies discrepancies in concomitant medication records

PROCESS AT A GLANCE

1. Identify the Medication Issue

- Review the protocol for the list of prohibited medications and concomitant medication recording requirements
- Compare the subject's reported medications against the prohibited list
- Confirm the medication name, dose, start date, and duration

2. Notify the PI Immediately

- Inform the PI of the prohibited medication use or documentation gap as soon as identified
- The PI must assess the clinical significance and any impact on subject safety
- Document PI notification and assessment in the source record

3. Contact the Sponsor / Medical Monitor

- Notify the sponsor per protocol reporting requirements
- The medical monitor may provide guidance on continued participation or discontinuation
- Document all communications

4. Assess Impact on Subject Safety and Data

- Determine whether the prohibited medication affects study endpoints or subject safety
- Arrange additional safety monitoring if indicated by the PI
- Document findings in the source record

5. Complete a Protocol Deviation Report

- Initiate a Protocol Deviation form documenting the prohibited medication use
- Include: subject ID, medication name/dose/dates, how identified, clinical impact, and CAPA
- Submit to the IRB and sponsor as required

6. Update EDC and Source Records

- Ensure the concomitant medication log is updated with all medications including the prohibited one
- Respond to any EDC queries related to the medication discrepancy
- Document the reason for any late entries transparently

7. Implement Preventive Actions

- Review the prohibited medication list with the subject at each visit
- Provide subjects with a written list of prohibited medications at enrollment
- Implement a concomitant medication review checklist for each visit

KEEP IN MIND

x Avoid: Do not omit prohibited medications from the concomitant medication log. Do not continue study procedures without PI and sponsor guidance after a prohibited medication is identified.

✓ Best practice: Notify the PI and sponsor immediately. Assess subject safety. Educate subjects about prohibited medications at every visit.

REFERENCES

- ICH E6(R2) Good Clinical Practice Guidelines
- Applicable Study Protocol — Prohibited Medications Section
- 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