Chicken Soup
for the Busy Coordinator

NHG Health

APRIL 2026

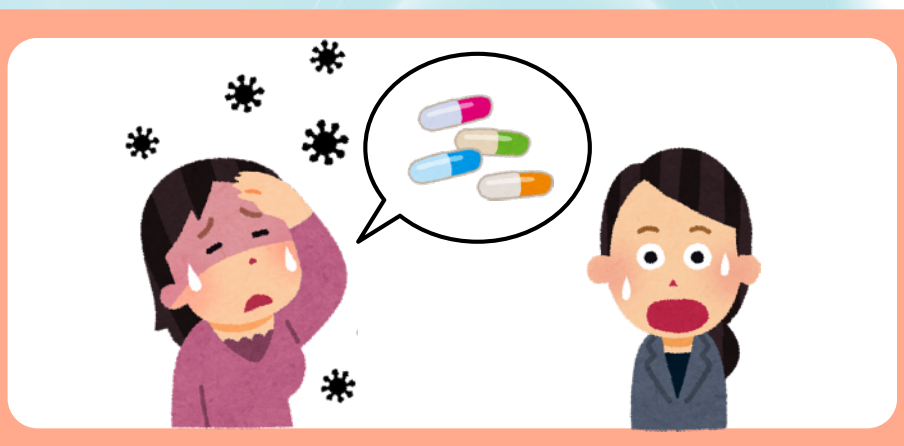
Management of Research Participants' Missed Study Visits and Procedures

Case Scenario

Is this scenario familiar to you?

Ms Sunshine, the Clinical Research Coordinator of a research study had been too busy and missed reaching out to one participant, Mrs Honey to arrange for follow-up visits and to check on her progress.

After many attempts to reach out, Ms Sunshine finally manages to convince Mrs Honey to come to the clinic for the physical follow-up visit. However, it was 2 months late.



On the day of visit, Ms Sunshine noticed that Mrs Honey's study diary had missing entries. Upon conversing, Ms Sunshine realised that Mrs Honey stopped taking the medication as she experienced mild side effects and did not inform the study team.

Key Issues Identified and What Should Be Done

Missed Study Visits & Procedures

Participant's missed medication or discontinuation without informing the study team compromises safety and data validity. Participant did not update the study diary per study requirements.

What should be done:

- Personally address participant's concerns, provide reassurance and enhanced education.
- Offer multiple contact methods for future concerns.
- Document medication discontinuation with dates and reasons.
- Report protocol deviations to IRB.

Delayed Safety Assessment and Reporting

Side effects were disclosed late and not formally assessed or reported, compromising subject safety.

What should be done:

- Firstly, inform PI of Mrs Honey's situation.
- Conduct immediate safety assessments and provide appropriate medical follow-up.
- Ensure safety event is reported accordingly to IRB/regulatory body as required if meets safety reporting criteria.

Data Integrity Risk

Mrs Sunshine considered performing retrospective completion of study diary entries based on participant's vague memory recount and past study diary entries to fill in the blanks.

What should be done:

- Data entries should be Attributable (entries done by research participants), Contemporaneous (current and not back dated), Original and Accurate (reflecting the actual participant's data).
- Assess reasons for discontinuation and discuss with subject in future.

Summary

Ensure research participants' continual engagement and understanding to enhance adherence to protocol.
Assess participant safety, report and escalate appropriately.

What would you have done in this scenario? Share your unique experiences with us today!

Reference: NHG Health PCR Standard Operating Procedures 501-B05 Documentation
NHG Health PCR Standard Operating Procedures 501-B06 IP Accountability
NHG Health PCR Standard Operating Procedures 501-C05 UPIRTSO and Expected SAE
ICH E6 (R3) Good Clinical Practice (GCP) Guideline: Section 2.12 Records & 3.12 Non compliance
NHG Health Responsible Conduct of Research (RCR) Manual (Version 1.1) Chapter 4: Conflict of Interests & Commitment

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