

HCP Check-In Questions for Participants

TOOL

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Introduction

This quick-reference guide is designed [for healthcare providers \(HCPs\)](#) supporting participants in decentralized clinical trials. It provides concise, scenario-based direction for what to do immediately when unexpected situations arise during participant care. Before you proceed with the following participant check-in questions, please refer to the [Instruction Sheet](#) first.

Clinical trials can present unexpected situations, including participant withdrawal, new medication needs, abnormal lab results, pregnancy, lost or compromised study medication, or participant death. **In each case, the healthcare professional (HCP) delivers immediate appropriate clinical care, then promptly notifies the research site and documents what was observed; protocol decisions such as investigational product (IP) continuation, eligibility, and causality remain the responsibility of the investigator and sponsor.**

This document is intentionally brief and scenario-specific, giving an HCP under pressure one clear answer: **what to do right now.**

Understanding Roles/Responsibilities:

The **HCP** takes the following actions:

Begin check-in visit

(use *Participant Check-in Questions* on the following pages as a guide for the visit)

Immediate safety risk?

(Abnormal findings, SAE, death, or acute emergency)

STEP 1

ALWAYS contact the research site as soon as possible!

Use the emergency number on the HCP Instruction Sheet. Do not wait until the end of the visit. Do not independently decide on IP changes (aside from emergency situations when stopping the IP is necessary), protocol eligibility, or causality — defer to the investigator.

STEP 2

ALWAYS document in the participant's medical records

Record: clinical findings, timing, participant's account, any interventions, and your communication with the study team. Share with the study team by fax, secure email, or EHR connectivity.

The **Research Site** manages all protocol decisions.

The **Investigator** determines:

- IP continuation or modification (unless IP is needed to be immediately stopped due to an emergency)
- AE/SAE classification
- Regulatory reporting
- Protocol deviations
- Re-consent requirements
- Next steps for the participant and family

HCP Participant Check-in Questions:

The HCP Participant Check-In Questions are intended to structure each visit and ensure key safety, adherence, and protocol-relevant issues are consistently assessed. Use these questions to guide the conversation, document findings, and promptly engage the research site when clinical or study-related concerns arise.

ASK THE PARTICIPANT:

RESPONSE:

ACTION TO TAKE:

1 Study Participation

Are you willing to continue the study?

NO ☐

Notify site; do not act independently

YES ☐

Continue study per protocol

2 Decision Making Capacity

Have you noticed any changes in your memory, thinking, or your ability to understand and make decisions?

YES ☐

Notify site ASAP; site determines re-consent

NO ☐

Document; continue visit

3 Adverse Events/SAEs

Have you had any new symptoms, side effects, or received any abnormal test results since your last visit?

YES ☐

Clinical care first; notify site ASAP

NO ☐

Document; continue visit

4 Unscheduled Procedure/Hospitalization

Have you had any unplanned procedures, surgeries, ER visits, or hospital stays since your last visit?

YES ☐

Document details; notify site ASAP

NO ☐

Document; continue visit

ASK THE PARTICIPANT:

| RESPONSE: | ACTION TO TAKE:

5 Medication Adherence

Have you been able to take your medication as prescribed?

NO ☐

YES ☐

Ask if they had missed/skipped doses or taken extra doses; document; notify site ASAP

Document; continue visit

6 Lost/Damaged Study Medication

Has your study medication been lost, damaged, stored incorrectly, or taken differently than prescribed?

YES ☐

NO ☐

*Do not advise participant to resume, stop, or adjust dosing > decision belongs to the site

Document details; notify site ASAP. Don't advise dosing*

Document; continue visit

7 New Concomitant Medications

Have you started any new medications, drugs, supplements, vitamins, or herbal remedies since your last visit?

YES ☐

NO ☐

*(urgent) Treat first > notify site as soon as possible after

Clinical care first; notify site ASAP*

Document; continue visit

8 Pregnancy/Suspected Pregnancy

Is there any chance of pregnancy since your last visit?

YES ☐

NO ☐

*Confirm clinically > contact site immediately > do not modify IP independently.

Confirm first; notify site*

Document; continue visit