



MAY 2026

Conducting Remote Re-consenting of Participants
Ensuring Compliance with PCR SOP and ICH E6 (R3) GCP Guideline

Case Scenario

1



Mr Tan, a 72-year-old participant, was recruited for a research 6 months ago. Recently, new safety information emerged which required participants to be re-consented using an IRB approved updated Participant Information Sheet and Consent Form.

2



Mr Tan's daughter requested for the re-consent to be done remotely, as travelling is difficult for her father who has mobility limitations.

3



Clinical Research Coordinator (CRC) Mindy recalled that during the initial process, Mr Tan had difficulty understanding medical terminology and often relied on his daughter for clarification.

4



Since remote consent had been approved by the IRB, CRC Mindy is wondering how to conduct this remote re-consent while supporting participant understanding and complying with PCR SOPs, ICH E6 (R3) GCP Guideline and applicable guidelines.

Considerations to Take

Remote Re-consent Approach

A video call could be arranged with Mr. Tan and his daughter. This allows visual interaction between the participant, family member and study team while reducing the need for onsite travel.

Before proceeding, CRC Mindy should:

- Verify participant's identity
- Ensure privacy and confidentiality
- Confirm that the participant is comfortable using the remote platform
- Provide a paper-based option if preferred or if technology use becomes challenging

Supporting Participant's Understanding

The study team could use supplementary materials such as (but not limited to):

- Simplified summary slides highlighting key updates
- Visual diagrams to explain study visits and procedures
- Larger fonts



Note: Medical terminology should be explained using simple, participant friendly language

Ensure that informed decision is made for continued participation.

During the discussion, assess participant's understanding using open-ended questions, e.g. "Can you share in your own words what this new information means to you?"



Participants are encouraged to discuss with their family before deciding to participate. CRC could follow up later and answer additional questions before obtaining formal consent through the approved remote consent process.

Continued Consent of Participation and Documentations Required

For participant(s) requiring re-consent, ensure that:

- The updated information is clearly explained
- Participant's questions should be addressed
- Willingness to continue participation is re-assessed



Also, ensure that the remote re-consent process is documented appropriately in participant's source records:

- Date of discussion
- Language and version of consent used
- Description of the informed consent process (e.g. methods used, presence of witness, translator)
- Confirmation of participant's agreement to continue participation.

Important Reminder: Ensure that amendments to the Informed Consent Process received IRB and regulatory (if applicable) approvals prior to implementation.

Reference: [NHG Health PCR Standard Operating Procedures 501-C01 Informed Consent Form and Process, Section 5](#)
[NHG Health PCR Doc 599-005 Guidance Document on Electronic Informed Consent Process, Section 4](#)
[NHG Health Investigator's Manual Chapter 5: Informed Consent](#)

Additional Readings: [ICH E6 \(R3\) Good Clinical Practice \(GCP\) Guideline: Section 2.8, Principles and Annex 1 - Overview of Major Changes](#),
[HSA Guidance documents for clinical trials: Electronic consent \(updated 2 Jan 2026\)](#).

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*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental.
Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/ guidelines relating to the above scenarios/case study.