

Participant Pause, Stop, and Modification Procedure

Accessible Adaptive VR | Public Dissemination Resource 3 | NeuroViu

Purpose. This standard operating procedure (SOP) provides a reusable process for supporting participant control and accessibility during VR, digital-health, behavioral, rehabilitation, wearable-technology, and other technology-assisted clinical research.

Scope. The procedure is cross-disability and should be adapted to the approved protocol, institutional policy, study population, technology, safety requirements, and applicable ethics or legal requirements. It does not replace clinical judgment, emergency procedures, or ethics review.

Core principle. A request to pause, modify, receive assistance, or stop should be treated as participant communication and an accessibility consideration - not automatically as noncompliance, treatment failure, or a reason for exclusion.

1. Before the Research Session

1.1 Explain participant control. Tell the participant, in an accessible communication format, that they may request a pause, assistance, a reasonable modification, or to stop the procedure.

1.2 Establish a communication method. Confirm how the participant will communicate a pause or stop request. This may include spoken language, gesture, button, communication device, support person, or another agreed method.

1.3 Review known access needs. Review relevant accommodations without requiring unnecessary disclosure of diagnosis or disability.

1.4 Check the environment and technology. Confirm positioning, mobility access, sensory settings, communication access, equipment fit, assistive-device compatibility when applicable, and safe access to controls or exits.

1.5 Identify nonmodifiable requirements. Explain any safety or scientific requirements that cannot reasonably be changed and discuss alternatives when available.

Suggested Participant-Facing Statement

"You can ask to pause, change something about the setup or procedure, get assistance, or stop at any time. If something is uncomfortable, inaccessible, confusing, or difficult to use, please tell us. We will discuss what can be adjusted safely and within the study requirements. You may also choose to stop or withdraw."

2. When a Participant Requests a Pause

2.1 Pause promptly. Stop or pause the research activity as soon as it is safe to do so.

2.2 Confirm immediate needs. Ask what the participant needs without requiring them to justify the request.

2.3 Maintain safety and privacy. Assist with equipment removal, seating, repositioning, communication, or environmental changes when needed and appropriate.

2.4 Do not infer the cause. A pause may reflect accessibility, fatigue, sensory load, equipment fit, communication needs, discomfort, anxiety, or another factor. Record the participant's explanation when offered rather than assigning an unsupported interpretation.

2.5 Ask whether the participant wants to resume, modify, or stop. Do not pressure the participant to continue.

3. Modification Pathway

Step	Research-team action
Identify	Clarify the barrier or access need relevant to the procedure.
Discuss	Ask the participant what change would help and consider available alternatives.
Evaluate	Confirm that the proposed modification is safe, feasible, and compatible with essential study requirements.
Implement	Apply the agreed modification and explain any change to the procedure.
Confirm	Ask whether the modification adequately addressed the barrier.
Document	Record the barrier, accommodation, participant response, and any effect on data collection or interpretation.

4. When a Participant Chooses to Stop or Withdraw

4.1 Stop the procedure safely. End the research activity and assist the participant with equipment or environmental transitions as needed.

4.2 Respect the decision. Do not pressure the participant to continue or require an explanation beyond what is necessary for immediate safety or required study documentation.

4.3 Follow the approved protocol. Apply the study's withdrawal, adverse-event, follow-up, and data-handling procedures as applicable.

4.4 Offer accessible follow-up information. Provide required instructions or contacts in a format the participant can access.

4.5 Review for preventable barriers. If an accessibility barrier contributed to stopping, document it for protocol, technology, material, or training review.

5. Documentation

Use the **Barrier -> Accommodation -> Participant Response -> Design Modification** process. Document only information necessary for research operations, safety, interpretation, and approved study records. Where relevant, record whether an accommodation affected measurement conditions so that disability- or accommodation-related differences are not automatically interpreted as psychological or behavioral outcomes.

Document	Examples
Barrier / need	Sensory intensity, positioning, mobility access, communication, equipment fit, fatigue, interface access.
Accommodation	Pause, repositioning, alternate communication, adjusted sensory setting, assistance, pacing change, accessible control method.
Participant response	Whether the modification addressed the barrier and whether the participant wished to resume.
Design modification	Change to protocol, technology, participant materials, environment, eligibility review, or staff training.

6. Post-Session Review and Continuous Improvement

6.1 Review accessibility events. Identify whether pauses, modifications, or withdrawals reveal a recurring barrier.

6.2 Close the feedback loop. When appropriate, use participant feedback to refine the procedure, technology, environment, materials, or staff training.

6.3 Avoid overgeneralization. An accommodation that works for one participant should not automatically be assumed appropriate for all people with the same disability or access need.

6.4 Escalate protocol changes appropriately. Changes that affect approved research procedures should undergo the institution's required review before implementation.

Implementation note: This SOP is a public dissemination component of the Accessible Adaptive VR framework. Skyward Sojourn provides the initial implementation context for the broader framework; the earlier eight-participant study was not designed to demonstrate disability inclusion.