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Clinical trial consent visit prep checklist for research sites

A consent visit preparation checklist for research sites coordinating patient materials, language access, version control, staff readiness, questions, and documentation workflows.

How to use this checklist

Consent visit preparation should connect approved materials, version control, language support, staff readiness, patient questions, and documentation steps before the appointment starts.

Quick checks

- [ ] Confirm the current approved consent materials and version before the visit.
- [ ] Prepare language access, staff coverage, question routing, and documentation steps ahead of time.
- [ ] Keep consent prep separate from any promise of eligibility, enrollment, or medical benefit.

Confirm the approved materials

- [ ] Before a consent-related visit, the site should confirm the current approved consent form, any translated versions, participant-facing materials, study contact information, and version dates.
- [ ] The checklist should also confirm where superseded versions are retired so staff do not accidentally prepare the wrong packet.

Prepare the right staff and setting

- [ ] Consent visit prep should include who will conduct or support the discussion, who can answer protocol questions, who handles documentation, and how interruptions will be minimized.
- [ ] If the visit requires a specific staff role, interpreter, or investigator availability, that dependency should be visible before the patient arrives.

Plan language access and accessibility support

- [ ] The site should confirm whether language assistance, translated materials, accessible formats, or additional communication support are needed.
- [ ] Those needs should be prepared through approved site processes, not improvised during the visit.

Route questions without rushing decisions

- [ ] Patients may have questions about study purpose, visit burden, risks, compensation, privacy, alternatives, and what happens next. The checklist should show who can answer which questions and how unanswered questions are followed up.
- [ ] A prepared workflow gives patients room to ask questions without turning the visit into a rushed administrative step.

Document the operational handoff

- [ ] After the visit, the workflow should capture the next operational status, documentation completion, follow-up owner, and any scheduling or records next step.
- [ ] The checklist should never frame consent as guaranteed enrollment. It is a required study process with its own documentation and decision boundaries.