

Clinical trial regulatory binder checklist for recruitment operations

A recruitment operations checklist for keeping site regulatory binders aligned with approved materials, recruitment sources, delegation, training, communication logs, and version changes.

How to use this checklist

Recruitment operations should stay aligned with regulatory binder expectations for approved materials, source documentation, delegation, training, and version control.

Quick checks

- Recruitment materials should be current, approved, and traceable to the right study version.
- Source routing, delegation, training, and communication expectations should match documented site processes.
- Version changes should trigger workflow updates so coordinators do not use stale scripts, forms, or public copy.

Link recruitment materials to approval status

- The recruitment checklist should confirm that flyers, landing pages, phone scripts, prescreening materials, referral language, and participant-facing documents are current and approved where approval is required.
- Each material should have an owner, version date, storage location, and retirement process for older versions.

Connect source workflows to documentation

- If the site uses multiple recruitment sources, the binder-adjacent checklist should show which sources are active, which materials each source uses, and how source performance is reviewed.
- That helps the operations team avoid a mismatch where a source is still active but its approved material, routing rule, or contact path changed.

Check delegation and training evidence

- Recruitment tasks should align with delegation and training documentation. Staff who answer calls, support prescreening, request records, schedule visits, or prepare sponsor updates should have the right workflow access and training context.
- When staffing changes, the recruitment queue and documentation should be updated together.

Track amendments and version changes

- Protocol amendments, consent updates, revised eligibility language, new recruitment sources, or changed sponsor instructions can all affect site recruitment workflow.
- The checklist should require a workflow review when those changes happen so coordinators know what changed, what stayed the same, and which old materials should stop being used.

Keep broad reports operational

- Regulatory documentation and recruitment reporting serve different purposes. A sponsor update can summarize source status, blockers, and next actions without exposing unnecessary patient details or replacing required essential-document processes.
- The checklist should help the site keep those boundaries clear.

Educational resource only. This checklist does not replace protocol requirements, IRB-approved materials, sponsor instructions, investigator oversight, site SOPs, or authorized study-team decisions.