

Site-Ready Amendment Checklist

To help sites implement protocol amendments smoothly, sponsors should be prepared to provide the right information, contacts, and support at each step.

AMENDMENT ANNOUNCEMENT READINESS

- ☐ Early notification that an amendment is coming (before IRB submission)
- ☐ Confirmation that the site team has been informed, not just the PI

AMENDMENT PACKAGE READINESS

- ☐ Clean and redlined protocol and summary of changes
- ☐ Impacted/updated informed consent documents
- ☐ Updated budget template (as applicable)
- ☐ A one-page amendment impact summary indicating:
 - ☐ Protocol amendment categorization and priority for implementation

Substantial modifications (e.g., patient safety impact, or substantial amendments), typically high priority

Non-substantial modifications, high or low priority

[See more examples from the National Institute for Health and Care Research](#)

- ☐ New cohorts or arms
- ☐ Schedule of assessments changes
- ☐ Anticipated budget impact or confirmation that no budget template is forthcoming/expected (yes/no)
- ☐ If yes, provide updated budget template with full amendment packet
- ☐ Anticipated coverage analysis impact (yes/no)
- ☐ Anticipated CTMS/calendar impact (yes/no)

If yes to schedule of assessment changes, this should also be “yes”

FINANCIAL READINESS

- ☐ Updated budget template included with the amendment packet
- ☐ Clear indication if budget re-negotiations will be required
- ☐ Alignment with previously agreed rate cards or templates where applicable



COMMUNICATION READINESS

- ☐ Named operational, financial, and escalation contacts
- ☐ Defined escalation path if timelines are missed or items are not received on time
- ☐ Timely responses during amendment negotiation (no prolonged “blackout” periods)

IMPLEMENTATION READINESS

- ☐ Acknowledgment that sites may need interim solutions
- ☐ Flexibility during implementation while contracts finalize
- ☐ Recognition of site compliance and billing constraints

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