# ACRP

# ACRP-PM

## ACRP Project Manager

# Latest Version: 6.0

## Question: 1

A CRO managing a study has, with the sponsor's knowledge, subcontracted central laboratory services to a third party. Sample turnaround times from that lab are slipping, and site staff are raising concerns. The project manager oversees the CRO under the master service agreement.
How should the project manager exercise oversight of the subcontracted lab?

A. Move to replace the subcontracted laboratory straight away, on the reasoning that swapping in a new lab is the most direct route to restoring the sample turnaround times the sites are complaining about.
B. Hold the CRO accountable under the master agreement for its subcontractor's performance, requiring the CRO to document the turnaround issue and its corrective plan.
C. Wait for the CRO to raise the turnaround issue on its own, on the reasoning that the lab is the CRO's subcontractor and its performance therefore sits within the CRO's remit to manage and report.
D. Contact the subcontracted laboratory directly and instruct it to correct its turnaround times, working around the prime CRO on the reasoning that a direct line to the lab resolves the slippage faster than routing it through the CRO.

**Answer: B**

## Question: 2

A project manager at an academic center is overseeing an investigator-initiated trial in which the institution's physician-investigator conceived the study and holds the sponsor obligations. Reviewing the draft protocol, the PM finds a detailed background and objectives section but cannot locate a clearly stated, testable study hypothesis, and the endpoints do not obviously map to any specific question.
What is the most appropriate action for the PM?

A. Defer to the CRO to insert a standard hypothesis template, treating the gap as a routine vendor deliverable rather than a scientific issue for the team.
B. Add a hypothesis independently as PM to keep the timeline moving and leave the investigator out of the wording, since it is essentially a documentation formality.
C. Flag that a testable primary hypothesis is missing and work with the investigator to articulate it, since it anchors the objectives, endpoints, and sample size.
D. Proceed, because in an investigator-initiated trial the investigator-sponsor is exempt from stating a formal hypothesis as long as the objectives are described in enough detail.

**Answer: C**

## Question: 3

A project manager is reviewing a double-blind protocol and preparing the unblinding SOP with the team. A coordinator suggests that, because randomization already balances the arms, masking treatment identity from participants and assessors adds little value.
How should the PM explain the distinct purpose of blinding?

A. Blinding limits performance and assessment bias by preventing knowledge of treatment assignment from influencing participant behavior, care, or outcome evaluation after randomization.
B. Blinding primarily protects participant confidentiality by concealing personal data from the study team during the trial.
C. Blinding exists mainly to simplify drug supply logistics by allowing identical-appearing kits to be shipped to participating sites.
D. Blinding is what makes the treatment arms comparable at baseline, so it serves essentially the same purpose as randomization and can be treated as largely redundant with it once the allocation sequence has been concealed from the sites.

**Answer: A**

## Question: 4

A project manager wants to set a team goal to improve how quickly the monitoring group resolves data queries, which has been inconsistent across sites on a dermatology study.
Which goal statement is most effective for driving and tracking improvement?

A. State that the monitoring team should aim over the course of this year to be recognized by the sponsor as a high-performing group that other study teams look to as a model.
B. The monitoring team will reduce the average query-resolution time to an agreed target level across all sites within the next quarter.
C. State that the monitoring team should resolve its outstanding data queries as fast as it possibly can across each of the study's sites, treating speed as the overriding aim.
D. State that the monitoring team should try hard to resolve its data queries faster than it has been over the coming period, and put real effort into improving the turnaround.

**Answer: B**

## Question: 5

At a monitoring visit, it emerges that a sub-investigator has been performing protocol-specified assessments, but the investigator site file contains no documented record of that person's protocol or GCP training.
What is the most appropriate action?

A. Confirm whether the training occurred, ensure it is completed and documented in the site file if needed, and verify the delegation log reflects the role.

B. Have the monitor create the missing training record on the site's behalf so the investigator site file looks complete for the assessments that were already performed.
C. Remove the sub-investigator's completed assessments from the study data set on the basis that the training was not documented in the site file at the time.
D. Ignore the documentation gap on the grounds that the sub-investigator is evidently experienced and qualified to carry out the protocol-specified assessments in question.

**Answer: A**

## Question: 6

Enrollment is lagging and retention is slipping on a chronic-disease study. The project manager has limited remaining discretionary budget and three proposals: a broad advertising campaign, funding for site-based participant travel and reminder support, and a per-participant completion incentive. IRB-IEC considerations bear on some options.
Which funding decision is most appropriate for the project manager to advance?

A. Fund the largest per-participant completion incentive that the remaining discretionary budget can support, on the reasoning that a bigger completion payment is the most powerful lever available for holding participants in the study to the end.
B. Fund the broad advertising campaign, on the reasoning that reaching a much wider pool of potential participants is the most direct single move to lift both the lagging enrollment and the slipping retention at the same time.
C. Fund site-based travel assistance and reminder support, which addresses documented retention barriers and can be structured to remain within ethical-review expectations.
D. Split the limited discretionary budget across the advertising campaign, the travel support, and the completion incentive together, on the reasoning that funding every proposal at once pursues all available avenues simultaneously.

**Answer: C**

## Question: 7

Reviewing compliance trends, a project manager notices that the same protocol deviation — a required assessment being performed outside its allowed window — is recurring at multiple sites.
Which study-level response is most appropriate?

A. Investigate the shared cause across sites and implement one study-wide corrective and preventive action.
B. Address each deviation individually at the site level without checking for a common underlying cause.
C. Instruct the sites to stop logging these occurrences so the study's overall deviation count is reduced.
D. Issue a formal protocol-violation notice to each site that recorded the recurring assessment-window deviation.

**Answer: A**

## Question: 8

While reviewing the eligibility section of a new dermatology protocol, a project manager checks that each inclusion and exclusion criterion is accompanied by a stated reason.
What is the scientific purpose of well-defined inclusion and exclusion criteria?

A. To allow investigators to enroll essentially any interested candidate who happens to present at a study site during recruitment.
B. To keep the eligibility criteria as broad as they can be so that overall enrollment finishes in the shortest time.
C. To let the sponsor market the approved product to the broadest possible audience once it has cleared regulatory review.
D. To define a study population suited to the research question and to participant safety, each criterion supported by a rationale.

**Answer: D**

## Question: 9

Midway through a multi-region cardiovascular study, a project manager identifies that a vendor delay will most likely push a key database-lock milestone past the date the sponsor's executive steering committee has publicly committed to investors. The project manager has a mitigation option that recovers part but not all of the slippage, and a committee update is scheduled in two days.
Which approach to managing the executive relationship is most appropriate?

A. Present the mitigation option at the committee and characterize the milestone as on track, so that executives are not alarmed before the recovery attempt has had a chance to play out.
B. Escalate the issue to the committee through the functional line manager instead, keeping the project manager out of the executive conversation and the direct line of questioning.
C. Give the committee a concise briefing that states the milestone risk, quantifies the exposure, presents the partial-recovery option and its residual gap, and names the decision needed.
D. Hold off on informing the committee until the delay is unavoidable and fully quantified, on the reasoning that the message will then be precise and defensible rather than speculative.

**Answer: C**

## Question: 10

During a routine visit at a cardiology site, the monitor finds that the investigator site file is missing the latest approved protocol amendment and two updated laboratory certifications, even though the site is already working to those versions.
What is the most appropriate action for the project manager to drive?

A. Log the omission as a reportable protocol violation and submit it to the ethics committee as a serious-noncompliance notification, treating a correctable filing lapse as though participant safety were affected.
B. Have the site bring its investigator site file current with the approved amendment, updated certifications, and delegation records, since the file must reflect what the site is actually using.
C. Direct the monitor to print copies from the sponsor trial master file and file them into the investigator site file personally so the documentation gap is formally closed out before the monitoring visit ends.
D. Escalate source data verification to full coverage at this site and pause new enrolment, treating the filing gaps as evidence that the clinical data already collected there can no longer be trusted.

**Answer: B**

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