

CRLN Decision Cards

Deck 01: twelve real site decisions for a 10-minute team huddle

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Each card is one decision a clinical research coordinator or site team member faces. Read it, vote, argue it out, then check your reasoning online. The discussion needs no phone and no login. The answers are not printed on the cards.

How to run a 10-minute huddle

Before (2 minutes)

Pick one card. Hand out the card or put it on the screen. Anyone can run it. The facilitator does not need to know the answer.

0:00 to 1:00, Read

Read the situation and the question aloud. Read all the options once.

1:00 to 2:00, Vote in silence

Everyone picks a letter on their own, by holding up fingers or writing it down. No talking yet. Spread across the letters is good news: it gives you something to discuss.

2:00 to 7:00, Discuss

Start with someone who picked a different letter from the majority. Ask: What is your first action? Who do you tell? What do you write down, and where? Which rule or SOP are you leaning on? What would make you change your pick?

7:00 to 9:00, Check the reasoning

One person scans the QR code and taps the group's pick. The page shows how that choice scores and why. No account is needed. The server does the grading, so the answers are never printed on the card. If the group is split, check the pick the group argued hardest about.

9:00 to 10:00, Close

Write one sentence: what do we do at this site when this happens? Name the SOP, the person to call, and where it gets documented.

Good to know. The cards are fictional situations written for training. They do not replace your protocol, your SOPs or your IRB. Where they differ, your site's approved documents win. No patient information belongs in a huddle. Use the cards, not real cases.

A new risk, a returning participant

An amendment adding a serious liver risk was approved by the IRB six days ago. A participant, consented earlier on the old form version, arrives for a visit that includes study drug dosing. The updated form is ready.

How do you proceed with today's visit?

- A** Continue as normal. A safety update is not a change to procedures, so no re-consent is needed
- B** Pause non-essential and dosing procedures, re-consent on the new IRB-approved form, and file the old one as historical
- C** Tell the participant about the risk verbally, note it in source, and get written re-consent whenever convenient
- D** Complete today's dosing, then re-consent at the next visit, since consent was given at baseline



Scan to check
your reasoning

The consent in front of you

In a neurology study, a participant signs the consent form before you have finished the first page of the discussion. The clinic is an hour behind and the investigator is in another room.

What do you do?

- A** Read the whole form aloud so every element is covered before signing
- B** Slow down and ask them to explain the study back in their own words before signing
- C** Ask them to explain it back, and offer to reschedule so they are not deciding against the clock
- D** Take the signature while they are willing, since they have already read the form on their own



Scan to check
your reasoning

You noticed it first

At a routine visit in an oncology study, a participant mentions mouth ulcers for the past week. It is not on any form, and she has not called it a problem.

What do you do with it?

- A** Leave it, since she did not call it a problem and it may be unrelated
- B** Record it as an adverse event and give the investigator the details at the medical review
- C** Mention it to the investigator verbally and let them decide whether to record it
- D** Record it, and ask about onset, severity and treatment now while she is here



**Scan to check
your reasoning**

The overnight stay

A participant on active study drug calls. She fell at home two days ago, stayed overnight in hospital for observation, and went home the next morning with no fracture. She says it is nothing serious and she is fine now.

How do you classify and act on this event?

- A** Note it in the chart. She says it was not serious, so no expedited action seems needed
- B** Decide a fall at home is not plausibly related to the drug, so no expedited report is needed
- C** Classify it as serious because of the overnight stay, assess causality with the PI, and report it on the expedited timeline
- D** Record it as an adverse event, document the details in source, and flag it for the next monitoring visit



**Scan to check
your reasoning**

The symptom that was already there

A participant mentions her knee pain again. Screening documented osteoarthritis in that knee, and she says it is unchanged since before the study. Nothing about it is different.

What do you do?

- A** Decide it is pre-existing from what she says, without checking what screening documented
- B** Confirm it is unchanged from screening and treat it as pre-existing medical history
- C** Record it as unchanged medical history, and note that you checked it against screening
- D** Log it as a new adverse event, since any symptom a participant reports is safest captured



Scan to check
your reasoning

The eligibility call

You are screening a candidate for a neurology trial. The screening MMSE score is 26, but the protocol requires 20 to 24 for enrollment. A colleague asks you to enroll today to help hit the recruitment target.

What do you do?

- A** Do not enroll. The criterion is not met. Document it and confirm with the PI or sponsor before any enrollment
- B** Do not enroll today. Record the screen failure and the specific criterion before anyone is randomized
- C** Enroll now to hold the recruitment window, and raise a protocol clarification with the sponsor in parallel
- D** Ask for the assessment to be repeated, since one borderline reading is often just measurement variation



Scan to check
your reasoning

The kit in your hand

You are dispensing at a visit in a neurology study. The blister pack is labeled for a different participant number. The participant is in the room and the visit window closes today.

What do you do?

- A** Dispense the kit the system names and fix the paperwork afterwards, since the window closes today
- B** Dispense the kit physically in front of you and note the discrepancy in the accountability log
- C** Stop, hold the product, and escalate to the investigator and sponsor before the participant leaves
- D** Stop, do not dispense, and ask the pharmacy to resolve the discrepancy before anything is handed over



Scan to check
your reasoning

The wrong kit, found two days later

You find that one participant received a kit assigned to another participant at the last visit, caught two days later. It is at once a protocol deviation, a possible safety issue, an accountability break, and possibly reportable to the IRB.

What do you do FIRST?

- A** Notify the PI, and hold the deviation report until the clinical assessment is done so it is filed once
- B** Notify the sponsor's medical monitor directly so the assessment starts at once, then tell the PI
- C** Put safety first: notify the PI and medical monitor to assess clinical impact, then document the deviation and quarantine the kit
- D** Notify the PI immediately so a clinician can assess the clinical impact on the participant



Scan to check
your reasoning

The missing source page

The CRA arrives tomorrow. Preparing the binder, you find that a participant's Visit 2 ECG strip is missing. The EDC says the PI reviewed it and found it normal on March 12.

What is your first action?

- A** Search the chart, ECG cart, scan queue and PI's office, document the search, and if it is still missing, file a Note to File
- B** Do all of that, also check whether other visits' ECGs are unscanned, and raise it with the CRA yourself
- C** Print a fresh copy from the EHR, label it as a reprint of the Visit 2 tracing, and file it
- D** Leave it for the CRA to raise at source data verification, as a documentation query is the normal route



Scan to check
your reasoning

The assessment nobody did

In a neurology trial, a participant's required cognitive rating battery was due within the Week 16 visit window but was not done. The window closed two days ago.

What is your first action?

- A** Leave it for the monitor to assess at the next visit, with the full source in view
- B** Document a protocol deviation, notify the sponsor, and confirm whether a late assessment is still useful for analysis
- C** Document a protocol deviation for the missed window and notify the sponsor of the assessment not done
- D** Perform the assessment when the participant can attend and record it at the scheduled date, since the assessment itself is unaffected



Scan to check
your reasoning

The holiday and the window

A participant's Week 12 visit falls on a public holiday. The next day they can attend is two days after the protocol window closes.

What do you do?

- A** Run the visit on the day they can attend, then complete and file the deviation report promptly
- B** Offer every remaining date inside the window first. If none works, agree a planned deviation with the investigator and sponsor beforehand
- C** Reschedule inside the window, even though the only date left is far less convenient for the participant
- D** Run the visit on the day they can attend and record the visit date as the last day of the window



**Scan to check
your reasoning**

Who is allowed to know

A printed infusion list with four participants' names on it is face-up on the shared desk. You are the only person who has noticed.

What do you do?

- A** Leave it where it is but turn it over, so the names are not showing
- B** Move it somewhere it cannot be seen or read by anyone passing through
- C** Put it out of sight straight away, and tell the coordinator it was left where you found it
- D** Leave it, since the area is staff-only and whoever put it there knows the site's rules better than you



**Scan to check
your reasoning**