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Clinical Research Coordination 101: A Practical Crash Course for Getting Started

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Learning Objectives

1. Describe the role and responsibilities of a Clinical Research Coordinator (CRC) throughout the clinical research lifecycle, including study start-up, participant recruitment, study conduct, and closeout.

2. Identify key ethical and regulatory requirements for conducting clinical research, including informed consent, Institutional Review Board (IRB) oversight, Good Clinical Practice (GCP), HIPAA, and participant safety reporting.

3. Recognize essential clinical research coordination activities and documentation practices, including maintaining regulatory files, managing study visits and procedures, documenting adverse events, and preparing for monitoring and audits.

NUCATS CRC Basic Training Course

https://www.nucats.northwestern.edu/training/research-staff-development/crc-training.html

Clinical Research Coordinator (CRC) Basic Training is a five-session, scheduled online training program for coordinators that provides practical information to get them up and running in the clinic, with many tools and templates to assist with study implementation

The training covers a variety of topics, including informed consent, regulatory, procedures, documents, binders, study initiation and close-out visits, drug compliance/storage/documentation, IRB submissions and HIPAA, adverse events, and FDA audits and monitoring



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Introduction to clinical research coordination

What is clinical research?

Clinical research involves studies designed to understand health e, evaluate interventions, or improve healthcare and health outcomes

Common types include:

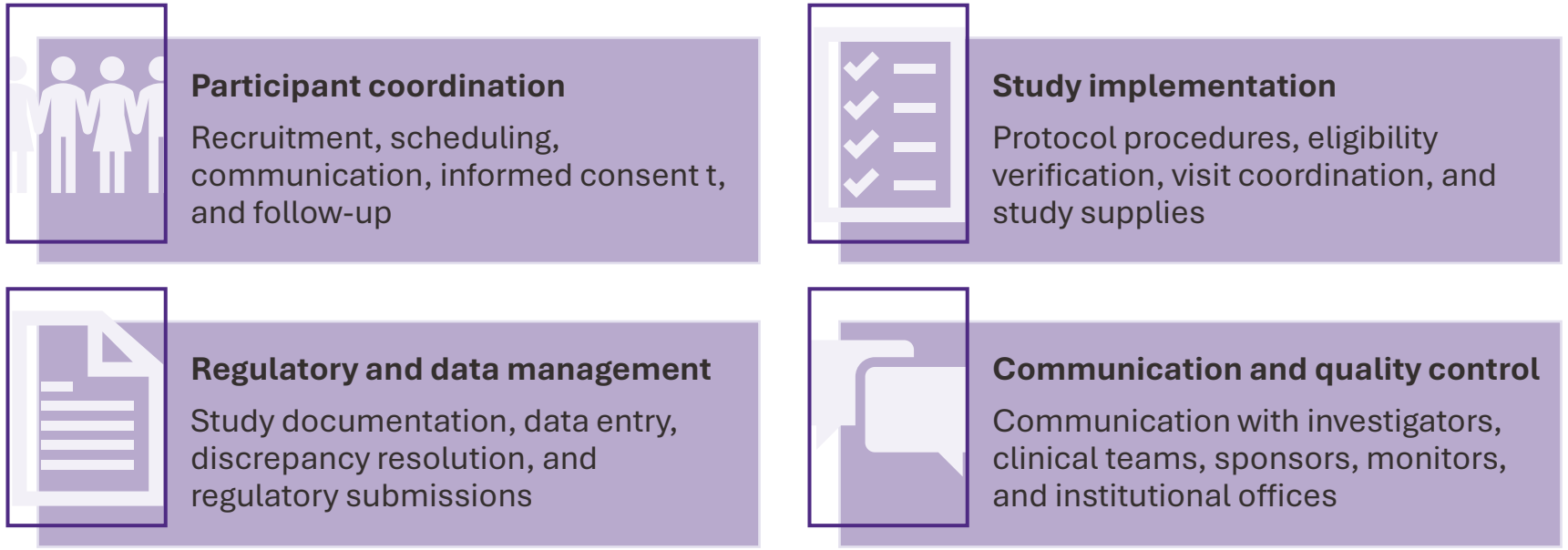
- Interventional studies: Researchers assign al program
- Observational studies: Researchers observe partici ssigning the intervention being studied
- Clinical trials: Studies that evaluate the effects of one o elated outcomes
- Behavioral and survey research: Studies examining ex vio r health-related practices

Clinical research may involve healthy volunteers, patie cal records, biologica ens, surveys, or combinations of these

NIH Definition of a Clinical Trial
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

What does a clinical research coordinator (CRC) do?

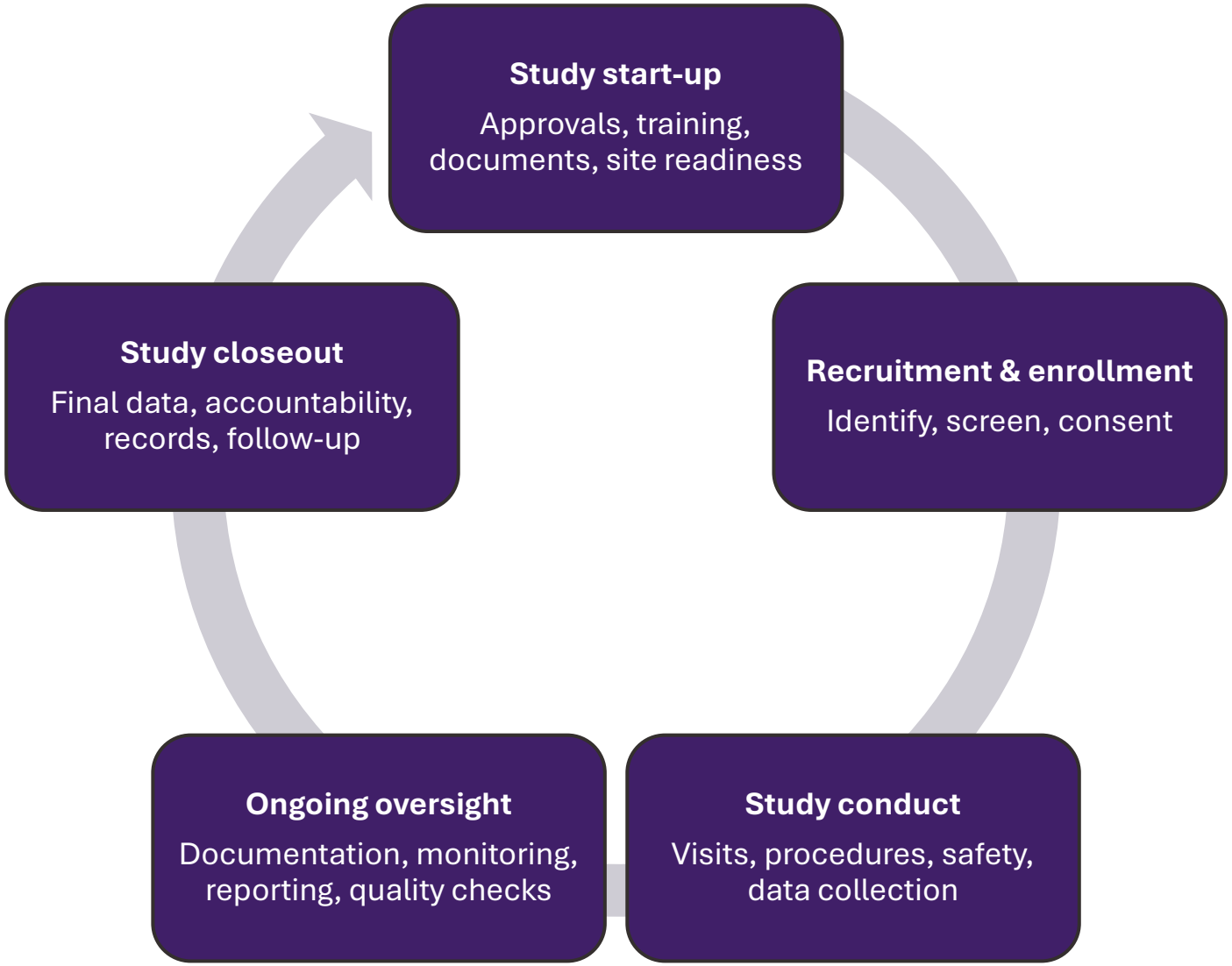
A CRC helps translate a research protocol into coordinated, day-to-day study activities



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The clinical research lifecycle

The clinical research lifecycle



Study start-up: before the first participant

Before a study begins, the team must establish that the site is ready to conduct it

Key activities may include:

- Confirm the current protocol, consent forms, investigator brochure, and other applicable study documents
- Obtain required IRB approval and other institutional or regulatory approvals
- Complete required training and document delegated study responsibilities
- Establish regulatory files, source documentation processes, and data-entry systems
- Coordinate laboratory procedures, equipment, study supplies, and investigational product processes where applicable
- Review recruitment materials, screening procedures, visit schedules, and communication plans
- Complete required sponsor or site initiation activities

Recruitment, screening, eligibility, & enrollment

Recruitment

- Identify potential participants through approved recruitment methods

Pre-screening

- Assess preliminary eligibility (when permitted by the protocol)

Screening

- Collect & review information needed to evaluate inclusion and exclusion criteria

Informed consent

- Conduct the consent process before any research procedures are scheduled/completed

Eligiblity confirmation

- Verify that all criteria are satified and documented

Enrollment

- Complete study-specific enrollment steps and begin protocol activities

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Ethics, consent, & regulatory responsibilities

Protecting research participants

Participant protection is the foundation of ethical clinical research

Core principles include:

- Respect for persons: respect autonomy and support informed, voluntary decisions
- Beneficence: minimize potential harms and maximize potential benefits
- Justice: ensure fair participant selection and equitable distribution of research burdens and benefits
- Privacy and confidentiality: protect personal information and limit access to authorized individuals
- Ongoing respect: communicate new information when required, respect participant decisions, and follow appropriate withdrawal procedures

What this means for a CRC:

- Put participant welfare ahead of recruitment or enrollment targets
- Communicate concerns promptly to the investigator and IRB (if applicable)
- Avoid coercion or undue influence
- Follow approved procedures for consent, privacy, and safety

Informed consent: More than a signature

Informed consent is an ongoing communication process that supports a participant's voluntary decision to join a study

The process typically includes:

- Providing the current IRB-approved consent information
- Explaining the study's purpose, procedures, duration, risks, potential benefits, and alternatives where applicable
- Allowing adequate time for questions and consideration
- Assessing understanding and answering questions within one's role
- Ensuring the decision is voluntary and free from coercion
- Obtaining and documenting consent before applicable research procedures begin
- Providing the participant with a copy of the signed consent form when required
- Completing the process again when revised consent or re-consent is required

Types of consent

Type	Description	Example
Written consent	The participant reviews the consent information and signs a consent form before participating, as required	A clinical trial evaluating a new medication
Electronic consent (online consent)	Consent information is presented and documented electronically	A participant reviews and signs consent through a secure online platform to complete a survey (Qualtrics)
Verbal consent	Consent information is communicated verbally, and the participant's agreement is documented according to the approved process	A minimal-risk interview study using an IRB-approved verbal consent process
Waiver of documentation of consent	The IRB waives the requirement to obtain a signed consent form when regulatory criteria are met; this does not necessarily waive the consent process itself	Certain minimal-risk survey or interview studies
Waiver or alteration of consent	The IRB approves a waiver of consent or permits specific consent elements to be altered when applicable regulatory criteria are satisfied	Certain qualifying minimal-risk research or specific emergency research circumstances
Legally authorized representative (LAR) consent	An individual legally authorized under applicable law provides consent on behalf of a person who cannot legally provide their own consent	Research involving an adult who lacks decision-making capacity, when permitted

IRB oversight and Good Clinical Practice

Institutional Review Board (IRB)

Reviews research to help protect participants' rights and welfare. Depending on the study, the IRB reviews protocols, consent materials, recruitment materials, amendments, and continuing oversight submissions

Good Clinical Practice (GCP)

An international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials involving human participants

Principal Investigator (PI)

Provides overall study oversight, ensures appropriate delegation and supervision, and addresses scientific, medical, and participant-safety decisions within their responsibilities

Clinical Research Coordinator (CRC)

Implements assigned study activities, maintains accurate documentation, follows approved procedures, and escalates concerns

Regulatory requirements and privacy

Clinical research may be governed by multiple overlapping requirements, depending on the study

FDA regulations

Govern applicable clinical investigations and investigational products or devices

HHS human subjects regulations

Apply to covered research under the relevant federal requirements

HIPAA

Protects the privacy and security of protected health information when applicable

GCP

Establishes ethical and quality standards for applicable clinical trials

Institutional policies

Establish local requirements for approvals, training, documentation, and conduct

Protocol and study agreements

Define study-specific procedures and responsibilities within applicable requirements

Privacy practices

- Access only the information needed for authorized work
- Use approved systems to store and share research information
- Follow institutional rules for secure communication and record retention
- Report suspected privacy incidents through the appropriate channels

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Running the study day-to-day

Conducting a study visit

A well-coordinated study visit includes preparation, execution, and follow-up

Before	**Prepare** Review the visit window, required procedures, consent status, supplies, staffing, and participant instructions
During	**Coordinate** Confirm identity using approved procedures, follow the protocol, coordinate procedures, assess and escalate concerns, and document activities
After	**Close the loop** Complete records, enter data, arrange follow-up, address outstanding tasks, and communicate relevant issues to the team

Documentation: if it isn't documented, it is difficult to verify

Common study records include:

- **Regulatory records:** approvals, training records, delegation logs, investigator qualifications, and applicable correspondence
- **Source documentation:** original records or authorized records of observations and clinical activities
- **Case report forms (CRFs/eCRFs):** data collected for the study and submitted to the sponsor or designated data system
- **Participant records:** consent documentation, screening records, visit records, and follow-up
- **Safety documentation:** relevant adverse-event information and reporting records
- **Study accountability records:** records for investigational products, devices, specimens, or other study materials, as applicable

Good documentation is:

- Accurate and attributable
- Complete and timely
- Consistent with source records and the protocol
- Corrected transparently, with an audit trail where applicable
- Maintained in approved systems with appropriate access controls

Data quality and protocol deviations

Data quality depends on collecting the right information, at the right time, using the right procedures

CRC responsibilities may include:

- Entering complete and accurate data
- Responding to data queries
- Reconciling discrepancies between source and study systems
- Tracking missing forms, procedures, and follow-up
- Identifying and reporting protocol deviations according to study procedures
- Supporting corrective and preventive actions when appropriate

What is a protocol deviation?

An instance in which study conduct differs from the approved protocol or applicable study requirements. Classification and reporting depend on the nature of the event and the relevant requirements

Examples:

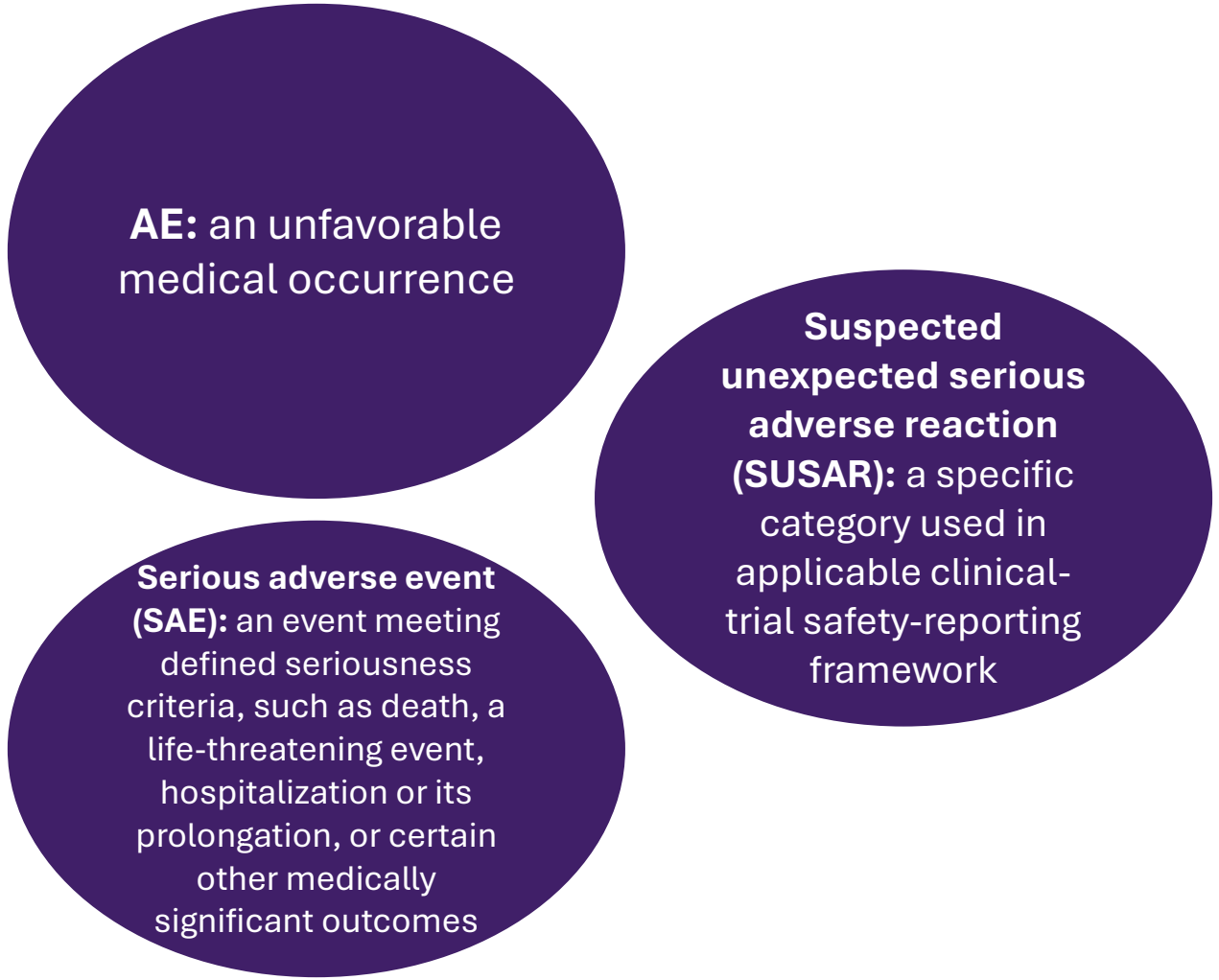
- A study visit occurs outside the permitted window
- A required assessment is missed
- A procedure is completed using an outdated instruction
- An eligibility criterion is not satisfied

Participant safety and adverse events

An adverse event (AE) is an unfavorable medical occurrence in a participant, whether or not it is considered related to the study intervention

A CRC may need to:

- Recognize and document information about a potential adverse event
- Notify the investigator or appropriate clinical team promptly
- Support assessment and follow-up as directed
- Record relevant dates, symptoms, outcomes, and other required information
- Follow study-specific timelines and procedures for reporting
- Document the actions taken and maintain follow-up records



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Oversight, teamwork, & study close-out

Monitoring, audits, & inspections

Clinical research oversight helps assess whether a study is being conducted according to applicable requirements and whether its records are reliable

Monitoring: ongoing review of study conduct and data quality, often performed by a sponsor; includes post-approval monitoring by the IRB

Audit: a systematic, independent examination of study activities and records

Inspection: an examination by a regulatory authority, such as the FDA, when applicable

How can CRCs prepare?

- Maintain complete, organized, current records
- Resolve outstanding data queries and document corrections
- Ensure the team follows the current approved protocol
- Make requested records available through authorized processes
- Track follow-up items and document their resolution
- Escalate findings and support corrective actions

Study close-out

Closeout is a structured process to confirm that required study activities have been completed and records are appropriately maintained

Typical activities include:

- Confirming participant follow-up and outstanding visits are addressed
- Resolving data queries and outstanding documentation
- Reconciling investigational products, devices, specimens, or supplies as applicable
- Completing required final reports and study notifications
- Ensuring essential records are complete and retained according to applicable requirements
- Completing sponsor closeout activities and addressing outstanding action items
- Confirming any ongoing participant-care or safety follow-up responsibilities

Key takeaway: the last participant's last visit is not necessarily the end of the coordinator's responsibilities

Working effectively with a research team

Study team member	Typical responsivities
Principal investigator (PI)	Overall study oversight and scientific or medical responsibilities
Clinical research coordinator (CRC)	Day-to-day study coordination and assigned study activities
Clinical care team	Clinical assessments and care within their professional roles
Regulatory team/IRB	Regulatory support and ethical review and oversight
Sponsor/CRO	Study oversight, monitoring, and other contracted responsibilities
Other (such as investigational pharmacy or CRU)	Provide study resources such as IP management or facility use

CRC best practices:

- Communicate early and clearly
- Maintain task lists, calendars, and follow-up logs
- Clarify responsibilities and delegation
- Escalate safety, eligibility, consent, and compliance concerns promptly
- Ask questions rather than make assumptions
- Close the loop on outstanding issues

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Knowledge checks

What would you do?

A participant arrives for a study visit, and you discover that the consent form on file is an outdated version. What should you do first?

A. Proceed with the visit because the participant already signed a consent form

B. Pause activities requiring valid consent and contact the appropriate study personnel to confirm the approved consent process

C. Replace the form with the newest version and ask the participant to sign it after the visit

D. Discard the outdated form without documenting the issue

What would you do?

During a study visit, you realize that a required assessment was missed. What is the most appropriate response?

A. Complete the assessment later and document it as if it occurred during the visit

B. Ignore the omission if the participant appears healthy

C. Document what happened accurately, notify the appropriate study personnel, and follow the deviation assessment and reporting process

D. Remove the participant from the study immediately

What would you do?

A participant calls after a study visit to report a new medical concern. What should the coordinator prioritize?

A. Wait until the next scheduled visit to discuss the concern

B. Determine independently whether the concern is related to the study intervention

C. Record the concern but avoid notifying the investigator unless it becomes severe

D. Assess whether urgent assistance is needed under site procedures, promptly notify the appropriate clinical team and investigator, and follow study-specific documentation and reporting requirements

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Key takeaways

Key takeaways

Remember these five principles:

- **Know your protocol:** it is the operational blueprint for your study
- **Protect your participants:** safety, informed consent, and respect come first
- **Document accurately:** records should reflect what actually happened
- **Communicate and escalate:** do not guess when requirements are unclear
- **Stay organized and proactive:** checklists, calendars, and routine reviews support quality research

Continue building your skills

- Complete required institutional and study-specific training
- Review applicable GCP training and human-subjects protection requirements
- Learn your institution's IRB, privacy, and regulatory procedures
- Seek guidance from experienced coordinators and investigators
- Use study-specific SOPs, checklists, and approved resources

References

- NUCATS Clinical Research Coordinator Basic Training — introductory curriculum covering consent, regulatory documentation, study procedures, safety, monitoring, and closeout
- ICH E6(R3) Good Clinical Practice — international guidance on clinical trial conduct and quality
- Office for Human Research Protections (OHRP) — resources on human-subjects protection
- U.S. Food and Drug Administration (FDA) — clinical trials and human-subject protection information

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