



SOP (STANDARD OPERATING PROCEDURES)

CRC JOB DESCRIPTION

Position: CRC (Clinical Research Coordinator)

Supervisor: Patricia J. Epple, RN, BS, CCRC, Research Director

Responsibilities:

To serve as a clinical research coordinator during the conduct of clinical research trials at the investigative site. By performing the job descriptions below and other duties as assigned, I will be able to facilitate the research process by increasing productivity and decreasing costs

Study Coordination:

Recruitment

1. Prescreen telephone calls for eligibility requirements
2. Screen charts (e.g., obtain physician permission for chart review, contact and schedule eligible subjects).
3. Attend teleconferences to review study progress and conduct.
4. Present study related information in the community to recruit for studies.
5. Present study related information to health care professionals (e.g., MDs, nurse groups, allied health groups).
6. Obtain medical history and demographics via phone, mail, or review of subjects' chart and review pertinent medical records as indicated by protocol.
7. Call or send reminders to subjects for scheduled visit.

Informed Consent

1. Explain study to subject (e.g., purpose, duration, risks/benefits).
Obtain all required signatures (e.g., legal guardian, assent of youth).
2. Make sure the subject has sufficient time and opportunity to ask the Investigator medical questions and that the Investigator signs the ICF.
3. Provide subject with copy of informed consent.
4. Document obtaining informed consent in source document.

Study Conduct

1. Perform subject interviews and assessments at study visits as required by protocol.
2. Assess and ensure subject safety throughout participation on trial.
3. Maintain close communication with principal investigator.

4. Manage multiple locations of sites where subjects may be seen by transporting the needed supplies and documents from the main site to the satellite site and back.

Case Report Forms

1. Incorporate applicable source documents (e.g., surgical reports, pathology reports, medical history).
2. Obtain and record ancillary service reports (e.g., x-ray, pathology, EKG, laboratory).
3. Maintain research progress notes.
4. Maintain weekly status reports and subject log.
5. Complete all required data fields.
6. Document written and verbal communication with study contacts (e.g., subject, sponsor, laboratory).
7. Schedule and prepare for CRA monitoring visit.
8. Address all queries and clarifications during monitoring visit.
9. Record and document protocol deviations.

Test Article Accountability

1. Receive test articles from sponsor and inventory test articles.
2. Store test article supplies according to FDA guidelines and sponsor requirements.
3. Dispense test articles (e.g., calculate dosage).
4. Retrieve test articles and calculate subject compliance.
5. Order supplemental test articles.
6. Return used and unused test articles to sponsor.
7. Maintain randomization and emergency codes of test article dispensing.
8. Document on accountability log and subject record (test article received, used, disposed, etc.).
9. Manage DEA controlled drugs appropriately.
10. Prepare emergency use report.

Laboratory Issues

1. Ensure proper collection, processing and shipment of specimens (centrifuge, preparation of slides, freezing, refrigeration, etc.).
2. Develop procedure and collection forms for pharmacokinetic collection and storage.
3. Communicate with laboratory, principle investigator, and sponsor regarding laboratory findings.
4. Maintain supply inventory.
5. Maintain equipment (e.g., calibration and preventive maintenance).
6. Recognize common laboratory values and alerts.

Adverse Events

1. Apply pharmacological knowledge to assist the investigator in determining idiosyncrasies, causality, expected and/or unexpected results.
2. Observe, query, and document medical events (adverse events).
3. Present principal investigator with relevant information for determination of seriousness, causality, and intervention.
4. Act on principal investigator's recommendation for adverse event intervention (e.g., stop test article, call subjects, retest, treat).
5. Maintain follow-up to determine resolution of adverse event.
6. Report serious adverse events to sponsor.
7. Assist investigator in classifying adverse events (e.g., serious, severe, moderate, mild, expected, unexpected).
8. Record adverse events and relevant information on source document, CRF, and sponsor specific forms.

Close-Out

1. Schedule and prepare for monitor visit.
2. Return or dispose of unused supplies per sponsor requirement.
3. Reconcile test article accountability.
4. Audit documents and pertinent files and prepare for storage.
5. Document patients who are lost to follow-up or who have dropped out (e.g., causes, contact efforts).
6. Prepare for and respond to sponsor or FDA audits.

I have read the above job description and have had the opportunity for my questions and concerns to be addressed. I understand that it is my responsibility to meet the requirements of my job description.

Signature of Employee or Subcontractor _____ Date

Signature of Supervisor _____ Date