Chapter 10
The Duties of a Clinical Research Coordinator

10.1 Introduction

Clinical trials are a team effort. It is essential that an investigator has colleagues who wish to assist with the trial. The 'principal investigator' is responsible for overseeing the trial and for the medical welfare of subjects who participate. A list of the usual responsibilities of the principal investigator is written below:

- Discuss, read and approve study protocol.
- Be familiar with all aspects of the trial and study drugs.
- Obtain ethics committee approval.
- Predict recruitment potential and identify suitable subjects.
- Undertake informed consent process (or supervise this, if delegated).
- Perform (or supervise) baseline and other trial-related assessments.
- Ensure that all other study personnel are kept fully informed at all times.
- Check that CRFs are being completed correctly.
- Sign off study documentation to confirm its validity.

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- Have regular meetings with trial monitor and other sponsor personnel.
- Take responsibility for the overall conduct of the study.
- Ensure that investigators' GCP responsibilities are fulfilled.

Coinvestigators might be needed to evaluate subjects at clinic visits. It should be kept in mind that the larger the number of assessors, the greater the variability; this means that the power of showing a difference between treatments is diminished.

Due to the large amount of administration and documentation generated during the course of a trial, it is recommended that a study administrator (e.g. a nurse coordinator or study site coordinator) is appointed to deal with these aspects [1].

10.2 Job Duties and Tasks of a Clinical Research Coordinator

1. Participate in the preparation and management of research budgets and monetary disbursements.
2. Inform patients or caregivers about study aspects and outcomes to be expected.
3. Code, evaluate or interpret collected study data.
4. Monitor study activities to ensure compliance with protocols and with all relevant local, federal and state regulatory and institutional polices.
5. Maintain required records of study activity including case report forms, drug dispensation records or regulatory forms.
6. Communicate with laboratories or investigators regarding laboratory findings.
7. Solicit industry-sponsored trials through contacts and professional organisations.
8. Order drugs or devices necessary for study completion.
9. Direct the requisition, collection, labelling, storage or shipment of specimens.

10. Arrange for research study sites and determine staff or equipment availability.
11. Review scientific literature, participate in continuing education activities or attend conferences and seminars to maintain current knowledge of clinical studies' affairs and issues.
12. Register protocol patients with appropriate statistical centres as required.
13. Prepare for, or participate in, quality assurance audits conducted by study sponsors, federal agencies or specially designated review groups.
14. Perform specific protocol procedures such as interviewing subjects, taking vital signs and performing electrocardiograms.
15. Interpret protocols and advise treating physicians on appropriate dosage modifications or treatment calculations based on patient characteristics.
16. Develop advertising and other informational materials to be used in subject recruitment.
17. Contact industry representatives to confirm the equipment and software specifications that are necessary for successful study completion.
18. Confer with healthcare professionals to determine the best recruitment practices for studies.
19. Organise space for study equipment and supplies.
20. Track enrolment status of subjects and document dropout information such as dropout causes and subject contact efforts.
21. Review proposed study protocols to evaluate factors such as sample collection processes, data management plans and potential subject risks.
22. Record adverse-event and side-effect data and confer with investigators regarding the reporting of events to oversight agencies.
23. Prepare study-related documentation such as protocol worksheets, procedural manuals, adverse-event reports, IRB documents and progress reports.

24. Participate in the development of study protocols including guidelines for administration or data collection procedures.
25. Oversee subject enrolment to ensure that informed consent is properly obtained and documented.
26. Maintain contact with sponsors to schedule and coordinate site visits or to answer questions about issues such as incomplete data.
27. Instruct research staff in scientific and procedural aspects of studies including standards of care, informed consent procedures or documentation procedures.
28. Identify protocol problems, inform investigators of problems or assist in problem-resolution efforts such as protocol revisions.
29. Dispense medical devices or drugs and calculate dosages and provide instructions as necessary.
30. Contact outside healthcare providers and communicate with subjects to obtain follow-up information.
31. Collaborate with investigators to prepare presentations or reports of clinical study procedures, results and conclusions.
32. Assess eligibility of potential subjects through methods such as screening interviews, reviews of medical records and discussions with physicians and nurses.
33. Schedule subjects for appointments, procedures or inpatient stays as required by study protocols [2].

10.3 Job Activities Associated with Being a Clinical Research Coordinator

1. *Getting information*: Observing, receiving and otherwise obtaining information from all relevant sources.
2. *Establishing and maintaining interpersonal relationships*: Developing constructive and cooperative working relationships with others and maintaining them over time.

3. *Making decisions and solving problems*: Analysing information and evaluating results to choose the best solution and solve problems.
4. *Organising*, *planning and prioritising work*: Developing specific goals and plans to prioritise, organise and accomplish your work.
5. *Updating and using relevant knowledge*: Keeping up to date technically and applying new knowledge to your job.
6. *Communicating with supervisors*, *peers or subordinates*: Providing information to supervisors, co-workers and subordinates by telephone, in written form, e-mail or in person.
7. *Documenting/recording information*: Entering, transcribing, recording, storing or maintaining information in written or electronic/magnetic form.
8. *Processing information*: Compiling, coding, categorising, calculating, tabulating, auditing or verifying information or data.
9. *Scheduling work and activities*: Scheduling events, programmes and activities, as well as the work of others.
10. *Interacting with computers*: Using computers and computer systems (including hardware and software) to programme, write software, set up functions, enter data or process information.
11. *Evaluating information to determine compliance with standards*: Using relevant information and individual judgment to determine whether events or processes comply with laws, regulations or standards.
12. *Identifying objects*, *actions and events*: Identifying information by categorising, estimating, recognising differences or similarities and detecting changes in circumstances or events.
13. *Communicating with persons outside the organisation*: Communicating with people outside the organisation, representing the organisation to customers, the public, government and other external sources. This information

can be exchanged in person, in writing or by telephone or e-mail.

14. *Training and teaching others*: Identifying the educational needs of others, developing formal educational or training programmes or classes and teaching or instructing others.
15. *Monitoring and controlling resources*: Monitoring and controlling resources and overseeing the spending of money.
16. *Coordinating the work and activities of others*: Getting members of a group to work together to accomplish tasks.
17. *Monitor processes*, *materials or surroundings*: Monitoring and reviewing information from materials, events or the environment, to detect or assess problems.
18. *Interpreting the meaning of information for others*: Translating or explaining what information means and how it can be used.
19. *Developing and building teams*: Encouraging and building mutual trust, respect and cooperation among team members.
20. *Guiding*, *directing and motivating subordinates*: Providing guidance and direction to subordinates, including setting performance standards and monitoring performance.
21. *Assisting and caring for others*: Providing personal assistance, medical attention, emotional support or other personal care to others such as co-workers, customers or patients.
22. *Resolving conflicts and negotiating with others*: Handling complaints, settling disputes and resolving grievances and conflicts or otherwise negotiating with others.
23. *Thinking creatively*: Developing, designing or creating new applications, ideas, relationships, systems or products including artistic contributions.
24. *Analysing data or information*: Identifying the underlying principles, reasons or facts of information by breaking down information or data into separate parts.

25. *Performing administrative activities*: Performing day-to-day administrative tasks such as maintaining information files and processing paperwork.
26. *Judging the qualities of things, services or people*: Assessing the value, importance or quality of things or people.
27. *Developing objectives and strategies*: Establishing long-range objectives and specifying the strategies and actions to achieve them.
28. *Estimating the quantifiable characteristics of products, events or information*: Estimating sizes, distances and quantities or determining the time, costs, resources or materials needed to perform a work activity.
29. *Provide consultation and advice to others*: Providing guidance and expert advice to management or other groups on technical-, system- or process-related topics [2].

10.4 Skills Needed for a Clinical Research Coordinator

1. *Reading comprehension*: Understanding written sentences and paragraphs in work-related documents.
2. *Active listening*: Giving full attention to what other people are saying, taking time to understand the points being made, asking questions as appropriate and not interrupting at inappropriate times.
3. *Writing*: Communicating effectively in writing as appropriate for the needs of the audience.
4. *Coordination*: Adjusting actions in relation to others' actions.
5. *Speaking*: Talking to others to convey information effectively.
6. *Critical thinking*: Using logic and reasoning to identify the strengths and weaknesses of alternative solutions, conclusions or approaches to problems.

7. *Monitoring*: Monitoring/assessing performance of yourself, other individuals or organisations to make improvements or take corrective action.
8. *Judgment and decision-making*: Considering the relative costs and benefits of potential actions to choose the most appropriate one.
9. *Time management*: Managing one's own time and the time of others.
10. *Management of personnel resources*: Motivating, developing and directing people as they work, identifying the best people for the job.
11. *Social perceptiveness*: Being aware of others' reactions and understanding why they react as they do.
12. *Complex problem-solving*: Identifying complex problems and reviewing related information to develop and evaluate options and implement solutions.
13. *Active learning*: Understanding the implications of new information for both current and future problem-solving and decision-making.
14. *Service orientation*: Actively looking for ways to help people.
15. *Persuasion*: Persuading others to change their minds or behaviour.
16. *Negotiation*: Bringing others together and trying to reconcile differences.
17. *Instructing*: Teaching others how to do something [2].

10.5 Abilities Needed to Be a Clinical Research Coordinator

1. *Written comprehension*: The ability to read and understand information and ideas presented in writing.
2. *Oral expression*: The ability to communicate information and ideas in speaking so others will understand.

3. *Oral comprehension*: The ability to listen to and understand information and ideas presented through spoken words and sentences.
4. *Written expression*: The ability to communicate information and ideas in writing so others will understand.
5. *Speech recognition*: The ability to identify and understand the speech of another person.
6. *Deductive reasoning*: The ability to apply general rules to specific problems to produce answers that make sense.
7. *Inductive reasoning*: The ability to combine pieces of information to form general rules or conclusions (includes finding a relationship among seemingly unrelated events).
8. *Problem sensitivity*: The ability to tell when something is wrong or is likely to go wrong. It does not involve solving the problem, only recognising there is a problem.
9. *Speech clarity*: The ability to speak clearly so others can understand you.
10. *Near vision*: The ability to see details at close range (within a few feet of the observer).
11. *Information ordering*: The ability to arrange things or actions in a certain order or pattern according to a specific rule or set of rules (e.g. patterns of numbers, letters, words, pictures, mathematical operations).
12. *Category flexibility*: The ability to generate or use different sets of rules for combining or grouping things in different ways.
13. *Selective attention*: The ability to concentrate on a task over a period of time without being distracted.
14. *Fluency of ideas*: The ability to come up with a number of ideas about a topic (the number of ideas is important, not their quality, correctness or creativity).
15. *Originality*: The ability to come up with unusual or clever ideas about a given topic or situation or to develop creative ways to solve a problem [2].

10.6 Knowledge, Experience and Education Required to Be a Clinical Research Coordinator

1. *Medicine and dentistry*: Knowledge of the information and techniques needed to diagnose and treat human injuries, diseases and deformities. This includes symptoms, treatment alternatives, drug properties and interactions and preventive healthcare measures.
2. *English language*: Knowledge of the structure and content of the English language including the meaning and spelling of words, rules of composition and grammar.
3. *Administration and management*: Knowledge of the business and management principles involved in strategic planning, resource allocation, human resources modelling, leadership techniques, production methods and coordination of people and resources.

References

1. Hutchinson D. The Trial Investigator's GCP handbook: a practical guide to ICH requirements. Brookwood Medical Publications Ltd.; Surrey, UK, 1997.
2. Clinical Research Coordinator. http://job-descriptions.careerplanner.com/Clinical-Research-Coordinator.cfm. Accessed online at 14 Oct 2015.