CTSA Research Coordinator Taskforce
Clinical Research Coordinator[1] Job Descriptions Recommendations

CRC Job Title	Minimal Education[2]	Years Experience	Qualifications/Scope
Assistant CRC	High School Diploma *or* General Educational Development /Diploma (GED)	0-2 years experience in related field	Under the direct supervision of the study team, assists in the coordination of the details of the human research subject study and documentation concerning study protocols, which may include: • Filing and office organization • Patient/research participant scheduling • Patient/research participant history • Data collection • Data entry • Data management • Follow-up care • Laboratory procedures • Order materials/supplies • Schedule research meetings • Comply with Institutional policies, SOPs and guidelines • Must comply with federal, state, and sponsor policies Must possess knowledge of IRB and human subject protection and must adhere to an IRB approved protocol.
CRC 1	Associates Degree *or* an allied health	1 year clinical research experience	Coordinate all clinical research activities with moderate supervision Expected to Perform all CRC Core responsibilities (as applicable): • Adhere to an IRB approved protocol • Participate in the informed consent process of study subjects • Support the safety of clinical research patients/research participants

	professional degree[3]		• Coordinate protocol related research procedures, study visits, and follow-up care • Screen, recruit and enroll patients/research participants • Maintain study source documents • Report adverse events • Understand good clinical practice (GCP) and regulatory compliance • Educate subjects and family on protocol, study intervention, study drug, etc. • Comply with Institutional policies, standard operating procedures (SOPs) and guidelines • Must comply with federal, state, and sponsor policies Also may be responsible for any of the following: • Manage essential regulatory documents • Register study on ClinicalTrial.gov • Complete case report forms (paper & electronic data capture) and address queries • Submit documents to regulatory authorities (e.g. IRB, FDA, etc.) and/or review/monitoring boards (ie, DSMB, independent safety officer) • Facilitate pre-study, site qualification, study initiation, and monitoring visits • Facilitate study close out activities[4] • Coordinate research/project team meetings • Collect, process and ship laboratory specimens • Schedule subject visits and procedures • Retain records/archive documents after study close out Requires effective writing and communication, work as part of a team, ability to multitask
CRC 2	BA/BS	2 years clinical research experience	Coordinate all clinical research activities with minimal supervision Perform all CRC Core and additional responsibilities as detailed for CRC 1. Also may be responsible for any of the following: • Manage study finances including sponsor invoicing & resolving study subject billing issues

			• Develop advertisement materials • Act as liaison for research subject, investigator, IRB, sponsor, and healthcare professionals • Document investigational product (drug/device) accountability • Self monitor and self-audit responsibilities • Develop informed consent document • Maintain Clinical Trial.gov / • Develop Case Report Forms Assignments to include more complex studies
CRC 3	BA/BS	3 - 4 years clinical research experience	Function independently in a clinical research setting and responsible for the complete coordination of assigned clinical research activities. May have supervisory responsibilities. Perform all CRC Core and additional responsibilities as detailed for CRC 1 and 2. Also may be responsible for any of the following: • Support a PI sponsored IND or IDE • Host/ prepare for external audits (sponsor, FDA, NIH, etc) • Monitor or audit studies in the institution • Facilitate and/or run research/project team meetings • Prepare study budget • May serve as a liaison for hospital billing for research subjects[5] • Educate and mentor clinical staff, research team and other coordinators • Coordinate multi-center studies • Assess protocol feasibility • Prepare, negotiate, manage study contract Effective problem solving, writing and communication skills. Ability to multi-task working as part of a team or independently.

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[1]The term "clinical research coordinator" refers to a research coordinator who supports any aspect of human subject research.
[2] While recommended minimal levels are provided, a given institution also may want to include *preferred* educational and/or research coordinator certification requirements.
[3] Institution may allow an Allied Health certificate program in lieu of a two year degree program
[4] Some of these activities may be project specific.

Please note: The above suggested job descriptions are recommendations and most likely there will be exceptions to the above in terms of having a candidate for a position who may not have the required education or experience, but may be eligible for a particular position. The job description recommendations are geared toward new people coming into an institution and as such, a given institution may need to make provisions to grandfather people into roles who do not meet the recommended minimal education experience.