SOCIAL/CLINICAL RESEARCH SPECIALIST

*Note: This material is not intended to represent a complete position description; it is meant as a job aid to provide a foundation for completing a detailed individual description. All functions and tasks listed below will not apply to every position and this is not an exhaustive list of potential duties. Supervisors should select any of this material which applies to provide a framework for their description, then add detail, context, and other functions relevant to their specific needs. This material is also competency-level neutral. In addition to functions and tasks, other considerations including but not limited to scope, organizational placement, and reporting relationship are key determining factors in position leveling.*

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| **FUNCTIONS** | **TASKS** |
| Data Management/ Analysis | * Enters data into databases, online systems, or other means depending on the study designs * Issues queries to resolve errors and missing data * Programs edit checks to query discrepant data, maps data points, and performs calculations * Performs validation checks to ensure completeness and consistency of data * Develops data collection and evaluation methodologies, including format design, project criteria and requirements, data compilation, relevancy, and usage issues * Reviews validated data received from scientists and provides to investigators for abstracts and manuscripts * Performs interim interpretation and analyses of data utilizing various systems/data analysis programs * Proposes and develops improved methodology for analyzing data * Establishes appropriate protocols for management of data * Uses professional knowledge of statistics/biostatistics to collect, analyze, scrub, summarize, and present data, as well as to draw conclusions |
| Research | * Coordinates the clinical research for multiple projects; collaborates on development of study protocols, data collection tools, lab manuals, case reports, and databases. * Conducts interview and recruits study participants * Tracks and interprets studies results * Interprets medical records and procedure reports, collects information from participants and records information on case report forms * Collects specimens for study protocols and other clinical duties as assigned. * Collects, labels, processes and stores biological specimens per each protocol. * Creates physician and lab orders for study visits within protocols-specified periods. * Prepares and edits study reports and publications; maintains enhanced knowledge of trends in field. * Prepares and submits IRB related documents |
| Project Management | * Plans, implements, and administers large and multi-center clinical trial research projects * Develops, maintains, and enforces written SOPs for staff to follow * Design and writes investigational clinical trial research protocols detailing study procedures, hypotheses, and aims. * Designs study flow of procedures and forms within data systems * Analyzes data and creates reports on findings * Reviews and modifies subject criteria * Determines and implements quality control measures * Performs quality control/quality assurance on regulatory forms to ensure compliance; tracks regulatory submissions and recognizes potential issues with regulatory submissions and compliance; recommends solutions. * Refines study protocols and creates data collection instruments including surveys and interviews. |
| Training | * Designs and writes detailed training materials * Provides training on new findings and regulations * Provides training to new staff members, lower-level staff, and study team committees |
| Personnel duties | * Reviews and signs off timecards of staff * Maintains HR records of assigned staff * Maintains documentation of all interactions with staff related to performance issues * Hires, trains, and evaluates multiple research staff across multiple sites * Builds reports for monitoring and evaluating performance of personnel |
| Finance | * Develops monthly budget * Calculates study-related costs * Handles reimbursements and invoice payments; monitors and reconciles budget. * Ensures billing for study procedures is compliant with federal regulations for clinical billing. |
| Team Lead | * Directs the daily workflow of other staff members by assigning tasks but does not exercise supervisory authority * Trains new staff members on work methods, policies, and practices * Provides feedback to supervisors on team members for performance evaluations * Serves as a resource to other team members for questions or work issues |
| Supervision | * Provides full supervision to [define subordinate positions]; interviews and makes hiring decisions/recommendations; recommends initial pay rates and subsequent adjustments; ensures employees are trained in job responsibilities and provides for ongoing development; manages the performance review process and assigns performance ratings; addresses performance deficiencies and disciplinary issues as needed; sets work schedules and approves leave requests |
| Other Duties | * Other duties as assigned by management to meet business needs |

**STATE–DEFINED COMPETENCIES** *(Use to complete section 7 of the position description by defining how these apply to your specific job. All competencies may not apply to all jobs. Do not add any additional competencies beyond those provided by the state.)*

* Knowledge – Professional
* Project Design
* Social/Clinical Research Project/Program Administration
* Data/Information Analysis/Management
* Communication
* Instruction

**MINIMUM TRAINING AND EXPERIENCE** *(Cut and paste into section 8 of the position description form with no additions or deletions):*

Bachelor’s degree in a discipline related to the field assigned and one year of related training or experience; or equivalent combination of training and experience. All degrees must be received from appropriately accredited institutions.