UNIVERSITY OF SOUTHERN CALIFORNIA

Senior Biostatistician

Job Code: 185531

OT Eligible: No

Comp Approval: 10/31/2017

JOB SUMMARY:

This position will serve as the lead biostatistician on multiple clinical studies or medical research projects with varying levels of complexity. The Senior Statistician will collaborate in protocol development, study design, conduct, analysis, and reporting/interpretation of study data. The position will also develop statistical analysis plans, evaluate statistical methodologies, and review or approve the work of other biostatisticians, as needed. The Senior Biostatistician will collaborate on the development and preparation of grant proposals, oversee the development of data quality review and integration, perform advanced statistical analysis and interface with leadership in the preparation of study reports and manuscripts. The position will also evaluate and engage outside resources, provide training, conduct independent research, and mentor others, as assigned. The Senior Biostatistician will encourage staff scientific development and research new methodological approaches, while maintaining personal awareness of changes and trends in the area of specialty and the field in general.

JOB ACCOUNTABILITIES:

- With minimal supervision, act as lead biostatistician on projects ranging in size and complexity, with responsibility for the statistical and analytical aspects of consulting projects.
- Collaborate with Principal Investigators (PI) and the scientific team in grant preparation, with particular emphasis on experimental/study design, sample sizes, data capture and monitoring, and statistical/analytical methodology.
- Writes and reviews the statistical analysis plans (SAPs) based on the study protocol, in collaboration with the study leadership.
- Serves as the biostatistics representative in the project team/product discovery or development team to ensure that the presentation of study results is clear and consistent with the statistical analysis provided and support study conclusions.
- Analyzes data and interprets results from studies to meet objectives of study protocol. Prepares oral and written reports to effectively communicate results to the project team, senior management, regulatory agencies or individual investigators.
- Monitors progress of study activities against agreed upon milestones and ensures the study timelines for project deliverables are met.
- Ensures proper conduct by documenting and archiving study related materials according to Standard Operating Procedures (SOPs).
- Provides training in research design and analysis for non-statistical groups.
- Provides leadership, guidance and direction to others, as needed. Mentors/trains peers/less experienced biostatisticians, as assigned.
- Stimulates the scientific development of staff by encouraging participation in departmental seminars, short courses, and the publication/presentation of scientific articles.
Conducts research independently on statistical methodology, pursues solutions to various technical problems, adapts known methods and develops new methods.

Maintains awareness and knowledge of current changes within legal, regulatory, and technology environments by reading journals and other pertinent publications, and participating in professional organizations, meetings and seminars, as required.

Performs other related duties as assigned or requested. The university reserves the right to add or change duties at any time.

*Select E (ESSENTIAL), M (MARGINAL) or NA (NON-APPLICABLE) to denote importance of each job function to position.

**EMERGENCY RESPONSE/RECOVERY:**

- Essential: [ ] No
- Yes  In the event of an emergency, the employee holding this position is required to “report to duty” in accordance with the university’s Emergency Operations Plan and/or the employee’s department’s emergency response and/or recovery plans. Familiarity with those plans and regular training to implement those plans is required. During or immediately following an emergency, the employee will be notified to assist in the emergency response efforts, and mobilize other staff members if needed.

**JOB QUALIFICATIONS:**

**Minimum Education:**

- Master's degree
- Combined experience/education as substitute for minimum education

**Minimum Experience:**

- 5 years

**Minimum Field of Expertise:**

- Degree in statistics, biostatistics, or a closely related field. Experience in Biostatistics, Statistics, Biometry or related field. Experience in statistical programming using standard statistical packages such as SAS, R, or STATA. Working knowledge of regulatory Data Standards (such as CDISC/ADaM). Knowledge of clinical research regulatory requirements [i.e., Good Clinical Practice (ICH / GCP), FDA / CFR]. Ability to interact effectively with people, internally and externally. Ability to present ideas clearly and effectively, both orally and in writing.

**Preferred Education:**

- Doctorate

**Preferred Experience:**

- 7 years

**Preferred Field of Expertise:**

- Degree in biostatistics preferred. Prior expereince supervising biostatistician in a medical research environment. Expert-level competency with standard statistical packages such as SAS, R, or STATA. Advanced knowledge of design concepts for and utilization of relational databases. Experience in the analysis of clinical, pharmaceutical, biological, pharmacokinetic, and/or toxicological data.

**Skills:** Other:
Analysis
Assessment/evaluation
Communication -- written and oral skills
Computer
Consulting
Organization
Planning
Problem identification and resolution
Statistical analysis
Teaching/training

Skills: Machine/Equipment:

Computer network (department or school)
Computer network (university)
Computer peripheral equipment

Supervises: Level:

May lead one or more employees and/or students performing similar work.
May oversee student, temporary and/or resource workers.

SIGNATURES:

Employee: ___________________________  Date: ___________________________

Supervisor: ___________________________  Date: ___________________________

The above statements are intended to describe the general nature and level of work being performed. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of personnel so classified.

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