Job Description

Job Title:	Data, Statistics and Website Manager
Department:	Centre for Ocular Research & Education (CORE)
Reports To:	Head of Clinical Research
Jobs Reporting:	Data Processing Coordinator, Data Management Coordinator, Recruitment/Administrative Assistant (Co-supervise)
Salary Grade:	USG 10
Effective Date:	November 2022

Primary Purpose

This position is responsible for the data management of studies involving CORE's resources, as well as providing statistical guidance and statistical oversight as required. The incumbent also manages clinical trial applications to Health Canada, maintains and updates several key CORE websites, and is part of the team that manages CORE's regulatory documentation and SOPs. This position is contingent upon funding.

Key Accountabilities

Study Data Management

- Supervises Data Management Team which includes assigning and monitoring workload, setting priorities, managing performance and evaluation, and participating in the hiring and training of personnel.
- Determines and implements data management strategies and associated software for storage of CORE data.
- Updates and maintains the participant tracking system for each ongoing study and clinical trial.
- Creates, organizes, stores, documents, extracts/exports, converts, merges, and manipulates data files.
- Communicates with internal and external data users for sending data or image files.
- Oversees the study database building, testing, data entry and querying of data and participates in these tasks when workload of the Data Management Team requires assistance.

Study Design and Deliverables

- Calculates appropriate sample size for studies.
- Determines what statistical tests will be required to answer study hypotheses.
- Provides guidance to study researchers to aid in the development of study proposals that meet sponsor requirements.
- Provides statistical consultation to research team as needed in order to ensure the data analysis meets the study objectives.
- Performs data analysis for study reports, publications, and presentations.
- Writes study reports, publications, and conference abstracts.
- Presents study data at conferences and for study sponsors.

Website Management

- Oversees the maintenance and updating of CORE websites by an external vendor, including the company site, the participant recruitment site, ContactLensUpdate.com and ContactLensCompendium.com.

- Performs and/or oversees ongoing updates of the current contact lens and solutions databases for ContactLensCompendium.com and organizes the yearly export and compilation of the annual print edition.
- Uploads and formats bimonthly updates of the ContactLensUpdate.com web magazine.
- Designs and sends monthly Contact Lens Update email newsletter and maintains the database of subscribers.

Management of Regulatory Requirements

- Co-supervises the position responsible for maintenance of elements of clinical trial documentation for regulatory compliance which includes assigning and monitoring workload, setting priorities, managing performance and evaluation, and participating in the hiring and training of personnel.
- Develops new CORE Standard Operating Procedures (SOPs) and Work Instructions (Wis) in collaboration with the Regulatory Team Leader.
- Conducts a biannual review and update of CORE SOPs and Wis in collaboration with the Regulatory Team Leader.
- Compiles and submits applications to Health Canada for Investigational Testing Authorizations (ITAs) for medical devices and Clinical Trial Applications (CTAs) for drug and natural health products.
- Registers and maintains registration of relevant clinical trials with ClinicalTrials.gov.

**All employees of the University are expected to follow University and departmental health and safety policy, procedures, and work practices at all times. Employees are also responsible for the completion of all health and safety training, as assigned. Employees with staff supervision and/or management responsibilities will ensure that assigned staff abide by the above, and actively identify, assess, and correct health and safety hazards, as required.*

Required Qualifications

Education

- Minimum of a Master's degree in a related field, requiring a solid knowledge of methods for database design and the analysis and reporting of data related to clinical research.
- Preference will be given to individuals with a PhD, particularly in the area of ocular, optical or vision-based research.

Experience

- At least 5 years' experience working in a data analytics field in a clinical research or related environment.
- Training as a Clinical Research Associate or similar would be an asset.
- Must have supervisory experience or the ability and initiative to assume responsibility for supervising the CORE Data Management Team and the regulatory personnel.
- At least 1 years' experience in website content management. Experience with Wordpress would be an asset.

Knowledge/Skills/Abilities

- Knowledge of quantitative and qualitative research methods and statistics as they relate to clinical research is required.
- Must have advanced skills in MS Word, Excel, PowerPoint, REDCap, Wordpress, HTML, SPSS, SAS, Minitab, and other statistical packages as required.
- Proven writing, communication and presentation skills are required.
- Strong organizational and time management skills are essential.
- Must be able to manage a high volume of work with conflicting priorities and deadlines.

Nature and Scope

- **Contacts:** Internally, this position works closely with CORE's Head of Clinical Research and research staff, discussing information, collaborating on ideas and problems, and offering consultation as required. In their role as Data Team Leader and supervisor of regulatory personnel, the incumbent is also involved in dealing with, influencing, and motivating employees. Externally, the incumbent will interact with study sponsors to exchange and discuss information, with Health Canada for product approvals and will represent CORE presenting to industry and at conferences.
- **Level of Responsibility:** This position is responsible and accountable for the management of all data requirements within CORE. This includes supervising the Data Management Team who will be responsible for implementing specific aspects of data management, as well as providing statistical support and guidance to the research staff in the statistical design and outcomes for studies as required. The incumbent is also responsible and accountable for applications to and communications with Health Canada to receive approval for use of any unapproved medical devices, drugs, and natural health products and maintaining CORE's regulatory compliance in relation to those approvals. They are also responsible for the updating of all outward facing educational, business and recruitment websites for CORE.
- **Decision-Making Authority:** This position is responsible and accountable for determining the data management and statistical direction of CORE. The incumbent will need to understand the dynamics of analyzing data so that they can provide proper guidance to the research staff in order to reach the required outcomes for each study. This will also involve knowing what statistical tests are possible and deciding on the appropriate ones for the data collected. The incumbent will have the authority to influence the staffing needs of the Data Management Team and the Regulatory Team. This position is also responsible for communicating with Health Canada for the purpose of regulatory approvals for unlicensed products, interpreting Health Canada requirements and determining appropriate responses to queries.
- **Physical and Sensory Demands**: The incumbent experiences physical and sensory demands typical of a position whose main focus involves attention to detail and computer use. It requires extensive sitting, repetitive hand/finger movements and concentrated visual tasks.
- **Working Environment:** There is minimal exposure to disagreeable conditions, although the incumbent is required to deal with many distractions over the course of the day. Travel to conferences and/or sponsor facilities may occasionally be required.