

# **Study Coordinator at the University of Michigan**

## **Job Summary**

The University of Michigan Kellogg Clinical Research Center (KCRC) is seeking a motivated and organized individual for an enriching work experience on an investigator-initiated study involving specialists of inherited retinal diseases, low vision rehab, and psychology. The ideal candidate will have experience with medical data abstraction, working remotely with visually impaired participants, and a desire to gain expertise in both the psychology and ophthalmology aspects of the project and a willingness to learn skills to extend to new projects as they come.

## **Responsibilities\***

Dr. Day, the PI, a specialist of low vision rehabilitation, Dr. Jayasundera, a retinal surgeon and inherited retinal diseases specialist, along with Dr. Fresco, a distinguished professor of psychiatry, have a comprehensive National Institutes of Health (NIH)-funded project that aims to address various conditions associated with inherited retinal diseases. These conditions often lead to distress, depression, and a spectrum of vision-related disabilities. Their unique intervention approach combines low vision rehabilitation and psychotherapy to alleviate distress and improve overall well-being.

As an integral member of the research team, this position will help ensure that this study and others supported by the KCRC are initiated and executed in the highest quality and compliant manner. This position will play a pivotal role in maintaining day to day operations of this trial, including tasks related to subject recruitment, the administration of patient-reported outcome measures/instruments (PROs), and record keeping.

**COMMUNICATIONS:** The CRC is expected to facilitate communications between team members, investigators, regulatory personnel, and other key contributors both in written and spoken form, using various software to document decision-making as needed. They will relay study details to potential and enrolled participants, create written materials (e.g. letters, flyers, and consent documents), and assist with submissions and reports as required by the IRB, NIH, and other stakeholders. They will also communicate with sponsors, the University of Michigan Clinical Trials Support Unit (CTSU), and contract research organizations as applicable. The communications will

include, but are not limited to scheduling participants appointments, meeting with investigators, interfacing with the regulatory and financial authorities, working closely with study monitors, and resolving issues that invariably arise.

**DATA:** The CRC will be involved in data entry and organization, tracking screening, recruitment, randomization, and completion of participant activities, inputting data into REDCap, Excel, and case report forms (CRFs), maintaining studies in the OnCore clinical trial management system, and resolving queries.

**REGULATORY COMPLIANCE:** Employees of the KCRC follow all local, state, and federal regulations regarding clinical research in addition to Good Clinical Practice and protocol specific guidelines. The CRC is expected to actively support an environment of strict regulatory compliance. The CRC will work within UM's eResearch regulatory system to create and revise IRB submissions, track any protocol deviations or adverse events and assure they are reported in a timely manner, and organize and store regulatory documents required by the NIH, UM, the Food and Drug Administration (FDA) and other regulatory authorities as required.

**RECRUITMENT AND PARTICIPANT INTERACTION:** The CRC will recruit and guide participants through study activities, including scheduling appointments with low vision and psychotherapy providers on the study team, conducting surveys, assessing suicidality, and assisting participants with accessing online materials and questionnaires. Communication with participants will take place in person, over the phone and potentially through video conferencing mediums (i.e. Zoom).

**PROTOCOL SPECIFIC NEEDS:** Each study often has unique needs. The CRC is expected to possess a willingness to learn protocol specific requirements.

**LEADERSHIP:** Delegate tasks to full-time research interns, part-time temps, and undergraduate volunteers.

**OTHER:** Clinical research regulations and best practices are frequently changing. The CRC is expected to incorporate these changes into the workflow as they occur.

## **Required Qualifications\***

- Associate degree in Health Science or an equivalent combination of related education and experience.
- **ONE** of the following:
  - Minimum 1 years of directly related experience in clinical research and clinical trials is necessary. Please review SoCRA's [Definition of a Clinical Research Professional](#) qualifying experience prior to applying.
  - An advanced degree in a health-related areas such as: Health Sciences, Behavioral Sciences, Public Health, Health Care Administration, Clinical Research Administration, Social Work, Psychology, Epidemiology, Foreign MD.
  - Minimum 3 years of human subject experience (clinical, lab or health regulations) such as related patient care, related community health and wellness, related clinical information, and research.
- Knowledge of general clinical research operations and regulations or a capacity to learn quickly
- Ability to work both independently and as part of a team
- Committed to prioritizing the welfare of the research volunteer
- Exceptional organizational skills
- Uncompromising integrity
- Capacity to learn new skills as the positional needs change
- Willingness to achieve professional certification such as SOCRA or equivalent
- Experience with computers and applicable software (e.g. MS Word, Excel, Power Point, Outlook or equivalent)

## **Desired Qualifications\***

- Bachelor's degree in Health Science or an equivalent combination of related education and experience

- Experience working with patients in a healthcare setting and/or an understanding of medical terminology,
- Familiarity with terms related to psychology and/or an interest in research that involves psychological interventions
- Ability to effectively communicate with staff and faculty of all levels
- At least one year of directly related experience in clinical research and clinical trials
- Knowledge of university policies and procedures
- Experience with the MiChart (Epic) electronic health record (EHR) system
- Experience with REDCap databases
- Experience with the OnCore clinical trial management system (CTMS)
- Ophthalmic technician skills (e.g. visual acuity, refraction, intraocular pressure, etc.) and phlebotomy skills or a willingness to learn as they may be needed in future studies.
- Willingness to accommodate occasional patient needs for contact outside of typical working hours.

[Apply here!](#)