

Clinical Research Project Mgr I - Child and Adolescent Mood Lab (CHAMP) (213877)

LINK:

<https://career4.successfactors.com/sfcareer/jobreqcareerpvt?jobId=213877&company=C0000169453P&st=86DD3AC943F1A085E33D103315B9694BC30D3273>

Location: LOC_ROBERTS-Roberts Ctr Pediatric Research

Req ID: 213877

Shift: Days

Employment Status: Regular - Full Time

About Us

We're seeking breakthrough makers! Children's Hospital of Philadelphia was built on the belief that we can change lives. Today, in every role throughout our hospital, research institute and care network, the 22,000 members of our workforce are finding new ways – big and small – to make a difference for the patients and families we serve.

If you are ready to challenge yourself, be inspired and grow – no matter what your role – you just may be the kind of breakthrough maker who will thrive at CHOP.

CHOP is proud to share that we are ranked No. 1 on Forbes' 2022 list of America's Best Large Employers!

Job Summary

The Child and Adolescent Mood Lab (CHAMP) is seeking a clinical research project manager. Research in our lab focuses on adolescent mood disorders and suicide, including understanding risk and protective factors. The clinical research project manager will oversee an ongoing registry of youth evaluated at a mood disorders specialty clinic and assist with several projects related to youth depression and suicide. Specific responsibilities include but are not limited to: 1) coordinating the day to day administration of research projects; 2) overseeing regulatory aspects of studies (i.e., IRB documents); 3) maintaining subject tracking system and scheduling subjects for assessments; 4) overseeing data collection; 5) organizing and overseeing data entry; 6) overseeing undergraduate research assistants; and 7) assisting in the analysis of data for presentations and manuscripts.

To learn more about [CHAMP](#)

key words: behavioral health research

Job Responsibilities

- Supervise the implementation of and adherence to study protocols. Educate research and clinical staff on established policies, processes, and procedures.

- Determine effective strategies for promoting/recruiting research participants and retaining participants in long-term clinical trials.
- Develop consent forms for approval by Human Subjects Panel.
- Coordinate new protocol submissions, renewals, and revisions to Institutional Review Board for multiple studies.
- Complete annual reports to Institutional Review Board, CSTA, FDA and other regulatory agencies. Submit Investigational New Drug applications to the FDA as required.
- Audit operations, including laboratory procedures, to ensure compliance with applicable regulations; provide leadership in identifying and implementing corrective actions/processes.
- Monitor Institutional Review Board submissions, and respond to requests and questions.
- Provide leadership and expertise in identifying and completing research grants.
- Oversee financial resources, create internal and external budgets for research protocols, assure financial accountability, and serves as primary liaison between sponsor, department accounting, and Research.
- Provide guidance and support for clinical research coordinators who are assigned to project specific protocols and who will help with the overall clinical research of the study team.
- May have minimal supervisory responsibilities.

Management Group

- Leads or chairs committees or task forces to address and resolve significant issues.
- Engage in high-level outreach and networking opportunities, representing the research program to a variety of internal and external audiences.
- Analyze trends in recruitment and assure there is a limited number of competing trials. Make recommendations for a variety of options within a trial; track physician compliance.
- Assist with analysis of data and preparation of manuscripts and scientific presentations.

Job Responsibilities (Continued)

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Required Licenses, Certifications, Registrations

Required Education and Experience

Required Education: Bachelor's degree

Required Experience: Two (2) years of relevant clinical research experience

Preferred Education, Experience & Cert/Lic

Preferred Education: Master's degree in related field

Preferred Experience: Three (3) years of relevant clinical research experience

Additional Technical Requirements

- Responsible for overall management of the trial(s) to ensure compliance with study protocol, FDA, NIH and IRB policies.
- Applied knowledge of Good Clinical Practice (GCP) guidelines including protection of human research subjects with particular emphasis on pediatrics, definitions and reporting

requirement for adverse events, elements of informed consent, Federal Codes, Regulations and Guidelines relevant to the performance and conduct of clinical trials.

**To carry out its mission, it is of critical importance for the Children's Hospital of Philadelphia (CHOP) to keep our patients, families and workforce safe and healthy and to support the health of our global community. In keeping with this, CHOP has mandated all workforce members on site at any CHOP location for any portion of their time be vaccinated for COVID-19 as a condition of employment. This mandate also applies to workforce members performing work for CHOP at non-CHOP locations. Additionally, all workforce members based in or regularly scheduled to work at any New Jersey location are mandated to be both vaccinated and boosted for COVID-19, with booster timing consistent with applicable guidelines. The CHOP COVID-19 vaccine mandate is in alignment with applicable local, state and federal mandates. CHOP also requires all workforce members who work in patient care buildings or who provide patient care to receive an annual influenza vaccine. Employees may request exemption consideration for CHOP vaccine requirements for valid religious and medical reasons. Please note start dates may be delayed until candidates are fully immunized or valid exemption requests are reviewed. In addition, candidates other than those in positions with regularly scheduled hours in New Jersey, must attest to not using tobacco products.
EEO / VEVRAA Federal Contractor**