

Research Study Coordinator

**Cleveland VA Medical Research and Education Foundation
Cleveland, OH 44106**

JOB TITLE: Study Coordinator

Contact: Emily Graczyk <elg46@case.edu>

Location: Louis Stokes Cleveland VA Medical Center and Case Western Reserve University

Reports to: Study Principal Investigator

POSITION OBJECTIVE

Member of multidisciplinary research and development team designing and investigating new Class III medical devices for neuromodulation with a focus on restoration of natural sensation in persons with limb loss.

This position will be responsible for providing technical and administrative support to both the technical and clinical project teams for upper and lower extremity projects. Technical team support: assist the quality systems engineer and systems engineer in generation of all quality system documentation. Clinical team support: coordinate test subject scheduling, support completion of regulatory documents for the Food and Drug

Administration (FDA), Institutional Review Board (IRB), and/or project sponsor as required. Will work closely with other project team members including, but not limited to, principal investigator, senior project director, research nurse, quality engineer, systems engineer, regulatory specialists, biomedical engineers, and students.

ESSENTIAL FUNCTIONS

Administrative support for clinical trials, including maintaining study-related documentation, scheduling team meetings, scheduling study sessions for clinical trial participants, and reimbursing subjects (20%)

Interpret specialized technical information and effectively provide it to a lay audience (10%)

Serve as the point of contact for current and potential study participants and answer participant questions about the study. Maintain regular contact with study sites, recruitment sites, and partner clinicians and therapists. (10%)

Assist with subject recruitment, including making and distributing recruitment fliers, visiting partner clinics, and corresponding with partner clinicians and researchers. Screen potential participants over the phone.

Maintain detailed records of all participant correspondence. (10%)

Support technical teams in maintaining detailed record keeping of system documentation and system Design

History File (10%)

Administer telephone surveys to study participants and enter study data into databases (5%)

Provide support for project management, project scheduling, and progress reporting tasks (5%)

Store and manage identifiable health information and de-identified data following HIPAA standards and all applicable regulatory guidelines (5%)

Manage communication, collaboration, and data transfer between study sites (5%)

Provide support for IRB submissions and modifications (5%)

Maintain equipment inventory and manage purchasing (5%)

Develop, oversee, and maintain standard operating procedures for clinical research data collection and documentation (5%)