Gabrielle Pelle

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Education

Bachelor of Arts in Psychology: Fairfield University Graduated May 2013

Master of Arts in Experimental Psychology: Brooklyn College Graduated May 2016

Work Experience

Senior Clinical Research Coordinator (09/2016- Present)

Icahn School of Medicine at Mount Sinai, New York, New York

- Assist with the daily operation of running a clinical trial, under the supervision and delegation of the PI
- Verify subject eligibility
- Consenting eligible patients
- Create and maintain source documentation
- Monitor patient's progress and adhere to visit windows
- Complete Case Report Forms and maintain protocol compliance
- Conduct study visits which include: obtain vital signs, blood samples, electrocardiograms, adverse events, concomitant medications, medical history, dispense study drug and assure drug compliance
- Coordinate various assessments with other departments including Radiology, Pulmonology, Ophthalmology, and Dermatology
- Administer tests commonly used with patients diagnosed with Multiple Sclerosis such as Low-Contrast Sloan Letter Chart Testing (LCSLC), Multiple Sclerosis Functional Composite (MSFC), Single Digit Modality Test (SDMT), Brief Visuospatial Memory Test (BVMT), Selective Reminding Test (SRT), and numerous other neuropsychological and fine motor assessments
- Process and ship biological specimens
- Initiate and maintain IRB approvals and regulatory upkeep of clinical trials
- Work closely with monitors and complete data queries
- Collaborate with PIs on internal protocol developments
- Build online database for data capture using Red Cap Software

Administrator, Clinical Trials/ Clinical Research Coordinator (04/2015- 09/2016)

Manhattan Medical Research, New York, New York

- Assist with the daily operation of running a clinical trial, under the supervision and delegation of the PI

- Management and development of site staff
- Initiate and maintain IRB approvals and regulatory upkeep of clinical trials
- Direct and conduct managerial and operational aspects of clinical trials
- Responsible for invoicing pharmaceutical companies
- Negotiate study budgets with pharmaceutical companies
- Complete feasibility phase and facilitate qualification visits with major pharmaceutical companies for potential research collaborations

Clinical Research Assistant (05/2013- 04/2015)

Manhattan Medical Research, New York, New York

- Prepared regulatory documents and IRB approvals throughout entirety of clinical trials
- Completed data entry for clinical trials
- Oversaw invoicing and advertising budgeting
- Executed miscellaneous clerical tasks

Skills/Training

- Proficient in Microsoft Office Software (Word, Excel, and PowerPoint), SPSS, and StatView
- Skilled in Electronic Data Capture portals (Inform, Medidate Rave, Oracle)
- Expert in CMTS program, specifically Clinical Conductor
- CITI and NIH Certified
- Trained in the following Clinical Trial Areas
    - Specimen Handling & Shipping according to IATA regulations
    - Protecting Human Research Participants NIH office of Extramural Research
    - Guidance for Industry: Investigator Responsibilities. Protecting the Rights, Safety, and Welfare of Study Subjects. October 2009 version
    - Information Sheet Guidance for Sponsors, Clinical Investigators and IRB's. FAQ- Statement of Investigator (Form FDA 1572)
    - Fundamentals of Good Clinical Practice