CLINICAL RESEARCH COORDINATOR MENTOR - QUALITY ASSURANCE
Career Focus

- Eight years of compliance experience
- Proficient with Microsoft office programs
- Proficient with University of Michigan systems; MiChart, Careweb, eResearch, Qualtrics, Velos, Wolverine Access
- Excellent organizational skills
- Ability to learn new databases, software, and processes quickly
- Member of UMHS Quality Month Committee

Professional Experience
August 2011
to
Current
Company Name City , State Clinical Research Coordinator Mentor - Quality Assurance

- Project Management for Quality Assurance Review Committee - Auditor for Regulatory, Investigational Drug Service and Informed Consents - Facilitate Physician chart audit - Preparation of audit reports - Follow-up on corrective action plans - Data Collection - Data Analysis - Database Maintenance - Protocol compliance
- Data Management (Sponsored Trials) - Provide data management and study coordination support to faculty members and research team in conduct of clinical trials research - Electronic and paper Case Report Form completion - Organize and participate in site initiation visits and monitor visits - Confirm eligibility and register patients on clinical trials - Act as liaison between Regulatory, Study Team, and Sponsor - Extract SAEs and AEs from medical records and report to IRB and Sponsor - Prepare deviation reports - Research chart maintenance
- Assist in preparation for external department audits
- Development of departmental training tools
- Member of eResearch Production Support Team
- Write, review and revise departmental Standard Practice Guidelines
- Maintain inventory for over 100 trials

February 2010
to
August 2011
Company Name City , State Clinical Subjects Coordinator - Regulatory

- Ensure and maintain regulatory compliance for 62 oncology clinical trials; Investigator Initiated, Cooperative Group and Sponsored
- Complete initial IRB applications and amend applications in eResearch
- Write and revise Informed Consent documents
- Submit reports such as Serious Adverse Events, Data Safety Monitoring, and Scheduled Continuation Renewals to the Institutional Review board
- Perform Quality Assurance for Regulatory Compliance (QARC) audits
- Perform audits for Investigational Drug Service (IDS)
- Regulatory preparation for Site Initiation Visits
- Train Interns and Preceptors
- Member of eResearch Production Support Team
- Process and submit protocol amendments to U of M Institutional Review Board
- Create and maintain postings on UMClinicalStudies.org and ClinicalTrials.gov

November 2007
to
February 2010
Company Name City , State Administrative Assistant Senior Healthcare

- Coordination of Quality Assurance Indicator Project (23 sites)
- Website maintenance

- Database Management
- Quarterly reports and presentations
- Proof reading high profile documents
- Chart Audits and chart review
- Pivot tables
- Minutes and coordination for three committees

August 2006
to
November 2007
Company Name City , State Administrative Assistant Intermediate Healthcare

- Website maintenance
- P-Card Reconciliation for five faculty members
- Calendar management for 5 faculty members.
- Coordination of Fellowship and Residency programs
- Expense reports
- Editing and proof reading high profile documents
- Responsible for mass ordering of supplies over $20,000 annually
- Preparation and creation of survey and survey mailings
- Lead on poster creation for Pediatric Academic Society annual conference
- Brochure and flyer creation
- Coordination of Health Services Research Fellow Seminars
- Supervision of work-study student

December 2000
to
August 2006
Company Name City , State Outpatient Clerk III

- Coordination of patient care with several departments
- General clerical duties
- Staff trainer

Education and Training
Eastern Michigan University City , State , US Bachelor of Business Administration : Management
Bachelor of Business Administration - Management Eastern Michigan University, Ypsilanti, MI
Certified Clinical Research Professional - SoCRA
City , State , US Associates : Society of Clinical Research The Society of Clinical Research Associates, Chalfont, PA
Certifications
CCRP Clinical Research Coordinator AEs Certified Clinical Research Professional - SoCRA
Affiliations
of UMHS Quality Month Committee
Presentations
Quarterly reports and presentations
Skills
Audits, Quality Assurance, Maintenance, Database, Clerical, Clerk, General Clerical, Outpatient, Clinical Trials, Clinical Research, Audit, Case Report, Case Report Form, Collection, Corrective Action, Corrective Action Plans, Data Analysis, Data Collection, Data Management, Inventory, Liaison, Marketing Analysis, Medical Records, Mentor, Project Management, Training, Administrative Assistant, Healthcare, Database Management, Pivot Tables, Ids, Oncology, Regulatory Compliance, Calendar Management, Ordering, Pediatric, Reconciliation, Access, Databases, Excellent Organizational Skills, Microsoft Office, Ms Office, Organizational Skills