

CURRICULUM VITAE

NAME H. Joseph Cardenas, BS, SCRA

EDUCATION

1989-1992 Bachelor of Science
University of New York, Regents College
New York, NY

1981-1983 Bachelor of Science
University Of California, Earl Warren College
San Diego, CA, USA

PROFESSIONAL EXPERIENCE

10/2007 to 5/2008 Senior Clinical Research Associate
PAREXEL International
San Diego, CA, USA

- Perform routine site visits, including pre-study, initiation, interim, and closeout visits. Visits to include monitoring of proper informed consent procedures, compliance with protocol, GCP/ICH Guidelines and other applicable regulatory requirements and assurance of good site performance. This is accomplished by detailed review of subject records, essential documents, investigational product disposition and accountability, site personnel and procedures.
- Manage assigned sites by regular contacts to ensure site compliance, adequate enrollment, and understanding of study requirements.
- Report to PAREXEL Research project team, client, and site personnel any findings noted at monitoring visits. This is accomplished by completion of monitoring reports and follow-up letters within the project-specific timelines. Significant issues noted must be reported to appropriate personnel immediately.
- Maintain CIMS or alternative project tracking system of subject and site information.

- Provide training for colleagues on clinical, regulatory, administrative, and company procedures and processes.
- Participate in company-required training programs.
- Perform necessary administrative functions (e.g., tracking of expense reports, time and attendance).
- Maintain home office (e.g., procurement of office supplies, submission of documents).
- Perform other duties as assigned.

9/2006 to 8/2007

Senior Clinical Research Associate
i3 Research
Cary, NC, USA

- Perform routine site visits, including pre-study, initiation, interim, and closeout visits. Visits to include monitoring of proper informed consent procedures, compliance with protocol, GCP/ICH Guidelines and other applicable regulatory requirements and assurance of good site performance. This is accomplished by detailed review of subject records, essential documents, investigational product disposition and accountability, site personnel and procedures.
- Manage assigned sites by regular contacts to ensure site compliance, adequate enrollment, and understanding of study requirements.
- Report to i3 Research project team, client, and site personnel any findings noted at monitoring visits. This is accomplished by completion of monitoring reports and follow-up letters within the project-specific timelines. Significant issues noted must be reported to appropriate personnel immediately.
- Maintain eClinical or alternative project tracking system of subject and site information.
- Serve as back up for Regional Manager, Regional Clinical Monitoring Group when required.
- Provide training for colleagues on clinical, regulatory, administrative, and company procedures and processes.
- Participate in feasibility studies.
- Assist with company's quality control initiative.

- Present study materials at Investigator/study launch meetings when required.

- Support project management team with assessment of workload and site assignments within the project team.
- Assist project management team with review of monitoring reports and study documents when required.
- Participate in the interview process of potential candidates when required.
- Participate in company-required training programs.
- Perform necessary administrative functions (e.g., tracking of expense reports, time and attendance).
- Maintain home office (e.g., procurement of office supplies, submission of documents).
- Perform other duties as assigned.

4/2006 to Present

Senior Clinical Research Associate

Research Resources International, Inc. (RRI) Lake Wylie, SC. USA

- Prepare budget and quotes for prospective clients.
- Manage general administrative duties within the company to maintain project budgetary goals.
- Generate and implement SOP and DOP process to insure proper adherence to projects, maintaining ICH and GCP compliance.
- Perform routine site visits, including pre-study, initiation, interim, and closeout visits. Visits to include monitoring of proper informed consent procedures, compliance with protocol, GCP/ICH Guidelines and other applicable regulatory requirements and assurance of good site performance. This was accomplished by detailed review of subject records, essential documents, investigational product disposition and accountability, site personnel training and procedures.
- Maintain client database up to date of project status of subject enrollment and general site progress reports.
- Generate accurate and timely site visit reports for the sponsor as required and insure the project manager is informed.
- Assist when needed as back up monitor as project need changes to expedite data collection.
- Other duties as assigned.

2000 to 2005

Senior Clinical Research Associate
SFBC International, Tampa, FL, USA

- Performed routine site visits, including pre-study, initiation, interim, and closeout visits. Visits included monitoring of proper informed consent procedures, reviewed compliance with protocol, GCP/ICH guidelines and other applicable regulatory requirements to insure site performance.
- Performed thorough review of subject records/essential documents.
- Performed investigational product shipment and disposition.
- Reviewed site personnel training records and site SOP/DOP compliance.
- Reviewed and collected completed Case Report Forms as required, Initiated and followed through of data queries as required by central data management
- Conducted thorough GCP/ICH metrics audits to ensure sites were compliant. Maintained open communication with the sites and sponsor to ensure the flow of data was accurate and timely.
- Conducted Investigator site training as required by the protocol to ensure the understanding of study requirements.
- Participated in the site selection process to ensure site capabilities and enrollment was appropriate for the needs of the projects.
- Generated study pertinent forms to allow for accurate reporting of study enrollment progress from the sites to the project managers and sponsors.
- Collaborated with the company President of Business development and Project Services in the budgetary aspects of protocol feasibility.
- Participated in Protocol development and implementation process.
- Participated in the conduct of in-house staff training and orientation for new hires.
- Assisted the Director of Project Services in the review of monitor reports and general correspondence with sponsor and sites to ensure CRA staff had maintained timeliness and accuracy.

- Conducted yearly stock inventory and participated in the purchasing of general office/clinic supplies.
- Performed other duties as assigned.

1995 to 2000

Site Director, Senior CCRC
ClinSites/LeeCoast Research Center, Inc.
Fort Myers, FL, USA

- I was Responsible for financial, clinical, and administrative day to day activities of the sites.
- Assisted the President of Clinical Operations with all clinical operations and study aspects.
- Ensured that the clinical operations personnel had appropriate training to perform their responsibilities including, but not limited, to ECG, pulmonary functions test, vital signs, phlebotomy, and other protocol specific procedures.
- Generated and supervised weekly work assignments for 30 staff members and ensured task were being completed timely and accurately for all departments.
- Managed the Recruiting Department and Clinic Manager to ensure enrollment goals were met of each study being recruited through the Tampa offices.
- Implemented clinical operation personnel budgets to ensure staff was performing as assigned.
- Ensured the essential documents for each protocol were maintained in compliance with the CFR, ICH Guidelines, and internal SOP/DOPs.
- Implemented and assisted the QA/QC department programs to ensure data capture was accurate and timely.
- Ensured that communication with the sponsors was conducted professionally and appropriately documented.
- Participated in Sponsor investigator and initiation meetings.
- Prepared work assignments for the CRC staff as appropriate when new protocol assignments were issued to the Tampa/Ft. Myers sites.
- Assisted the CRC staff with receipt and dispensation of drug, retained samples and final disposition of study drug as required.

- Participated and prepared staff in corporate, sponsor and FDA audits to ensure integrity of data.
- Delegated and participated in the purchasing of clinic supplies, office supplies and equipment as needed.
- Performed other duties as assigned.

1991 to 1995

Clinical Research Coordinator

IRAD Corporation

Fort Myers, FL, USA

- Conducted all Protocol-related activities under the direction of the Principal Investigator
 - Performed diverse administrative duties that required analysis, sound judgment and knowledge of specific protocols and procedures.
 - Executed activities, implemented project schedules and supervised Research assistant staff.
 - Recruited and screened prospective subjects.
 - Participated in corporate training programs to maintain technical skills as appropriate for the protocols.
 - Ensured that GCP compliance within the scope of practice and adherence to the protocol was maintained by all staff involved.
 - Demonstrated and performed supervision to the staff on ECG, Vital Signs, Pulmonary functions test and other specific task as appropriate.
 - Maintained accurate and professional communication with the sponsor, subject and investigator.
 - Consented and instructed the prospective subjects for studies as required.
 - Managed the collection, processing and shipment of sample collection.
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- Assisted the Clinic Manager and provided back up when necessary in the day to day clinic needs.
 - Prepared, submitted and maintained Regulatory Documents in compliance with CFR and GCP as well as internal SOP/DOPs.
 - Managed the investigational Product receipt and dispensing records as appropriate.

- Performed other duties as assigned

LICENSURE/CERTIFICATION

2001 American Translator Association (certified)
English/Spanish/English-Translator/Interpreter-ATA
Alexandria, VA, USA

1995 Clinical Research Coordinator (Certified)
ACRP
Washington, DC, USA

1991 Medical Laboratory Technician (certified)
Lee Memorial Hospital, Cleveland Campus
Fort Myers, FL, USA

PROFESSIONAL MEMBERSHIPS

2007 Associates of Clinical Research Professionals

2008 Drug Information Association

2007 American Translators Association

2007 American Society of Medical Technologist

FOREIGN LANGUAGES

Spanish Speak, Write and Read

SUMMARY OF THERAPEUTIC EXPERIENCE:

Extensive Phase I to IV

Allergy/Immunology
Dermatology
Cardiovascular (HTN and Lipid)
Consumer Health (sunscreen-cosmetics)

Migraine and headaches
Ophthalmology
Pain Management
Pulmonary Disease

Contraception
Endocrinology
Gastroenterology
Hormone Replacement Therapy
Infectious Disease (Including HIV & topical antiviral)
Insomnia

Rheumatology
Smoking Cessation
Sexual Dysfunction
Vaccine Trials

Therapeutic areas in which I have 12+ months of experience. Allergy and Immunology (vaccine trials), Contraception, Dermatology, Endocrinology, Cardiology, Gastroenterology, Insomnia, Ophthalmology, Pain Management, Rheumatology, Smoking Cessation, Sexual Dysfunction and Multiple (180+) Phase I studies in a large variety of indications

SUMMARY OF CLINICAL TRIAL PHASE EXPERIENCE

Phase I Number of studies: 210+
Phase II-III Number of studies: 118+
Phase IV Number of studies: 15+

AUTHENTICATION

The information in this document is accurate and complete to the best of my knowledge.

H Joseph Cardenas
Signature

01AUG08
Date