SAMPLE CRA CV

Sharon H. Johnson, BS, MS
123 Main Street
Capital City, VA 00000
Phone: 434-555-1234
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Education:

Masters of Science, Healthcare Administration, Capital City University, 2001.
Bachelors of Science, Nutrition, The University of Hometown, 1998.

Professional Experience:

Clinical Research Associate
PharmaBuild December 2008 to Present
Capital City, VA

Responsible for monitoring sponsor initiated and federally funded clinical research studies for normal volunteers and subjects diagnosed with Endocrinology Diseases.

Specific responsibilities include:

- Lead monitor (CRA) mentoring and supervising other monitor(s).
- Assist in investigator study site selection and study start-up.
- Create clinical project documents according to the protocol, including, but not limited to, source documentation forms and guidelines, monitoring Standard Operating Procedures (SOPs), monitoring visit templates and reports.
- Implement and monitor clinical trial to ensure sponsor/investigator obligations are met and are compliant with applicable local requirements and FDA and ICH guidelines.
- Conduct monitoring visits to confirm protocol compliance, assess qualifications of study personnel, ensure "Good Clinical Practice", and conduct close-out visits.
- Identify site issues and initiates correction plans based on monitoring reports.
- Perform investigative site file reconciliation: requests any new and updated site-related essential and non-essential documents and reviews them for content, consistency with other documents, and compliance with appropriate local regulatory requirements, ICH guidelines, project Standard Operating Procedures (SOPs), and sponsor requirements.
- Verify data in source documents are in agreement with source, initiate data query resolution and confirm resolution in timely manner.
- Ensure subject safety and adverse event reporting to sponsor and IRB/IEC.
- Verify drug accountability logs and storage requirements.
- Responds to requests from investigative sites in a timely fashion.
- Provide study status updates to team members and project management, including interaction to resolve site issues and facilitate project timelines.

Clinical Research Manager
Bigcity Hospital Research Center July 2004 to July 2008
Bigcity, VA

Clinical Research Manager for the hospital's several large multi-center, randomized, double-blind, placebo-controlled clinical trials

Specific duties include:

- Assist with the preparation of IRB applications, including protocol and informed consents and obtain approval to conduct the study.
- Maintain appropriate correspondence with the IRB, including adverse events, annual renewals and protocol amendments.
- Create Standard Operating Procedures for each study or clinical trial.
- Conduct telephone interviews to determine subject eligibility. Schedule intake appointment to recruit subjects to study. Obtain informed consent and HIPAA authorization, conduct intake interview, and enroll subjects.
- Maintain source documents and regulatory documentation of clinical trial. Ensure quality of data on CRFs.
- Monitor health and safety of subjects with frequent contact and ensure subject compliance with the study protocol.
- Present adverse event documentation to Principal Investigator and sponsor where appropriate.
- Train, supervise and evaluate clinical research coordinators and research assistant in the performance of their duties. Update training module and retrain study staff as required.
- Create and maintains database of subject information and generates reports and shipments of data to coordinating center, as needed.

Clinical Research Assistant
General Clinical Research Center August 2001 to May 1994
Hometown, VA

Assist investigators in the development of the nutrition component of research protocols and in the evaluation of results; confer with principal investigators and the Advisory Committee regarding dietary aspects of individual aspects of the specific research diet; provides information of food composition data and balance diet procedures to physicians, and others involved. Calculate various types of research diets according to the research protocol and patient's preferences; develops new recipes for highly restrictive and/or specialized diets.

SAMPLE CRA JOB DESCRIPTION

PharmaBuild, LLC

Clinical Research Associate – Lead Monitor

Job Description: Responsible for monitoring the progress of clinical studies at investigator sites and ensuring that studies are conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), ICH-GCP, and all applicable regulatory requirements.

Directly accountable to: Director of Study Management, PharmaBuild

Responsibilities include:

- Proactively leading project success, including communicating and working closely with project leaders, site coordinators, investigators, monitors, data management staff, and data analysts
- Participating in the site selection process so as to assure adequate qualifications, training and resources for the investigative sites
- Creating, maintaining, and reviewing monitoring standard operating procedures, monitoring tools for conducting monitoring tasks including: monitoring plans, monitoring reports, corrective and preventive action plans
- Assigning, coordinating and supervising day-to-day activities of clinical study monitors
- Training investigative site personnel on study protocols
- Reviewing and approving monitoring reports, tracks ongoing issues and query resolution
- Escalating compliance and study issues to Director, Study Management
- Working with coordination and data management teams to identify, capture, document and resolve problems in subject enrollment, study data and study progress
- Conducting monitoring visits, as needed, to: assess protocol adherence; conduct source verification; verify drug accountability and storage requirements; and ensure compliance with regulatory requirements and AE reporting requirements.

Travel: 20% at study initiation; as needed during study; total employment not to exceed 2100 hours per year.

Skills and Experiences:

- Undergraduate degree in a clinical, scientific, or related field required
- Advanced degree (M.S., M.B.A., PharmD, etc.) preferred
- Clinical project management experience required
- Monitoring experience required: minimum 2 years
- Supervisory experience as monitor – preferred
- Substantial experience using computerized information systems, Outlook, Word, Excel, PowerPoint, CTMS required
- Through knowledge of ICH-GCP and awareness of local regulatory regulations regarding drug research is required

SAMPLE CRC CV

Sharon H. Johnson

99 Canal Center Plaza, #200
Alexandria, VA 22314

(703) 555-1234 (mobile)
shjohnson@email.com

Education

- University of Hometown, B.S. in Genetics and Cell Biology, May 2005

Research Experience

Hometown Research Center
Hometown, VA
Hometown Community
Clinical Research Center

Clinical Research Coordinator
May 2012 – Present

Clinical Research Assistant
February 2010 – April 2012

- Conducted day-to-day execution of clinical research protocols including obtaining informed consent, completing study procedures, and dispensing, accounting for study drug, and documenting drug compliance.
- Responsible for recruiting prospective research subjects for clinical trials.
- Responsible for clinical communication with central and local IRBs and maintaining ethical approval for studies, from initial study approval through study amendments, annual continuations, and finally termination.
- Documented and conducted appropriate correspondence regarding adverse events, including multiple severe adverse events.
- Responsible for clinical tasks including venipuncture, vital signs, body measurements and ECG.
- Working with contracts and budgets with study Sponsors from study start-up through study close-out.
- Assisted with diabetes management tasks insulin dose adjustment, home blood glucose monitoring, and diet and exercise counseling.

Bigcity Hospital Center
Washington, DC 00000
Giant Medical Laboratory

Research Intern
June 2008 - January 2010

- Produced kits for research sample collection and storage in environments without refrigeration, computers or Internet access.
- Responsible for 20,000+ entry database of human tissue samples including daily intake, processing, diagnostics and sample retrieval.
- Worked with other interns in extensive data-mining operation to create a complete and accurate computer database of all extant research patients and samples since 1988.

SAMPLE CRC JOB DESCRIPTION

Hometown Research Center

Clinical Research Coordinator

Job Description: Responsible for safe and effective implementation of clinical trial protocols and ensuring that protocols are conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), ICH-GCP, and all applicable regulatory requirements.

Directly accountable to: Research Manager, Hometown Research Center

Responsibilities include:

- Assist with the preparation of IRB applications, including protocol and informed consents and obtain approval to conduct the study.
- Maintain appropriate correspondence with the IRB, including adverse events, annual renewals and protocol amendments.
- Create Standard Operating Procedures for each study or clinical trial.
- Conduct telephone interviews to determine subject eligibility. Schedule intake appointment to recruit subjects to study. Obtain informed consent and HIPAA authorization, conduct intake interview, and enroll subjects.
- Maintain source documents and regulatory documentation of clinical trial. Ensure quality of data on CRFs.
- Monitor health and safety of subjects with frequent contact and ensure subject compliance with the study protocol.
- Present adverse event documentation to Principal Investigator and sponsor where appropriate.
- Create and maintains database of subject information and generates reports and shipments of data to coordinating center, as needed.
- Prepares documents for review by sponsors, monitors and regulatory authorities, as necessary
- Participates in meetings with sponsors, monitors and regulatory authorities, as necessary.

Skills and Experiences:

- Undergraduate degree in nursing preferred
- Clinical trial experience minimum 1 year
- Supervisory experience desirable
- Substantial experience using computerized information systems, Outlook, Word, Excel, PowerPoint, CTMS required
- Through knowledge of ICH-GCP and awareness of local regulatory regulations regarding drug research is required