Denise G. Lambert, RN
CURRICULUM VITAE

PROFESSIONAL EXPERIENCE

Jul 2011 - Present Project Manager
Pennington Biomedical Research Center

Assist in development and implementation of the International Study of Childhood Obesity, Lifestyle and the Environment (ISCOLE), a multi-national cross-sectional study conducted in 12 countries (Australia, Brazil, Canada, China, Colombia, Finland, India, Kenya, Portugal, South Africa, United Kingdom and United States). Assist with establishing priorities, timelines and processes for the project as well as oversee regulatory submissions. Monitor study progress and make appropriate adjustments to meet project goals. Ensure integrity of study data through ongoing training, data monitoring, process improvement and team facilitation. Assist in development of presentations and reports to the sponsor and advisory committees. Monitor subcontracts, budgets and project spending, and liaise with fiscal operations and sponsored projects.

Aug 2010 - Jul 2011 Project Coordinator
Pennington Biomedical Research Center

Assist in development and implementation of protocols, oversee regulatory submissions. Assist with establishing priorities, timelines and processes for projects. Monitor study progress and make appropriate adjustments to meet project goals. Ensure integrity of clinical trial data through ongoing training, data review, process improvement and team facilitation on projects. Monitor budgets and project spending, serve as liaison with fiscal operations and sponsor projects.

Feb - Sep 2008 Clinical Research Associate II
i3 Research
Cary, NC, USA

- Performed routine site visits, including interim, and closeout visits for Phase III Type 2 Diabetes trial. Performed responsibilities with minimal support from management. Visits included 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 and procedures.
- Managed assigned sites by regular contacts to ensure site compliance, adequate enrollment, and understanding of study requirements.
- Reported to i3 Research project team, client, and site personnel any findings noted at monitoring visits. This was accomplished by completion of monitoring reports and follow-up letters within the project-specific timelines.
- Maintained project tracking system of subject and site information.
- Participated in company-required training programs.
- Performed necessary administrative functions (e.g., tracking of expense reports, time and attendance).
- Maintained home office (e.g., procurement of office supplies, submission of documents).

2005 - 2008 Clinical Trials Coordinator
Pennington Management of Clinical Trials, LLC
Baton Rouge, LA

- Performed identification and selection of investigative sites.
- Performed site visits, including initiation, interim, and closeout visits.
- Trained and supported site staff in use of PMCT electronic subject scheduling and data capturing system (web based).
- Managed internal call center operations and served as oversight to external call center for multi-site clinical trials.
- Executed recruitment campaign including media buys for multi-center clinical trial.
- Participated in company-required training programs.
- Performed other duties as assigned.
- Experience included Phase II, III and IIIb trials in Pre-diabetes, Type II Diabetes and Weight Loss.

2003 - 2005 Clinical Research Coordinator
Woman's Health Research Institute, Woman's Hospital
Baton Rouge, LA

- Assisted investigators with Research & Development (R&D) and Institutional Review Board (IRB) submission process.
- Served as liaison between principal investigators, medical staff, legal counsel, hospital departments and administration and outside institutions regarding research protocols.
- Created and reviewed source documents and study specific checklists.
- Provided training for new research staff.
- Screened, scheduled and enrolled subjects. Performed data collection for Phase III and IV clinical trials in High Risk Pregnancy and Infertility.

1999 - 2003 Research Nurse
Woman's Health Research Institute, Woman's Hospital
Baton Rouge, LA

- Assisted investigators with R&D and IRB submission process.
- Created and reviewed source documents and study specific checklists.
- Screened, scheduled and enrolled subjects. Performed data collection for Phase II, III, IIIb, IV clinical trials in Menopause, Infertility and High Risk Pregnancy.

1996 – 1999 Staff Nurse/Charge Nurse
Woman's Hospital
Baton Rouge, LA

- Cared for patients on Mother/Baby Unit and Newborn Nursery.
- Coordinated patient assignment for nursing staff as needed.

EDUCATION

1996 Associate of Science Degree in Nursing
Our Lady of the Lake College of Nursing and Allied Health
Baton Rouge, LA

LICENSURE/CERTIFICATION

1996 to Present Registered Nurse
Louisiana State Board of Nursing
Baton Rouge, LA, USA