

**LAFAYETTE PUBLIC TRUST**  
**FINANCING AUTHORITY**

**RESUME LIST:**

Alleman, Karen

\*Roussel, George

*\*incumbent*

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# Karen Alleman

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## **VOLUNTEER EXPERIENCE**

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- **Hospice of Acadiana**  
2020 – 2022
- **The Hub Lafayette Urban Ministries**  
2021 - 2022

## **PROFESSIONAL EXPERIENCE**

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### **WOMENS AND CHILDRENS HOSPITAL**

*Registered Nurse*

**Lafayette, LA**

*May 1988 – Present*

- **Staff Nurse in Urogynecology office setting**
  - Created protocol for receptionist to determine patient urgency in scheduling appointments to avoid ER/Walk-in Clinic visits.
  - Assisting management with consumer assessment and health grade ratings to keep quality scores high.
  - Scheduling surgeries using ICD-9/10 codes, CPT codes, pre-cert surgeries, and working with insurance companies for approvals on surgeries/medications/procedures.
  - Review surgery coding to capture all codes (procedure diagnosis and place of service)
  - Billing for patient visits and in office procedures (J codes, modifiers, CPT and ICD 9/10 codes)
  - Assuring the MD assigns and locks charts daily.
  - Maintain screening for BMI (med list), Mammogram, Colonoscopy, fall risk, smoking status and Blood Pressure with patient visits
  - Opened office on behalf of Hospital
  - Developed OSHA Policies/Procedures
  - Negotiate with vendors for best pricing on supplies and equipment
  - Developed and direct a support group for patients with Interstitial Cystitis
  - Spoken in multiple classroom settings about nursing as a career.
- **Case Management**
  - Audited patient charts for quality measures to continue hospital coverage
  - Documented patient's case management plans and on-going activities
  - Identified patient's insurance coverage or other sources of payment for services
  - Identified and addressed client risk factors and/or obstacles to care
  - Screening patient for healthcare needs
  - Developing a patient-focused case management plan
  - Educated patient/caregiver about the process and evaluating their understanding of the process
- **Labor/Delivery nurse**
  - Worked in NICU, Nursery and Pediatrics
  - Volunteered with Shots for Tots
  - Taught Childbirth classes

- **Coordinated the opening of a remote office in Lake Charles for a Breast Cancer Surgeon**
- **Recovery Nurse for In vitro fertilization unit**
- **Day Surgery/Holding Recovery Nurse**  
-Presented in hospital meetings on how to improve the Pre-Admit process
- Ability to interact and communicate with patients of all ages and ethnic backgrounds, giving quality medical care and treatment

## **EDUCATION**

**UNIVERSITY OF SOUTHWESTERN LOUISIANA**  
*Bachelor of Science Degree in Nursing, 1987*

**Lafayette, LA**

# George “Butch” Roussel, MS

Lafayette, LA 70506

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## TITLE

### Clinical Research Consultant

Clinical Development, Monitoring, Site Auditing, CRA Auditing, Site/Study Management, Protocol Development/Implementation, Investigational Pharmacy Consulting, Pre-FDA Audit Site Preparation

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## EDUCATION

The Johns Hopkins University, Rockville, MD  
Masters of Science, *Biotechnology Business*

May 2009

The University of Louisiana Lafayette, Lafayette, LA  
Bachelor of Science, *Biological Sciences*  
Minor: *Chemistry*

December 2006

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## EXPERIENCE

### Vivo Research, LLC

Owner / Research Consultant / Lead Clinical Research Associate

September 2011-Present

#### Therapeutic Expertise:

Area	Indication(s)	Phase(s)	Year(s)	No. of Protocols	No. of Sites
Infectious Disease	ETEC-Cholera, Typhoid, Tularemia, pneumonia, Covid-19	I & II	2007 – 2013, 2021	6	10
Gastroenterology	Intestinal Microbiome, Surgical Site Infection Irrigation	N/A	2009, 2010, 2020, 2021	2	5
Ophthalmology (includes gene therapy)	Age Related Macular Degeneration, Central Serous Choroidopathy, Uveitis, Graft versus Host Disease (dry eye), Stargardt's and Usher's Syndrome	I	2008 – 2022	10	15
Allergy/Immunology	Food Allergy	I/II	2009	2	1
Cardiovascular (Pediatrics included)	Hypertension, Stroke, TIA	II/III	2010-2011	2	7
Neurology (Pediatrics)	Epilepsy, Status Epilepticus, Super Refractory Status Epilepticus, Trigeminal Neuralgia, ALS.	II/III	2010 – 2022	5	115
Psychiatry	Manic Depression (pediatrics included), PPD	II	2010 – 2014 2018	3	10
Pharmacokinetics	Infection	I	2011	2	2
Oncology	Lung, Prostate, Bone Marrow Transplant, Anal Cancer, Cutaneous Melanoma, Solid Tumor	I/II/III	2011, 2013, 2014, 2020, 2021 - 2022	7	48
Behavioral Health	Opioid Abuse Potential	II	2018	1	1

The EMMES Corporation, Rockville, MD

**Clinical Research Associate Manager (CRA Manager)**

April 2010-September 2011

***CRA Management Responsibilities:***

- Trained and managed a team of nine (9) CRAs responsible for determining project assignments, conducting performance reviews, ensured annual training, project training and SOP training. conducted expense report review and monitored timekeeping and conducted interviews.
- Responsible for the progress and overall direction of monitoring plans, metrics requirements, and sponsor requirements.
- Managed the process of study start-up documents, clinical operations, and timelines in conjunction with Statisticians, Investigators, Data Managers, and Scientific Advisors; supervised activities of internal data management activities
- Troubleshoot and facilitate resolution of clinical study issues
- Provided logistics and process consulting support to Investigational Pharmacies.

***CRA-Related Responsibilities:***

- Served as a lead CRA on Site Initiation, Interim, For Cause, and Study Closeout visits for pediatric clinical trials under the Best Pharmaceutical Children's Act (BPCA).
- Served as the primary unblinded protocol monitor for pediatric clinical trials under the BPCA; trained unblinded protocol monitors the techniques and safeguards taken when performing unblinded monitoring visits in pharmacies.
- Created CRA guidelines, monitoring tools, and SOPs for newly created Corporate CRA group; served as an instructor for employees seeking CRA certification.

**Protocol Specialist/Protocol Monitor**

April 2008-March 2010

- Assisted with the submission of Investigational New Drug (IND) Applications and Protocol Amendments to the Office of Clinical Research Association (OCRA) and FDA. Assisted in the development and maintenance of protocols, ICFs, and regulatory documents required for study start-up. Prepared and submitted IRB materials to ensure Investigator reporting responsibilities for continuing and/or annual reviews. Facilitated operations of a Protocol Development Team (PDT) to ensure communication of study progress and outcome to sponsor.
- Performed Protocol Monitoring in the following areas: Site Activation and Initiation (FWD IRN and NEIS), Interim Monitoring (FWD IRN, CoFAR and NEIS), and For Cause Visits (NEIS). Trained site personnel and created training materials on functionality of EMMES' proprietary EDC software.
- Experience writing corporate/project-specific Standard Operating Procedures (SOP) and created project compliance tables for corporate QA department.

**Clinical Systems Analyst**

September 2007- March 2008

- Perform data management and operational support for two federally funded clinical trials: one domestic ETEC Cholera vaccine trial (Phase I), and one domestic longitudinal study to define human intestinal microbiome.
- Responsibilities include protocol review, MOP development, source document development, setup of the IDES system and coordination with the IT department to provide necessary customizations in the EMMES proprietary EDC software AdvantageEDC, data querying (both automated and manual), lead site communication activities, maintenance of daily reports (to monitor halting rule criteria, enrollment accrual, adverse events, and protocol deviations), study website maintenance, site training, and reports generation (e.g. Safety Reports and IND Annual Reports).

**Vitalogy Inc., Hammond, LA****Lab Technician**

January 2007-August 2007

- Planned and coordinated all set-up times, configuration, and technician roles for lab screenings. Trained lab technicians in screening procedures such as cholesterol, glucose monitoring, blood pressure monitoring, and spirometry
- Developed ways to target the public sector to open up new market areas for our lab work.

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**PUBLIC SPEAKING****Social Media Day – Tapping Into Your Inner Social Story**

June 2017

**TEDx Vermillion Street – 'How Release Your Inner-Citizen... In 48 hours'**

September 2015

**Mission Renew Spiritual Director – 'Mission Renew vs. Mission Impossible'**

July 2015

**Plan Lafayette – Public Art Speaker Series**

February 2015

**PATH Vaccine Monitoring Series – 'GCP- The Good, The Bad, The Ugly'**

April 2014

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### **AFFILIATIONS**

<b>Lafayette Public Trust Authority Trustee</b>	August 2017 - Present
<b>Founder of The 24 Hour Citizen Project</b>	April 2016 - Present
<b>Founder of Community Crowdfunding Website (www.civicside.com)</b>	March 2014- March 2016
<b>Leadership Lafayette Institute of Acadiana</b>	October 2012 – October 2016
<b>Member, Association of Clinical Research Professionals</b>	October 2008- June 1, 2022
<b>Ministry, Cathedral Carmel Catholic Church</b>	June 2007- Present

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### **SKILLS AND INTERESTS**

**Computer Skills** – Proficient with MS Office (Excel, Outlook, PowerPoint, Word), Mac iWork (Keynote, Pages, Numbers), Rapidweaver; Wordpress, AdvantageEDC, Oracle, RAVE, working knowledge of SAS and html.

**Other** – Strong writing and presentation skills; interest in business development, strategic planning and community outreach.

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