# Bridget Giles PhD, CCRA

# The Virginia Modeling Analysis & Simulation Center

**bgiles@odu.edu**

**EXPERIENCE**

Dec 2011 to Present

**Assistant Director for Special Programs and STEM/Research Assistant Professor**, Old Dominion University, Suffolk, VA

**Research Activities:**

2018-2019, Giles (PI), Development of an Opioid Crisis Interactive Dashboard, Old Dominion University

2016-2017, Giles (PI), Development and Evaluation of Zika Awareness and Prevention Game, Old Dominion University

2016-2017, Giles (Co-I), Modeling Temporary, Interim & Permanent Housing Demand & Capacity for Medically Fragile & Vulnerable Populations, HUD

2016, Giles (PI), Development of a Canine Abdominal Ultrasound Simulator for Veterinary Training

2014-2015, Giles (Co-I), Adaption Response to Recurrent Flooding: Portsmouth Comprehensive Planning Support, City of Portsmouth Virginia.

2013-2014 Giles (Co-I), Hampton Roads Regional Catastrophic Planning Team for the Twenty Four Jurisdictions of the Greater Hampton Roads Region in Southeastern Virginia and North-eastern North Carolina; develop and grow emergency management capabilities in support of a catastrophic emergency response.

2013-2014, Giles (Project Manager), A Theoretically Driven Investigation of the Efficacy of an Immersive Interactive Avatar Rich Virtual Environment in Pre-deployment Nursing Knowledge and Teamwork Skills Training, US Army, $2 Million.

June 2011 to Dec 2011

**Clinical Research Coordinator,** Naval Medical Center Portsmouth,Norfolk, VA

* Monitoring and review of medical records, quality assurance and procedures according to clinical trial protocol and procedures, and adherence to FDA guidelines and Good Clinical Practice.
* Proposal Development
* Auditing of IRB processes related to patient safety and procedures.
* Manager of “Wounded Warrior Project.”

May 2009 to June 2011

**Regulatory Specialist,** Giles Clinical Research Consulting LLC., Regional, Smithfield, VA, US

* Managing of clinical trials (typically multi-center projects) to ensure timely delivery of project required objectives and timelines within the scope of the client agreements for assigned projects.
* Development of study management plans, team assignments and accountabilities.
* Served as primary project contact with Sponsor to ensure communication is maintained and reporting schedules are adhered to.
* Collected information on team performance against contract, customer expectations, and project baselines.
* Identified quality issues within the study to implement appropriate corrective actions.
* Provided input for the development of proposals for new work and managed project budgets.
* Prepared and presented project information at internal and external meetings.
* Retrieved, reviewed, and approved the regulatory documents according to regulatory and company procedures (ICH/GCP guidelines).
* Participated in the quality control review process.

Jan 2008 to May 2009

**Clinical Trial Manager**, Premier Research Group Limited, Regional, Smithfield, VA, US

* Participated in the identification and recruitment of investigators.
* Developed patient recruitment strategies and materials.
* Attended bid defenses when needed.
* Coordinated Clinical Monitors on-site and in-house monitoring responsibilities and schedules.
* Managed aspects of the clinical projects including development of the Clinical Monitoring Plan (CMP) and review and sign-off of monitoring reports. Assisted in preparation of the monthly status report.
* Managed vendors for the central lab as required.
* Ensured master files complied with SOPs, GCPs and other regulations.
* Prepared for and attend project team meetings and provided updates of project performance.
* Designed and developed investigator, regulatory, and operations guidelines and training materials.
* Prepared for and attend project launch meetings.
* Prepared for and attended client meetings. Provided follow-up with client regarding any study issues as requested by Project Manager.

Sep 2002 to Jan 2008

**Clinical Research Associate**, Pharmaceutical Product Development, Wilmington, NC.

* Performed start-up, interim monitoring and close-out visits according to applicable Standard Operating Procedures (SOPS) and FDA guidelines.
* Resolved CRF discrepancies/queries and/or clarifications via site visit, telephone, or fax as deemed appropriate.
* Reviewed case report forms for completeness, clarity, legibility, conformity to available source documentation, and adherence to protocol requirements.
* Performed drug accountability and laboratory audits.
* Ensured adverse events and serious adverse events were reported promptly and accurately.
* Verified completeness of Regulatory documents; knowledge of ICH regulatory requirements.
* Trained new CRAs.
* Coordinated and reviewed assignments for CRAs.
* Worked with Medical Writing Group in review of study protocols, informed consent forms, CRFs, Investigator Brochures and Manuals of Procedures.
* Worked closely with sponsor to generate Clinical Monitoring Plans, notes to file etc. for government sponsored vaccine clinical trials project.
* Functioned as team leader, managed status reports, lead calls with sponsor; organized agendas, meeting minutes, updated SOP’s etc.
* Supervised PIs in completing online Feasibility Questionnaire.

May 2001 to Sep 2002

**Microbiologist,** Norfolk Public Health Department, Norfolk VA, US

* Provided arbovirus surveillance and laboratory testing for potential Biological warfare agents and member of Biological Terrorism Taskforce Team for City of Norfolk Virginia.

# THERAPEUTIC CLINICAL RESEARCH EXPERIENCE

* Malaria
* Lyme Disease
* Cytomegalovirus
* Influenza
* Smallpox
* Anthrax
* WNV
* Hepatitis B
* Human Papillomavirus
* HIV
* COPD
* Type 2 Diabetes
* Oncology
* COVID19

# EDUCATION

2001 Ph.D., Biomedical Sciences, Eastern Virginia Medical School Norfolk, VA

1994 MA, Biology, Hampton University Hampton, VA

1993 BS, Biology, Virginia Commonwealth University Richmond, VA

# CERTIFICATIONS

Certified Clinical Research Associate, Association of Clinical Research Professionals

# CLEARANCE

Eligibility of Secret on 2012 05 01

# PUBLICATIONS

• Hanson, L.K., B.Dalton-Giles, Z. Karabekian, H.E. Farrell, W.D. Rawlinson, R.M. Stenberg and A.E.Campbell. 1999. Transcriptional analysis of the murine cytomegalovirus Hind III I region: Identification of a novel immediate early gene region. Virology 260, 1, 156-164.

• Hanson, L.K., L.F. Cageao, R.E. Brock, J.S. Slater, B.Dalton-Giles, J.A. Kerry, and A.E. Campbell. 2005. Characterization and regulation of essential murine cytomegalovirus genes m142 and m143. Virology 334:166-177. NIH grant RO1-CA41451 awarded to A.E.C.

• Diaz, R., Behr, J., Ng, M., Jeng, A., & Giles, B. (2013). The Effects of Transit Corridor Developments on the Healthcare Access of Medically Fragile Vulnerable Populations. International Journal of Privacy and Health Information Management (IJPHIM), 1(2), 57-75.

• Rafael, D., Joshua, B., Ange-Lionel, T., Bridget, G., ManWo, N., Francesco, L., & Letizia, N. (2013, July). Humanitarian/emergency logistics models: A state of the art overview. In Proceedings of the 2013 Summer Computer Simulation Conference (p. 24). Society for Modeling & Simulation International.

* Bradshaw, B. T., Bruhn, A. P., Newcomb, T. L., Giles, B. D., & Simms, K. (2014). *Disaster Preparedness & Response: A Survey of US Dental Hygienists* (Doctoral dissertation, Old Dominion University).
* Newcomb, T. L., Bruhn, A. M., & Giles, B. (2015). Mass Fatality Incidents and the Role of the Dental Hygienist: Are We Prepared? Journal of Dental Hygiene, 89(3).
* Bruhn, A. M., Newcomb, T. L., & Giles, B. (2016). Evaluating imaging techniques for intraoral forensic radiography with the dental hygienist as part of the forensic radiology team. Journal of Forensic Identification, 66(1), 22.
* Newcomb, T. L., Bruhn, A. M., Giles, B., Garcia, H. M., & Diawara, N. (2017). Testing a Novel 3D Printed Radiographic Imaging Device for Use in Forensic Odontology. *Journal of forensic sciences*, *62*(1), 223-228.