# Nicole C. Close, PhD
## Principal Biostatistician

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**Key Skills**

Regulatory expertise with the United States Food and Drug Administration (including IND, IDE, PMA, NDA, BLA, HUD, 510ks, and Emergency Use INDs), CE Marking, Asia Filings and European Filings.

Serving as a member of the senior sponsor team as Director of Biometrics for emerging biotech, pharma and device companies. Developing infrastructure, overseeing the selection of CROs and budget and providing expertise and quality control over all data, statistical and programming deliverables for the Sponsor.

Risk-Based Monitoring expertise and implementation, co-creator and Statistical programmer for Web-based software package for Sponsors with Partner Company.

Study design (including adaptive randomization methodology and adaptive trial designs) and implementation of Phase I, II and III/IV studies, including multi-center clinical trial environments. Non-inferiority trials expertise and workshop educator.

Design and statistical analysis of clinical trials and registry analysis in various therapeutic areas, including those under Emergency Use INDs and Orphan Drug Status.

Execution of clinical trials in special settings including, but not limited to, intensive care units (ICUs), villages, and military settings.

Statistical Analysis Plan (SAP) writing with mock tables, listings and figures.

Statistical programming, analysis, quality control reviewing and interpretation of results.

Data and Safety Monitoring Board expertise as the DSMB statistician sitting on the board, the Sponsor biostatistician and unblinded statistician presenting to the board. Assembly of DSMBs and training of new board members for the sponsor.

Integrated Summary of Efficacy (ISE) and Integrated Summary of Safety (ISS) writing and review for NDA and BLAs.

**Key skills (Continued)**

Study and project management (Coordinating Center) including clinical data management, biostatistics and Data and Safety Monitoring Board administration (Charter writing and management)

Corporate auditing of processes and systems for clinical data management and biostatistics

**Additional Recent and Relevant Knowledge Training**

Statistical training Courses onsite, client locations, and via Web Trainings

Completion of NIH course on the Protection of Human Research subjects (ongoing)

Department of Defense two-day course on Protection of Human Subjects (2006, 2008)

HIPAA training and certification annually, CITI Training (every 2 years)

Clinical Data Interchange Standards Consortium (CDISC) participation and continued education (Annual Meetings)

Clinical Study Report Writing Training Course, Drug Information Association, February 2007

Statistical Analysis of Safety Data, Drug Information Association, June 2007

**Key Computer Skills**

SAS, PASS, N Query, S Plus, R, Epi Info, Microsoft Office (Word, Excel, PowerPoint, Project), WinNonLin and Graphpad Prism.

**Security Clearance**

Global Entry, 2014

Security Upgrade, US Food and Drug Administration, November 2011

NAC Position of Trust, 31 July 2006

**Education**

Ph.D. Epidemiology, The George Washington University, Washington, D.C. 2007

- Dissertation: "Predicting Clinical Outcomes: An Exploratory Analysis of the Collaborative Islet Transplant Registry"

M.S., Epidemiology and Biostatistics, Case Western Reserve University, Cleveland, Ohio. 1994

- Thesis: "Knowledge, Attitudes and Practices of Cholesterol Management in Rural versus Urban Health Care Practitioners"

B.S., Biology, Juniata College, Huntingdon, Pennsylvania. 1992

**Current Responsibilities**

*EmpiriStat, Inc.*, Mount Airy, MD
**President and Principal Biostatistician**

Founder of the statistical organization in 2008 and responsible for all business and statistical organization and implementation. Responsible for conducting, managing and overseeing biostatistics and programming, safety monitoring and reporting, clinical monitoring, quality, and all training programs of the organization.

Dr. Close has worked on over 200 protocols in various therapeutic, biologic and device areas. She has prepared and participated in person on over 25 regulatory meetings with clients for devices, drugs and therapeutics with Regulatory Agencies in the US, Europe and Asia.. She is also the Senior Statistician for the FDA on two FDA internal projects.

**Sample** of recent specific statistical and regulatory projects for Dr. Close include:
* Additional therapeutic and device areas upon request

- United States Food and Drug Administration (Bioresearch Monitoring Program Compliance Programs); Key Technical member for the Development of Advanced Engineering Methods for Risk-Based Prioritization for Clinical Development and Pharmacovigilance Inspections Project with the FDA. This project includes the creation of a new FDA tool for monitoring and auditing Sponsors and CROs in the IND application phase to complement the Office of Scientific Investigations current GCP inspection tool.

- United States Food and Drug Administration (Compounding Pharmacy Inspections Team); Key Technical member for the Development of Data Warehousing and Methods for Risk-Based Prioritization for Compounding Pharmacy Inspections Project with the FDA. This project includes the creation of a new FDA tool for compiling, tracking and monitoring and auditing US Compounding Pharmacies.

- United States Army Medical Research and Materiel Command (USAMRMC); USAMMDA, Division of Regulatory Affairs and Compliance; provide statistical and programming support for studies such as Malaria prevention (US, Africa and Thailand), HIV vaccine trials (US, Thailand and Africa), meningococcal, dengue (Thailand and Puerto Rico), and topical products for leishmania (Tunisia, Peru, Panama and Guatemala). Prepare for FDA briefings and submissions, as well as provide statistical and programming summaries for yearly reports, and provide study design and powering support.

- Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury transferred to USAMRMC, Clinical and Regulatory Affairs Manager to manage all clinical trial operations for two pilot studies, an outcome validation study and a Phase 3 Clinical trial, including Regulatory Submissions to the US FDA and IRBs, data management, biostatistics including sample size and power, safety reporting, and medical writing. Oversee all CRO vendors and deliverables.

- Alexza Pharmaceuticals, provide statistical and programming oversight and guidance for the clinical program and 13 clinical studies, create the ISS statistical analysis plan, and preparation for a successful submission of their NDA with the FDA. Identify critical quality gaps for statistical issues and provide recommendations for improvement and then implement those recommendations. NDA was approved.

**Sample Responsibilities (continued)**

• Royer Biomedical, provide regulatory, statistical and clinical implementation, oversight and guidance for the clinical program of antibiotic wound care product under current IND. Identify critical quality gaps for statistical issues and provide recommendations for improvement and then implement those recommendations.

• R&D Antibodies, provide regulatory, statistical and clinical implementation, oversight and guidance for the clinical program of their invitro diagnostic test for sepsis. Identify critical quality gaps for statistical issues and provide recommendations for improvement and then implement those recommendations.

**Previous Positions**

**Senior Biostatistician (Chief), Biostatistics and Clinical Data Management***
*United States Army Medical Research and Materiel Command (USAMRMC), Division of Regulated Activities (DRAC)*
Ft. Detrick, MD • April 2007 – June 2009

Responsible for 35 open INDs in various therapeutic areas, working internationally with clinical investigators and nationals, providing all statistical support for Medical Affairs, Medical Writing and Pharmacovigiliance, in additional to Regulatory Affairs. Implemented and visited onsite to clinical settings in Thailand, Kenya, Tanzania, Tunisian, Uganda, Egypt and Nigeria.

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**Lead, Biostatistics and Statistical Programming***
*Medical Research Information Technology (MeRITS) Program Management Office, USAMRMC*
Ft. Detrick, MD • July 2006 – April 2007

*DoD contractor position at Ft Detrick via Clinical Research Management, Inc, Hinckley, Ohio

Principal Duties and Responsibilities:
• Establish an infrastructure for the discipline of biostatistics and statistical programming for FDA regulated clinical studies sponsored by The Office of the Surgeon General for the Army,

• Develop biostatistics Standard Operating Procedures (SOPs), templates and forms for the organization

• Author and contribute to writing statistical methods and sections of clinical protocols including sample size calculations and power analyses

• Review and comment upon protocols prepared for FDA regulated clinical studies in human subjects by Principal Investigators and industry partners

• Review study specific procedures and documents that are prepared and submitted by contractors and clinical study personnel, including, but not limited to statistical analysis plans, randomization procedures, unblinding procedures, statistical programming plans and tables, listings and figures for FDA regulated clinical trials in humans

• Formulate and provide education and training on statistical concepts, effectively interpret statistical analyses and author statistical and final clinical report sections

**Previous Positions (Continued)**

- Assist regulatory affairs with the completion and review of clinical meeting packets and materials for submission to the FDA including providing statistical support at FDA meetings

- Develop documents and mechanisms for managing statistical Contract Research Organizations (CROs), including soliciting bids, monitoring CRO progress, intervention and problem solving for statistical and monetary issues

- Develop and conduct standard Company audits of statistical vendors to develop and utilize a "preferred and qualified vendor" list

- Perform, integrate and assist colleagues in regulatory affairs, safety and monitoring, clinical data management, medical writing and project management

- Recruiting, interviewing and hiring biostatistical unit members to support infrastructure, including statistical programmers and biostatisticians

- Supervise and manage CRM contractors in support of the USAMMDA mission

Therapeutic and Trial Experience:

Assisted Investigators at the Armed Forces Research Institute of Medical Services (AFRIMS-Thailand), US Army Medical Research Institute of Infectious Diseases (USAMRIID), US Army Medical Materiel Development Activity (USAMMDA), US Army Medical Research and Materiel Command (USAMRMC) and Walter Reed Army Institute of Research (WRAIR-Silver Spring/Kenya) in multiple therapeutic areas for clinical protocols in Phase 1, 1b, II and III. Areas include product development for and clinical cure of dengue, Group B meningococcal (vaccine), malaria (IV artesunate, artesunate-mefloquine combination, DOT regimens), shigella (dose ranging), leishmaniasis (punch biopsies and scar studies, topical cream, heat), pre-clinical animal studies and camouflage face paint/repellant products (EPA registered product) for studies conducted in the various labs in the United States, Thailand, Kenya, Tunisia, and Belize.

Provided to Investigators is support and advice on formulation of testable research hypotheses, data collection methods to address hypotheses, study methodology, design and logistics, protocol review, review of sample size determination and power analysis, development of Statistical Analysis Plans (SAPs), mock table, listings and figures development, statistical Contract Research Organization (CRO) management, clinical study report preparation,abstract and manuscript preparation, and attendance with the Investigator team and regulatory affairs at FDA meetings to provide biostatistical representation of the Sponsor.

- For support of the biostatistical infrastructure, planned, purchased and implemented SAS (Statistical Analysis Software) for the Command and supplementing statistical software, developed appropriate job descriptions for supporting biostatistical staff, integrated biostatistics with clinical data management activities and established working procedures within Regulatory Affairs for biostatistical support and access. Ongoing work with the Validation Department for completing and maintaining the validation documentation for the statistical software executed in the Biostatistics Unit. While developing this biostatistical unit, responsible for supplementing the current services with the addition of seminars on the essentials of clinical trials and biostatistical topics. Providing statistical programming for descriptive analyses, inferential statistical analysis, and interpretation of results and preparation of study tables, listings, figures and graphs. Responsible for planning and developing a process for a centralized infrastructure of biostatisticians and statistical programmers to help support additional and expanded statistical analysis efforts.

**Previous Positions (Continued)**

*The EMMES Corporation*
Rockville, MD • April 2001 – July 2006

**Senior Statistician**.

Principal Investigator, Co-Investigator, Corporate Quality Overview Team permanent member, EMMES Orientation mentor and lecturer, and EMMES University faculty.

Principal Investigator and Director of Coordinating Center for The Collaborative Islet Transplant Registry (www.citregistry.org), sponsored by the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Served on the Executive Committee and as an ex-officio member of the Scientific Advisory Committee (SAC). Responsible for the overall design, development of all Registry materials and data collection instruments, and management of this North American Research Registry plus five European centers. Responsible for leadership of team (6 FTEs), quality assurance mechanisms, summary tables, statistical analyses, reports, manuscript writing and interpretation of all results.

Responsible for summarizing support data for the first Biologics License Application (BLA) in pancreatic islets, and for helping to write and assemble the accompanying Investigator's Brochure for pancreatic islets. Responsible for interacting with subcontractors and NIH project officers from NIDDK, NCRR, and NIAID on this $4 million contract.

Won re-compete of the contract as key personnel, Principal Investigator, which was expanded from a five year period to a seven year funded period for the re-compete and new contract. (2006)

**Senior Statistician and Co-Investigator**, University of Pittsburgh, Phase I-II/III trials in Efficacy of Voice Therapy for Phonotrauma in Teachers. Responsible for guidance in study design, data collection methods and statistical analyses. Responsible for DSMB statistical analysis preparation and participation.

**Islet Transplant Senior Statistician and Co-Director and Autoimmune Senior Statistician for EMMES** on the Immune Tolerance Network. The Immune Tolerance Network is a collaborative effort that solicits, develops, implements and assesses clinical strategies and biological assays for the purpose of inducing, maintaining and monitoring tolerance in humans for kidney and islet transplantation, autoimmune diseases, and allergy and asthma. The Network is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the Juvenile Diabetes Foundation International (JDFI). Responsible for experimental design, sample size determination, case report form design, development and documentation for standard operating procedures, interim analyses, safety reports and study progress reports. Responsible for statistical analysis interpretation of results at NIAID Transplant Data and Safety Monitoring Board (DSMB).

<u>Corporate Responsibilities:</u>

**Corporate Quality Overview Team permanent member**: Senior Statistician permanent member of the Corporate Quality Overview team (CQOT). Responsible for evaluating and monitoring adherence to regulatory, corporate and project expectations of performance by conducting periodic reviews of projects. Where applicable, regulatory procedures and compliance are assessed in relation to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Good Clinical Practices (GCP) and Title 21 of the Code of Federal Regulations as it applies to clinical investigations.

**Previous Positions (Continued)**

**EMMES University faculty**: The EMMES Corporation embraces lifelong learning values and self-directed achievement in promoting excellence for all staff members. The program strives to support and assist staff improvement by maintaining, developing and enhancing professional performance both technically and managerially. Responsible for providing lectures in the Management Series (including business etiquette, professional development, and professional Recruiting). International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Good Clinical Practices (GCP) and Title 21 of the Code of Federal Regulations as it applies to clinical investigations.

**EMMES Orientation mentor and lecturer**: All new employees must attend a 12-week orientation session to learn about job responsibilities and the company. Responsible for leading orientation session in the Role of the biostatistician at EMMES and providing mentorship for new employees.

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*The Biostatistics Center, The George Washington University*
Rockville, MD • August 1996- April 2001

Overall responsibilities included statistical analyses, recruitment and outcome report generation, clinic monitoring, protocol and case report form development, study management, reporting to the Sponsor, Data and Safety Monitoring Boards and Mortality and Morbidity Review Committees, interpretation of results and report writing.

**Biostatistician and Clinical and Statistical Coordinating Center Co- Investigator** on The Prevention of Events with Angiotensin Converting Enzyme Inhibition (PEACE) trial, sponsored by the National Institutes of Health, National Heart, Lung and Blood Institute. Over 160 clinics from North America and Italy are involved in this large, simple clinical trial. Key responsibilities included coordinating the writing of protocol and manual of operations, new form development, developing study recruitment and follow-up strategies, clinic monitor duties, initiate and develop methods of communication between the Clinical and Statistical Coordinating Center (CSCC) and clinical sites, function as Region Chairman for overseeing recruitment and follow-up strategies within this region, conduct clinical site visits and submit reports as needed, identify and incorporate new software and develop programs as appropriate for the different aspects of the trial including patient adherence, communication internally and externally, and clinic monitoring, supervise CSCC staff including clinic monitors, statistical programmer, database management and administrative staff, and provide staff training on an ongoing basis, oversee the management of the PEACE Central Biochemistry Laboratory, request and review reports submitted by the Laboratory and make monthly contact with them for study updates concerning the shipping, handling and storing of blood and urine specimens. Responsible for the implementation of the PEACE protocol in Italy and oversee the management of all logistics for the mini-coordinating center located in Italy, maintain and document all study unmaskings and oversee the monitoring of protocol violations and possible adverse events reported by study coordinators. Work with the PI in designing all study reports and provide statistical programming for reporting unmasked PEACE outcomes to the Data and Safety Monitoring Board. Assist PI with the planning and execution of all study meetings including Investigator's Meetings and training sessions, attend all meetings of the Executive and Steering Committees, Data and Safety Monitoring Board, and Investigators Meetings.

**Previous Positions (Continued)**

**Operational Statistician and Project Manager** for The Neonatal Intensive Care Unit (NICU Network) sponsored by the National Institute of Child Health and Development. This Network is responsible for conducting clinical trials and epidemiological studies in neonatal medicine and was established in 1985 by NICHD. The NICU Network consists of twelve NICU clinics in the US

**Operational Statistician and Project Manager** for the In-Utero Magnesium Sulfate Exposure and Cerebral Palsy Observational Study. The primary objective will be to ascertain whether in-utero magnesium sulfate exposure is associated with a reduction in the incidence of IVH and cerebral palsy in ELBW infants. Responsible for protocol, manual and form development, recommending study design and analysis, sample size calculations, study management, statistical programming, interpretation and report writing. Study ended in 1997.

**Operational Statistician and Project Manager** for the Effects of Erythropoietin (BPO) on the Transfusion Requirements of Preterm Infants 401-1250 grams. The primary objective is to determine if the administration of EPO will decrease the average number of erythrocyte transfusions in the control group compared to the EPO group. Responsible for protocol, manual and form development, recommending study design and analysis, sample size calculations, statistical programming, study management, interpretation and report writing. Study ended in 1998.

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*The CDM Group, Inc.*
Chevy Chase, MD • 1994-1996

**Statistician**

Statistician and statistical/scientific consultant on 4 government funded studies. The studies were funded through Administration on Children, Youth and Families, the National Heart, Lung, and Blood Institute, SAMHSA, and CMHS. Responsibilities included identifying national databases for comparison with the study data, selecting appropriate statistical methods for analyses, identifying and implementing sampling strategies, providing scientific guidance on the production and editing of scientific abstracts and articles, managing and responding to scientific questions posed by consultants, writing rapid turnaround papers for Congress, providing methodology and options for the aggregation of data from state and individual agency annual reports into a national report, data analyses, interpretation of results, report writing and providing oral briefings to the Project Directors and government staff at 'brown bag seminars'.

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*Case Western Reserve University, School of Medicine, Department of Epidemiology and Biostatistics*
Cleveland, OH • 1993-1994

**Research Assistant**

Responsible for conducting in-home and phone interviews with the elderly, assessed symptoms of heart disease, blood pressure, cholesterol, diabetes, smoking, physical activity, family history, hormone use, and diet and alcohol consumption.

**Previous Positions (Continued)**

*The Cleveland Clinic Foundation, Department of General Internal Medicine*
Cleveland, OH • 1993-1994

**Research Consultant**

Assisted on two studies and responsible for medical record abstraction, determination of census tracts, data entry and data management for both studies.

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*University Hospitals, Ophthalmology Department and Emergency Medicine*
Cleveland, OH • 1992-1993

**Research Consultant**

Ophthalmology department statistical consultant on two studies,responsible for data collection, data management, statistical programming and analyses, interpretation of findings and manuscript preparation. Emergency Medicine junior statistician on their quality assurance studies. Responsibilities included software installation and training, design and database development, statistical analyses and interpretation of results.

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*Pennsylvania Department of Health and Welfare*
Harrisburg, PA • 1991-1992

**Acute Infectious Disease Epidemiology Intern**

Data analyst for 1991 Rabies data and 1991 Legionnaire's disease data. Responsible for on-site assistance and investigation of infectious disease outbreaks, outbreak questionnaire development, report writing for cases to be included in MMWR.

**Book Chapters**

*Clinical Transplants 2003*, Eds. Cecka M, Terasaki P; UCLA. Chapter 9, Close NC, Hering BJ, Anand R, and Eggerman TL. Collaborative Islet Transplant Registry (CITR).

**Publications**

Effects of hyperbaric oxygen on symptoms and quality of life among service members with persistent postconcussion symptoms: a randomized clinical trial.
Miller RS, Weaver LK, Bahraini N, Churchill S, Price RC, Skiba V, Caviness J, Mooney S, Hetzell B, Liu J, Deru K, Ricciardi R, Fracisco S, Close NC, Surrett GW, Bartos C, Ryan M, Brenner LA; HOPPS Trial Team.
JAMA Intern Med. 2015 Jan;175(1):43-52. doi: 10.1001/jamainternmed.2014.5479. PMID: 25401463

Col Brian F. Mc Crary, Lindell Weaver, LCDR Kevin Marrs, Col R. Scott Miller, Cheryl Dicks, Kayla Deru, Nicole Close, and Col Marla DeJong, *Hyperbaric oxygen (HBO2) for post concussive syndrome/chronic TBI Product summary*, UHM 2013, Vol. 40, No. 5.

Field-user acceptability evaluation of a new stick camouflage face paint formulation with and without the insect repellent DEET.
Lawrence KL, Benante JP, Close NC.
Mil Med. 2012 Nov;177(11):1322-7.

Association of HIV neutralizing antibody with lower viral load after treatment interruption in a prospective trial (A5170).
McLinden R, Paris R, Polonis V, Close N, Su Z, Shikuma C, Margolis D, Kim J.
AIDS. 2012 Jul 17;26(11):1452. doi: 10.1097/QAD.0b013e3283550b8e. No abstract available.

Robert J. McLinden, Robert M. Paris, Victoria R. Polonic, Nicole C. Close, Zhaohui Su, Cecilia M. Shikuma, David M. Margolis, Jerome H. Kim. *Association Of HIV Neutralizing Antibody With Reduction in Viral Load After Antiretroviral Therapy Interruption in a Prospectively Evaluated Cohort (A5170). AIDS;Vol.26(1);p1-9 (2Jan2012)*

Todd CS, Nasir A, Stanekzai MR, Scott PT, Close NC, Botros BA, Strathdee SA, and Tjaden J. *HIV Awareness and Condom Use among Female Sex Workers in Afghanistan: Implications for Intervention*; AIDS Care, 2011 Mar;23(3):348-56.

Lawrence K, Benante JP, Close N, and Achee N. *Evaluation of Efficacy and Duration of the Stick Camouflage Face Paint with 30% DEET Against Mosquitoes in Belize*. Operational and Public Health Entomology, The United States Army Medical Department Journal; July-September 2009, 84-90.

Close N, Alejandro R, Hering B, and Appel M. *Second Annual Analysis of the Collaborative Islet Transplant Registry*. Transplant Proc. 2007 January/February; 39(1): 179-182.

Close N, Alejandro R, Hering B, and Appel M. *Results from the Inaugural Year of the Collaborative Islet Transplant Registry*. Transplant Proc. 2005 Mar; 37(2): 1305-8.

Close NC, Hering BJ, Anand R, and Eggerman TL, for the CITR Research Group. *NIH Supported National Transplant Registry*, Cell Biochemistry and Biophysics, 40/3 Supplement, 2004.

**Publications (Continued)**

Shapiro AMJ, Ricordi C, Hering B, DiMercurio B, Lindblad R, Cagliero E, Brendel M, Robertson P, Berney T, Secchi A, Brennan D, Ramos E, Viviano L, Ryan E, Close N, Lakey J. *International multicenter trial of islet transplantation using the Edmonton protocol in patients with type 1 diabetes*. Amer J Transplantation, 2004; 4 (8): 552.

Ohls R., Ehrenkranz R., Wright L., Lemons J., Korones S., Stoll B., Stark A., Shankaran S., Donovan E., Close N., and Das A. *Effects of Early Erythropoietin Therapy on the Transfusion Requirements of Preterm infants Below 1250 Grams Birth Weight: A Multicenter, Randomized, Controlled Trial*, Pediatrics, October 2001.

*Descriptive Study of the Head Start Health Component*, Volume I-IV. Submitted by Michael Keane, Dr.P.H., Robert W. O'Brien, Ph.D., David C. Connell, Ph.D., and Nicole C. Close. M.S., U.S. Department of Health and Human Services, Administration on Children, Youth, and Families. Released to public December 1996.

*Hypertension in Hispanic Americans, American Indians and Alaska Natives, and Asian and Pacific Islander Americans*, Nicole C. Close, M.S. Scientific Coordinator, U.S. Department of Health and Human Services, NIH, NHLBI, Division of Epidemiology and Clinical Applications, February 1996.

*Blood Pressure Studies in Selected Minority Populations*, Public Health Reports Supplement, Journal of the U.S. Public Health Service, Nicole C. Close. M.S., Scientific Coordinator, Volume III, Supplement, September/October 1996.

Havas, S., Fujimoto, W., Close. N., et al., *The NHLBI Workshop on Hypertension in Hispanic Americans, Native Americans, and Asian/Pacific Islander Americans*, Public Health Reports, September/October 1996, Volume III, pp. 451-458.

**Abstracts**

Boivert D and Close N. Antibiotic Clinical Trials: Conduct and CDISC Implementation Challenges, International Society for Clinical Biostatistics, Poster. Birmingham, UK August 2016.

Vincente, JT, Weir, C, Close, N, Schumacher, M, Friede, T, Siegel, J. Gerlinger, C, Beder, R, Nakas, C, Seldrup J and Chadha-Boreham, H. Statistics in Regulatory Affairs in www.wikipedia.org; Initiative of the ISCB Statistics in Regulatory Affairs Subcomittee (SiRA SC) Poster. Birmingham, UK 2016.

Close, N. Statistical Risk Based Monitoring and Software, Invited Session, MAGI, Philadelphia, PA, May 2014.

Close, N. Statistical and Clinical Risk Based Prioritization Monitoring, Invited Oral Presentation, Society for Clinical Trials (SCT), Philadelphia, PA, May 2014.

Close, N. Statisticians Implementing Change and Cost Effectiveness in Clinical Trials Through Risk Based Prioritization Monitoring, Oral Presentation, International Society for Clinical Biostatistics, Bergen, Norway, August 19-23, 2012.

Start, F and Close N., Cross Training Within a Clinical Research Organization: Does it Work or Does it Muddy the Waters?, Oral Presentation, The Society for Clinical Trials, Miami, FL, May 20-23,2012.

Hunt, D and Close N., Implementation of Digital Pen Technology to Capture Clinical Trial Data, Oral Presentation, The Society for Clinical Trials, Miami, FL, May 20-23, 2012.

Close, N. Successful Statistical Consulting: The Practicalities, Joint Statistical Meetings (JSM), American Statistical Association, Miami Beach, Florida, July 30–August 4, 2011.

**Abstracts (Continued)**

Close, N. Retention Strategies, Methodology and Considerations: An Example from a 3.5 Year Prospective, Closed, Combined Community/Workplace Clinical Epidemiological Study in Kenya, Oral Presentation, The Society for Clinical Trials, Vancouver, BC, May 15-18 2011.

Apostolides, JK., Sing, Kieko, Hunt, D., Close, N. The Effect of Short Messaging Service (SMS) Use for Subject Compliance in Clinical Trials, Oral Presentation, The Society for Clinical Trials, Vancouver, BC, May 15-18, 2011.

Start, F. and Close, N. Close-out Gets the Attention: But who turns out the lights?, Poster, The Society for Clinical Trials, Vancouver, BC, May15-18, 2011.

Yau, Tilly, Close, N. Facilitating Research: Project Managers are Worth Their Weight in Gold, Invited Session, The Society for Clinical Trials, Vancouver, BC, May 15-18, 2011

Close, N. Outsourcing Biostatistics and Statistical Programming: Essentials of Vendor Audits, Poster, The Society for Clinical Trials, Atlanta, GA, May 2-4, 2009.

Hunt, D. and Close, N. Building a Clinical SAS® Group from the Ground Up, Oral Presentation, The Society for Clinical Trials, Atlanta, GA, May 2-4, 2009

Hunt, D. and Close, N. SAS® Program Testing and Validation for Clinical Trials, Oral Presentation, The Society for Clinical Trials, May 2-4, 2009.

Close, N. and Das, A. The Importance of Capacity Building and Transference of Knowledge in Clinical Trials: A Biostatistical Example, Poster, The Society for Clinical Trials, Atlanta, GA, May 2-4, 2009.

Close, N. Invited Session Speaker on Strategies for Successful Statistical Consulting/Collaboration in Drug and Vaccine Discovery and Development, American Statistical Association, ENAR, San Antonio, TX, March 15-18, 2008.

Peel, S., Malia, J., Close, N., Scott, P., Shriver, K., Bailer, R., Michael, N., Graham, B., and O'Connell, R. HIV-1 Western Blot False Positivity is Common and Associated with Low Pre-existing AD5 Titer Among Recipients of a DNA Prime/rAD5 HIV-1, ADS Vaccine 2008, Cape Town, South Africa, October 13-16, 2008.

Hunt, D. and Close, N. Building a Clinical SAS Programming Group from the Ground Up, SouthEast SAS® Users Group 2008 Conference, St. Pete Beach, Florida, October 19-22, 2008.

Close, N. The Best Of Both Worlds: Medical Science And Statistics, Topic Contributed Session presentation, Joint Statistical Meetings, American Statistical Association, Denver, CO, August 3-8, 2008.

Close, N. Uncle Sam Wanted Me: A Biostatistician's Career Move, Oral Presentation, The Society for Clinical Trials, St. Louis, MO, May 18-21, 2008.

**Abstracts (Continued)**

Close N. A Look at the Statistical Analysis Plan, Oral Presentation, The Society for Clinical Trials, Montreal, Canada, Oral Presentation, May 20-23, 2007.

Close N. and Ovington L. Best of Friends: A Look at the Relationship Between the Biostatistician and Data Manager for Collecting Quality Data, Oral Presentation, The Society for Clinical Trials, Montreal, Canada, Oral Presentation, May 20-23, 2007.

Close N. Creating and Implementing a Data Sharing Agreement Between Coordinating Centers, Oral Presentation, The Society for Clinical Trials, Orlando, Florida, May 21-24, 2006.

Close N., Alejandro, R., Hering B. and Appel, M. Results From The 2005 Annual Report Of The Collaborative Islet Transplant Registry (CITR). Poster, 2005 Rachmiel Levine Diabetes and Obesity Symposium, Los Angeles, California, November 9-12, 2005.

Close, N., Yaffe, A. and Lindblad, A. Lessons Learned During the Internal Auditing of Clinical Trials and Procedures, Poster, 26th Anniversary Meeting of the Society for Clinical Trials, May 22-25, 2005.

Hunt, D., Wease, S. and Close, N. Improving the Quality of Data Using and Internal Data Review Process, Poster, 26th Anniversary Meeting of the Society for Clinical Trials, May 22-25, 2005.

Close N, Hering B, and Eggerman T for the CITR Investigators. Results from the Inaugural report of the Collaborative Islet Transplant Registry (CITR). Oral Presentation, American Transplant Congress (ATC) 6th Joint Annual Meeting of the American Society of Transplant Surgeons (ASTS) and American Society of Transplantation (AST), Seattle, Washington, May 21-25, 2005.

Close N., Hering B. and Eggerman T. Results from the Inaugural Year of the Collaborative Islet Transplant Registry (CITR). Oral Presentation and Poster, 2004 Rachmiel Levine Diabetes and Obesity Symposium, Los Angeles, California, October 6-9, 2004.

Hering BJ, Close NC, and Eggerman TL. Results from the Inaugural Year of the Collaborative Islet Transplant Registry (CITR). Poster, XX International Congress of The Transplantation Society, Vienna, Austria, September 5-10, 2004.

Hering B, Close N, Anand R, and Eggerman T. Collaborative Islet Transplant Registry (CITR). Poster, American Diabetes Association (ADA) 64th Annual Scientific Sessions, Orlando, Florida, June 4-8, 2004.

Shapiro J., Ricordi C., Hering B., DiMercurio B., Lindblad R., Alejandro A., Cagliero E., Brendel M., Robertson P., Berney T., Secchi A., Brennan D., Ramos E., Viviano L., Ryan E., Close N., and Lakey J. International Multi-Center Trial of Islet Transplantation Using the Edmonton Protocol in Patients with Type 1 Diabetes. Poster, American Diabetes Association (ADA) 64th Annual Scientific Sessions, Orlando, Florida, June 4-8, 2004.

**Abstracts (Continued)**

Lakey JRT, Ricordi C, Hering B, DiMercurio B, Lindblad R, Olack B, Reems JA, Ansite J, Brandhorst D, Bertuzzi F, Berney T, Viviano L, O'Neil J, Close N, Shapiro AMJ. Standardization of human islet isolation procedures for a multicenter transplant trial. 64th Scientific Sessions of the American Diabetes Association, Orlando, FL, June 4-8, 2004.

Shapiro J, Ricordi C, Hering B, DiMercurio B, Lindblad R, Cagliero E, Brendel M, Robertson P, Berney T, Secchi A, Brennan D, Ramos E, Viviano L, Ryan E, Close N, Lakey J. International multicenter trial of islet transplantation using the Edmonton protocol in patients with type 1 diabetes. [Abstract 1434] American Transplant Congress, Boston, MA, May 14-19, 2004.

Wease S, Neyzari O, and Close N. Minimizing Data Entry Workload, An Example from the Collaborative Islet Transplant Registry (CITR). Oral Presentation, 25th Anniversary Meeting of the Society for Clinical Trials (SCT), New Orleans, Louisiana, May 23-26, 2004.

Hering B, Close N, Anand R, and Eggerman T. Collaborative Islet Transplant Registry (CITR). Poster, American Transplant Congress (ATC) 5th Joint Annual Meeting of the American Society of Transplant Surgeons (ASTS) and American Society of Transplantation (AST), Boston, Massachusetts, May 14-19, 2004.

Eggerman T, Close N, and Hering B. Collaborative Islet Transplant Registry (CITR). Collaborative Islet Transplant Registry (CITR). Collaborative Islet Transplant Registry (CITR). Oral Presentation, Islet Summit Conference Series 2003, Miami Beach, Florida, November 13-16, 2003.

Eggerman T, Close N, and Anand R. Collaborative Islet Transplant Registry (CITR). Oral Presentation, 4th Annual Rachmiel Levine Diabetes Symposium: Advances in Islet Cell Biology, 2003, Universal City, California, November 4-8, 2003.

Close, N., and DiMarino, M. A Look at the Odds Ratio Versus the Relative Risk, abstract/ poster, The Society for Clinical Trials, July 2003, London, England.

Close, N., Yaffe, A., Brandt, D., and Nelson, K. Audits Are Not for Clinical Centers Only: Internal Corporate Auditing of Clinical Trials and Procedures, abstract/ poster, The Society for Clinical Trials, July 2003, London, England.

Hering BJ, Close NC, Anand R, and Eggerman TL, for the CITR Research Group. NIH Supported National Transplant Registry, Oral Presentation, 9th Annual International Pancreas and Islet Transplant Association Congress, Dublin, Ireland July 9-11, 2003.

Hering BJ, Close NC, Anand R, and Eggerman TL, for the CITR Research Group. NIH Supported National Transplant Registry, Presentation, 3rd Annual Rachmiel Levine Diabetes Symposium: Advances in Islet Cell Biology, 2002, Anaheim, California, October, 2002.

**Abstracts (continued)**

Close. N, and Verter, J. for the PEACE Investigators, The Importance of Conducting a Complete Randomization Audit During Recruitment Closeout in a Large, Simple Clinical Trial: The Prevention of Events with Angiotensin Converting Enzyme Inhibition (PEACE) Trial, abstract/ poster, The Society for Clinical Trials, May 2000, Denver, Colorado.

Close. N, Green, J., Curnow, E., and Vetter, J. for the PEACE Investigators, Creating and Managing a Morbidity and Mortality Review Committee (MMRC) in a Large, Multi-Center International Clinical Trial, abstract/ poster, The Society for Clinical Trials, May 2000, Denver, Colorado.

Close. N, Gagne, W., Fye, C., and Verter, J. for the PEACE Investigators, The Use of Capsule Testing as a Quality Control (QC) Method in a Large, Simple Clinical Trial, abstract/ poster, The Society for Clinical Trials, May 2000, Denver, Colorado.

Curnow, E., Close. N, and Verter, J. for the PEACE Investigators, Monitoring Protocol Violations in a Large, Simple Trial, abstract/poster, The Society for Clinical Trials, May 2000, Denver, Colorado.

Fye, C., Gagne, W., Jones, M., Raisch, D., Close, N., and Verter, J. for the PEACE Investigators, A Large Simple Trial: Challenges Encountered by the PEACE Pharmacy Coordinating Center, abstract/ poster, The Society for Clinical Trials, May 2000, Denver, Colorado.

Close, N., Lorimer, A, Maggioni, A., and Verter, J. for the PEACE Investigators, Remote Mini Data Coordinating Center (DCC) Within a Large, Simple, Multicenter International Clinical Trial, abstract/ poster, The Society for Clinical Trials, April 13, 2000, Toronto, Canada.

Close, N., Curnow, E., Rosenberg, Y., and Verter, J. for the PEACE Investigators, Clinic Certification in a Large, Simple Trial, abstract/ poster, The Society for Clinical Trials, April 13, 2000, Toronto, Canada.

Close, N., and Verter, J. for the PEACE Investigators, Use of a Certification Quiz for Research Coordinators in a Large, Simple Clinical Trial, abstract/ poster, The Society for Clinical Trials, May 4, 1999, Anaheim, California.

RK Ohls, RA Ehrenkranz, JA Lemons, SB Korones, BJ Stoll, AR Stark, LL Wright, S Shankaran, EF Donovan and NC Zimmerman for the NICHD Neonatal Research Network, A Multicenter, Randomized, Double-Blind, Placebo Controlled Trial of Erythropoietin Administration to Preterm Infants <1251 grams Birthweight, abstract, The Society of Pediatric Research, San Francisco, California, May 1-4,1999.

RK Ohls, RA Ehrenkranz, JA Lemons, SB Korones, BJ Stoll, AR Stark, LL Wright, S Shankaran, EF Donovan and NC Zimmerman for the NICHD Neonatal Research Network, A Multicenter, Randomized, Double- Blind, Placebo Controlled Trial of Erythropoietin Administration to Preterm Infants <1251 grams Birthweight, abstract, The Western Society of Pediatric Research, Carmel, California, January 27-30, 1999.

**Abstracts (continued)**

Verter, J., Domanski, M., Pfeffer, M., Rosenberg, Y., Cleary, P., Geller, N., Zimmerman, N., and Braunwald, E., for the PEACE Investigators, Issues of Protocol Modification After Initiation of a Large Multi-Center Trial abstract, The Society for Clinical Trials, May 18, 1998, Atlanta, Georgia.

Mele, L., Verter, J., Temprosa, M., Katsikiotis, V., Langer, J., Levy, A., Parrish, A., Powers, T., Younes, N., and Zimmerman, N. for the NICHD Research Network, Experiences of a Biostatistical Coordinating Center for a Network of Low Birth Weight Infant Research Studies, abstract, The Society for Clinical Trials, May 18, 1998, Atlanta, Georgia.

Zimmerman, N., Cleary, P., Verter, J., Domanski, M., Rosenberg, Y., for the PEACE Investigators, Case Report Form Design and Version Updates in a Large, Simple Clinical Trial, abstract, 1998, Drug Information Association, Washington, D.C.

Close, N., O'Brien, R., Connell, D., Keane, M., and Griffin, J., Use of Multiple Data Sources for Determining Head Start Immunizations, abstract, 30th National Immunization Conference, The Centers for Disease Control and Prevention, April 1996, Washington, D.C.

Close, N., O'Brien, R., Keane, M., Connell, D., and Griffin, J., Meeting Nutritional Needs and Providing Education for Head Start Children and Parents, abstract, 1996 APHA Meeting, New York, New York.

Keane, M., O'Brien, R., Close, N., Connell, D., and Griffin, J., The Integration of Health Services into Early Childhood Education: Lessons from Head Start, abstract, 1996 APHA Meeting, New York, New York.

Close, N,. and Bowlin, S. Knowledge, Attitudes and Practices of Cholesterol Management for Physicians and Nurses, Epidemiology Contributed Papers: Risk Factors and Behaviors, abstract, 1995 APHA Meeting, San Diego, California.

Connell, D., Close, N., Hailey, L., and Griffin, J., Head Start Children's Health Conditions, abstract, 1995 APHA Meeting, San Diego, California.

O'Brien, R., Close, N., Jacobs, M., and Griffin, J., Head Start's Relationship with Community Health Providers, Symposium: Head Start's Relationship with Community Providers, 1995 APHA Meeting, San Diego, California.

**Workshop Faculty/Invited Speaker**

Risk-Based and Centralized Monitoring: Implementation, MAGI. Multiple years/locations. 2013-2016

Non-Inferiority Trials: Issues and Applications, Society for Clinical Trials, Montreal, Quebec, May 2015.

Aerospace Medical Association, Research and Practices, Workshop Presenter (Research and statistical methodology), Chicago, IL, May 2013.

Recent Updates and Overview of Non-Inferiority Trials, Society for Clinical Trials, Vancouver, BC, May 2011.

Study Designs, International Society for Clinical Biostatistics, Copenhagen, August, 2008.

Non-Inferiority Trials, Society for Clinical Trials, St. Louis, MO, May, 2008.

Essentials of Clinical Trials Part I, Society for Clinical Trials, May 2003-2007.

Essentials of Clinical Trials Part II (Biostatistics), Society for Clinical Trials, May 2004-2007.

**Awards and Recognitions**

2014-current Omnicron Delta Kappa, The National Leadership Honor Society, Alumni Member. Inducted 2014.

2012 Tech Council of Maryland Frederick County Awards, Small Business of the Year

2012 Nominee for Fellowship to The Society for Clinical Trials, Peer Nomination.

2011 Best Places to Work in Frederick County Maryland, Small Business Award.

2011 Entrepreneur of the Year for Women in Technology, Dr. Nicole C. Close, Washington, DC.

2011 Maryland Chamber of Commerce Finalist for Small Business of the Year. EmpiriStat, Inc.

2011 Frederick County (MD) Chamber of Commerce Finalist for Small Business of the Year. EmpiriStat, Inc.

Reach for the Stars Nominee 2007, Women in Defense (WID) Greater Frederick Chapter, nominee for exceptional leadership, mentorship, and ability to generate enthusiasm among our local youth in the math, science, and technical fields.

Young Investigator Scientific Achievement Award, City of Hope National Medical Center, Duarte, California, October 6, 2004.

**DSMBs**

Blinded Sponsor Statistician. XXXXXXXXX Crestovo, 2016-current.

Blinded Sponsor Statistician. Efficacy and Safety study of cenicriviroc for the treatment of non-alcoholic steatohepatitis in adult subjects with liver fibrosis. Tobira, 2014-2016.

Unblinded Statistician, A Multi-Center, Double-Masked, Parallel-Group, Placebo-Controlled Study to Assess the Efficiency and Safety of XXXX as Therapy in Subjects with XXXX, Lux Biosciences, Inc. 2011-2013.

Unblinded Statistician, Efficacy and Safety of XXXXXXXXXXX, Cerecor, 2013.

Ex-Officio, Statistician and Clinical Trial Specialist, 2005-2006, Phase I- II/III trials in Efficacy of Voice Therapy for Phonotrauma in Teachers, University of Pittsburgh, NIDCD.

DSMB Member, Clinical Trial Specialist, 2001-2006, Prevention of Transmission of Mutants Streptococci from Mothers to Children, University of Pittsburgh, School of Dental Medicine, NIH DE 13534.

Ex-Officio, Statistician, 1996-2001, The Prevention of Events with Angiotensin Converting Enzyme Inhibition, The Biostatistics Center, The George Washington University, NHLBI.

**Peer Review Grant Panels**

2016 Grant Reviewer. National Institutes of Health, National Eye Institute. Coordinating Center Grants.

2016 Scientist Review. Seven Panel Names Embargoed Defense Health Program, Defense Medical Research and Development Program, Department of Defense, Congressionally Directed Medical Research Programs.

2015 Scientist Reviewer. Five Panels. Defense Health Program, Defense Medical Research and Development Program, Department of Defense, Congressionally Directed Medical Research Programs.

2014 Scientist Reviewer Three Panels. Defense Health Program, Defense Medical Research and Development Program, Department of Defense, Congressionally Directed Medical Research Programs.

2013 Scientist Reviewer Two Panels. Defense Health Program, Defense Medical Research and Development Program, Department of Defense, Congressionally Directed Medical Research Programs, Panel Membership Embargoed.

2012 Scientist Reviewer. Two Panels. Defense Health Program, Defense Medical Research and Development Program, Department of Defense, Congressionally Directed Medical Research Programs, Gulf War Illness Research Panel.

2010 Scientist Reviewer. The United States Army Medical Research and Materiel Command Congressionally Directed Medical Research Programs, Rehabilitation Panel.

2009 Scientist Reviewer. The United States Army Medical Research and Materiel Command Congressionally Directed Medical Research Programs, CRI-1 Panel Traumatic Brain Injury

2006 National Institutes of Health, National Heart. Lung, and Blood Institute, Coordinating Center Peer Review Panel.

**Teaching Experience**

Fall 2008: Hood College Graduate Adjunct Faculty, Course: Biostatistics for Regulatory Professionals, Regulatory Affairs Graduate Program, Frederick, Maryland.2007, 2008: Biostatistics Guest Lecturer, Regulatory Affairs Graduate Program, Hood College, Frederick, Maryland.

2003, 2004, 2005, 2006, 2008, 2010: Educational Testing Service (ETS): College Statistics Reader for The College Board's Advance Placement (AP) Statistics Test. Responsible for seven days of on-site grading of essay statistics questions on the College Board Advance Placement Statistics Test, June,

Spring 2004, 2005, 2006 and Fall 2004, 2005, 2006: Department Teaching Assistant, School of Public Health and Health Services, The George Washington University, Washington, D.C.

Spring 2006, Fall 2006: Department Teaching Assistant, School of Public Health and Health Services, The George Washington University, Washington, D.C. Responsible for teaching small group sessions exploring experimental health designs and study design issues. MPH required course.

Spring 2003: Department Teaching Assistant, School of Public Health and Health Services, The George Washington University, Washington, D.C. Responsible for two separate courses. Statistical Software System programming (SAS) course for Master of Public Health Students. Database development course using ACCESS for the Master of Public Health Students.

Fall 2002: Adjunct Faculty, School of Public Health and Health Services, The George Washington University, Washington, D.C. Responsible for teaching Biostatistics course (PUBH 233) for Master of Science Exercise Science students.

Fall 2000, Spring 2001: Adjunct Faculty, School of Public Health and Health Services, The George Washington University, Washington, D.C. Responsible for teaching 9 lecture weeks to Physician Assistant students on statistical methods and research. Class title: Epidemiology and Biostatistics for Physician Assistants: Research Methods I and II.

Spring 2000, Spring 2001: Adjunct Professor, Statistics Department, The George Washington University, Washington, D.C. Responsible for teaching first section of course (STAT 127) covering data presentations, numerical summary measures, rates and standardization, life tables, probability, theoretical probability distributions, sampling distributions and confidence intervals.

1994-1996: In-house consultant at The CDM Group, Inc. provided statistical seminars to senior level managers twice per month. Responsible for identifying theoretical and practical areas for introduction, developing lesson plans, and presenting the material to a non-statistical audience.

**Professional Memberships**

Current Active Member:
***American Statistical Association*** (ASA)
(Committee Chair: 2005, 2008)

***The Society for Clinical Trials***
(Board of Directors Member 2010-2013, Development Committee Co-Chair 2010-2013, Finance Committee Member (multiple years), Education Committee Co-Chair, pre-Conference Workshop Faculty [multiple years])

***International Society for Clinical Biostatistics***
(pre-Conference workshop faculty, Education Committee Member, Book Reviewer)
Secretary: SiRA, Statistics in Regulatory Affairs Subcommittee (2014-current)

Omnicon Delta Kappa, The National Leadership Honor Society,

Past Memberships:
Drug Information Association (DIA)
Regulatory Affairs Professionals Society (RAPS)
CDISC DC Implementation Network, Washington, DC; Steering Committee Member (2006-2008)

**Organizations**

American Legion Auxiliary Gold Star Unit #191 (Historian, 2004-2005, 2005-2006; Chaplain 2006-2007; Vice President 2007-2008; Western Maryland District Girls State Representative 2006-2007, National Visit Coordinating Committee (2007, 2008), Western Maryland District Chaplain 2007-2008, Order of the Eastern Star Chapter 121, Juniata College Alumni Mentor (ongoing), Juniata College Elected Alumni Council Member (2005-2008) and Chair of the Juniata Career Team and Job Shadow Program (2006-2008).

**Board of Directors and Board of Trustees**

Juniata College Center for Entrepreneurial Leadership (JCEL), Board of Directors Member (2012-2014), Board of Directors Co-Chair (2014-2015), Board of Directors Chair (2015-current)

Southern Shores Boat Club, Board of Directors, Officer (Secretary), Event Coordinator (2014-current)

Juniata College, Huntingdon, PA. Alumni Trustee, Term 2013-2016.

Juniata College, 2016 Strategic Planning Committee and Writer, Trustee Member (2015)

**Interests**

Scuba Diving (PADI Open Water Advanced Diver), travel, cooking, reading, football.