

## **Biostatistics and Clinical Research Core | UNC Center for Gastrointestinal Biology and Disease**

The Biostatistics and Clinical Research Core provides state-of-the-art services from conception through completion of a project. Starting with consultation, study design, and data management, the Core then assists with the collection, analysis and integration of biological and epidemiological data. It provides assistance with database implementation and maintenance, web applications, validated and secure data capture, quality control, and statistical analysis. The Core provides an interface between basic scientists, clinical researchers, and informatics specialists to support translational research. Clinical research support includes IRB submission, contract negotiation, regulatory issues, IND, and tissue procurement. The Core maintains access to a set of large administrative databases utilized by members of CGIBD as well as trainees.

### **Services**

Consultation on biostatistics and study design during the design, conduct and analysis phases of research.

Data collection and data management services including forms development, enrolment tracking, data capture, data validation, data security and confidentiality, database closure, statistical programming, application development.

Access to large claims databases such as IMS Pharmedics, MarketScan and Medicare

Clinical research support through regulatory advice, contract negotiations, and data and specimen collection provided by a team of experienced study coordinators.

Training and education about sample size and power calculations, study design and analysis.

### **Rates**

Core services are performed on a fee-for-service basis. Center members are entitled to 8 hours of the core without charge. The hourly rate for members, non-members and corporate users are listed below.

## People

### Evan S. Dellon, MD, MPH, Core Director

Evan Dellon is Professor of Medicine and Adjunct Professor of Epidemiology at the University of North Carolina in Chapel Hill. Dr. Dellon received his undergraduate degree from Brown University and his medical degree from Johns Hopkins School of Medicine. He completed internship and residency in Internal Medicine at Massachusetts General Hospital. He performed a clinical and a research fellowship in Adult Gastroenterology at UNC, during which he also received a Masters of Public Health degree in Epidemiology from the UNC School of Public Health. His current research, focuses on optimizing the diagnosis, characterizing the epidemiology, studying the pathogenesis, and refining the treatment and monitoring of eosinophilic esophagitis (EoE), with the overall goal of improving patient care and outcomes in EoE. He has extensive experience in clinical, epidemiologic, and translational research, including multiple collaborations with CGIBD members. His work spans single and multicenter clinical trials, prospective cohort studies, device studies, and biobank/registry studies. He has deep familiarity with the data management and bioinformatics strategies necessary for successful translational of research to the clinical realm, and many of his past and ongoing projects have utilized CGIBD Core services.

### Susan E. Moist, MPH, CCRP, Director of Clinical Trials Operations

Susan Moist is the director of clinical trials for the UNC Center for Esophageal Disease and Swallowing (CEDAS) at UNC and has expanded her role to the CGIBD. She has extensive experience with study start-up, regulatory issues, and project management for multiple studies including clinical trials, device studies, diagnostic investigations, and tissue procurement and biobanking studies pertaining to GI diseases. She has worked extensively with multiple CGIBD members.

### Chelsea Anderson, PhD, MPH, Biostatistician

Chelsea Anderson is a Biostatistician with CGIBD. She completed her PhD and postdoctoral training in Epidemiology at the UNC School of Global Public Health. She has a background in epidemiologic methods and data analysis and management. Her experience includes analyses of data from prospective cohorts, large administrative databases, and clinical studies.