



JOHNS HOPKINS BIOSTATISTICS CENTER (JHBC)

ROLE OF OFFICE

Johns Hopkins Institute for Clinical and Translational Research (ICTR) Biostatistics Program is part of the Quantitative Methods Core that *provides a biostatistics service organization to support Johns Hopkins biomedical scientists in clinical and translational research.*

The ICTR Biostatistics Program is an integral part of the Johns Hopkins Biostatistics Center, the applied arm of the world-renowned Department of Biostatistics. JHBC's well-coordinated team provides biostatistics and data management expertise to Johns Hopkins Medical Institutions (JHMI) and external organizations in support of research, education, and service.

Biostatistics consultations focus on research study design and protocol development (including sample size justification, randomization, sampling, development of statistical analysis plans), statistical analysis and interpretation, manuscript and report preparation, independent statistical reviews, fully automated and reproducible reports, including for DSMB, and advanced computing and innovative methods.

Data management consultations include reviews of database design and data collection instruments, programming and development of analyzable datasets from the EPIC electronic medical record database, development of custom data collection systems, preparing data for analysis and reporting (including extracting and merging data from multiple sources, creating analytic datasets from raw data, data reconfiguration and formatting), administration, access and support to the REDCap (Research Electronic Data Capture) web application

Our distinct features include:

- A coordinated team of data managers/programmers and biostatisticians allows for continuity of service
- We offer access to world-class biostatistics faculty experts and innovative methods
- EPIC/EMR and "big data" experience makes us effective collaborators in clinical research
- Our "workflow" programming approach emphasizes auditability and scientific reproducibility

These consultations are provided to the Hopkins Research Community, including faculty, staff, pre-doctoral and post-doctoral researchers, through the following key activities:

- Three times a week In-person 30-minute walk-in consultations for short questions
- Extended (up to 5 free hours) biostatistical and/or data management consultations
- ICTR studio sessions
- Educational activities, such as additional resources to ICTR-sponsored Scholar Programs: KL2 (postdoctoral) and TL1 (predoctoral) Scholar Programs, and Introduction to Clinical Research course
- Professional development and sharing of best practices through the Community of Biostatisticians (since 2015); participation in the ICTR Data Management Workgroup

PERFORMANCE IN THE PAST YEAR

- In 2018, *the Biostatistics Program provided free support for 291 requests* to 272 researchers. We also conducted *275 ICTR walk-in sessions*.
- The majority of these consultations were for SOM researchers (67% of requests and 61% of walk-in sessions); Assistant professors received 8% and fellows and post-docs received 27% of the ICTR request consultations.
- ***Biostatistics Center hosted*** a one-day showcase in December of 2018 to highlight JHBC's work and to improve networking across research areas. This event included introductions by the ICTR director, Dr. Daniel Ford, and the Department of Biostatistics chair, Dr. Karen Bandeen-Roche, as well as prominent clinical and public health researchers who have collaborated with JHBC over the years. The showcase highlighted the center's biostatistics and data management expertise and capacity in support of clinical and translational research.
- In 2018, JHBC provided data management and biostatistics support for the inaugural EPIC Faculty Scholars Program (EFSP). The goal of the program is to support clinical research teams to develop and publish projects using EPIC database. In particular, JHBC consultants worked with four research teams in 2018 to address the following research questions: readmission outcomes post renal transplantation, utility of follow-up visits for acne treatment, prevention of cesarean section for first-time delivery and the role of diet in Type 2 Diabetes/Pre-diabetes.
- Major grant funding obtained:
In 2018, the center assisted Dr. Dean Wong, Professor and Director of the High Resolution Brain PET Imaging, with a successful competitive renewal of his R01 that aims to quantify the alpha-7 subtype of the nicotinic acetylcholine receptors (nAChR) and alpha-4 beta-2 subtype nAChR in subjects with schizophrenia.

NEW DEVELOPMENTS FOR UPCOMING YEAR

In 2019, we will continue to provide free webinars and workshops of interest to ICTR researchers as offered by the American Statistical Association and ones organized and developed by JHBC.

We will also host additional educational events, which will be deployed through our continuous work with Community of Biostatisticians and will be open to all JHU and UMB scientists interested in developing new knowledge and skills in specific areas. These will include events that focus on specific analytic topics, day-long workshops, brown-bag seminars and an annual symposium to stimulate and engage debate on specific statistical topics of widespread interest.

Building on the leading work in this area by the Department of Biostatistics, the center will help create a specialization on CT Biostatistics. This will be freely available across the CTSA network and beyond.

The Center biostatisticians will collaborate with the Trial Innovation Center funded by the NCATS by participating in consultations to JHMI and external researchers on clinical trial planning and design.

We will continue to support the EFSP projects for the second cohort of clinical researchers who were selected in the program.

INCORPORATION OF SERVICES INTO GRANT APPLICATION

The Biostatistics Program supports grant applications through requests submitted through its portal. These consultations include study design, sample size justification and development of the statistical analysis plan. Investigators should contact the program as early as possible so that timely and successful support for grant applications can be provided. JHBC typically requests having at least three weeks prior to the internal review deadline for new grant submissions.

JHBC can provide support letters that describe the planned level of support for the grant application and outline available resources for budget justification. Researchers should notify their consulting biostatistician if such a letter is needed.

BEST WAY TO WORK WITH PROGRAM

Biostatistical and data management requests can be submitted through the ICTR Biostatistics Program portal at https://ictr.johnshopkins.edu/programs_resources/programs-resources/clinical-research-units/biostatistics-program/.

ICTR Requests are assigned on a rotating basis among masters and PhD biostatistics and data management faculty. Researchers should expect up to 5 business days between placing a request and

initial contact. Consultations are free up to 5 hours per researcher project. If the work requires additional consultation, beyond these 5 hours, researchers can consider a fee-for-service contract with the JHBC. For scientific questions, investigators can contact Dr. Gayane Yenokyan, Executive Director, JHBC (gyenoky1@jhu.edu). Administrative inquiries should be directed to Ms. Erica Tunstall (jhbc@jhu.edu)