



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 University 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, and independent statistical reviews.

Data management consultations include reviews of database design and data collection instruments, programming and 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.

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

- 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
- ICTR Protocol Review Committees
- 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 2017, *the Biostatistics Program provided free support for 367 requests to 295 researchers. We also conducted 264 ICTR walk-in sessions.*

- The majority of these consultations were for SOM researchers (70% of requests and 56% of walk-in sessions); Assistant professors received 25% and fellows and post-docs received 30% of the ICTR request consultations.
- *Biostatistics Program hosted 10 webinars* on topics important for clinical and translational researchers, such as statistical methods, scientific transparency and reproducibility, data science and data management. These webinars included a total of 148 registrations for 93 registrants from basic scientists to clinical and translational researchers across Johns Hopkins.
- 2017 survey indicated researchers' appreciation for timely and effective service (*85% of responders satisfied or very satisfied*) and 86% would recommend Biostatistics Program service to others.

CHANGES IN THE PAST YEAR

As the Community of Biostatisticians continued to develop and expand in the past year, the Biostatistics Program has been active in leading these efforts. Mr. Joshua Betz, a Research Associate, has been working to develop and share resources on best practices in data science. He also organizes educational opportunities within the Biostatistics Program that are useful to the community's support of clinical research.

Dr. Leah Jager joined the Biostatistics Program in 2018. She is an Assistant Scientist in the Department of Biostatistics and teaches in the undergraduate Program in Public Health Studies. She is one of the biostatisticians who provides free walk-in consultations.

NEW DEVELOPMENTS FOR THE UPCOMING YEAR

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.

JHBC is planning to host biostatistics and data management extended help sessions in fall of 2018. The goal is to provide additional resources and topic-specific help to clinical and translational researchers in a roundtable format. Preregistration will be required.

A JHBC mini-symposium is being planned for late 2018 to highlight JHBC's work and to improve networking across research areas. This event will bring together researchers across Johns Hopkins and will showcase the biostatistics and data management expertise and capacity in support of clinical and translational research.

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. Nita James (jhbc@jhu.edu)