

UCSF Department of Surgery (DoS) Biostatistics Core (BC)

Mission

The mission of the Biostatistics Core is to provide DoS investigators – both faculty and learners – expert and innovative statistical support to design and conduct rigorous research. A full range of services is available, including:

- i. Assistance with data analysis and interpretation
- ii. Performing power calculations and development of statistical analysis plans
- iii. Preparation of the statistical portions of abstracts, presentations, and manuscripts
- iv. Development of novel statistical methodology

Submission and Review Process

All requests for services must be submitted by completing the online Biostatistics intake form (https://ucsf.co1.qualtrics.com/jfe/form/SV_b3Hir5MDdXhGUEI). Please provide as much information as possible to facilitate expeditious review. Prior to consultation, please take the time to review the following resources:

<u>Downloadable Instruction</u> for Researchers-Creating a Dataset

Abbreviated Instructions for Researcher-Creating a Dataset

Prioritization and Timelines

All proposals will be reviewed by the DoS Biostatistics Core. Priority will be given to (1) residents and fellows and (2) unfunded faculty seeking help with grant submissions.

We urge investigators to contact the DoS Core early, well before any deadlines, to ensure adequate time for consultation, planning, and/or analyses. The DoS Core may decline to undertake a project for which they are unable to meet a stipulated deadline. The DoS Core will estimate the required time to complete the task or project.

- Abstract submission must submit at least four to six weeks prior
- o Grant submission must submit at least six to eight weeks prior

Inquiries

The Biostatistics Core welcomes and encourages inquiries. We will handle special circumstances or considerations on a case-by-case basis. Please send an email to DoSBiostathelp@ucsf.edu. You will either receive a response or someone from the DoS Core will contact you.

Authorship and Acknowledgement of DoS Biostatistics Core

It is expected that the DoS Biostatistics Core staff will be strongly considered for authorship for all abstracts and manuscripts for which they have provided meaningful statistical support. Authorship should be discussed among the investigator, his/her mentor (if applicable) and the DoS Biostatistics Core staff at the initiation of any project. The discussion should be revisited at the end of the project.

The support of the Department of Surgery should also be acknowledged. Possible language for the acknowledgement follows but if these do not seem appropriate for a particular situation, please propose an alternative for review and approval by emailing DoSBiostathelp@ucsf.edu.

If DoS Biostatistics Core staff are authors:

"A.S. (or appropriate initials) is part of the Biostatistics Core that is generously supported by the UCSF Department of Surgery."

If the Biostatistics Core staff are not authors:

"Statistical support was expertly provided by the Biostatistics Core which is funded by the UCSF Department of Surgery."

Free Services

- <u>Residents or fellows</u> (defined in Appendix): 20 total hours during their residency or fellowship, including time spent by both the Core Director and/or senior statisticians on the planning (excluding initial consultation) and execution of the project.
 - Residents will need to identify a mentor at project initiation who will be responsible for charges beyond the free allocation.
 - Requirement for services beyond 20 hours or for a disproportionate effort by the Core Director will incur charges (see Fee Structure section).
 - Biostatistics Core staff will review project status with resident and mentor on a regular basis and prior to incurring any charges. Notification will be sent at 15 hours and again at 18 hours of utilization.

• <u>Any faculty member</u> (defined in Appendix): One free consultation per year; three free lifetime consultations

- Core director will determine, based on the intake form, which member of the Biostatistics Core will conduct the consultation.
- A consultation is any interaction / discussion that takes more than 15 minutes of time by any member of the Biostatistics Core.
- If a project involves more than one faculty member, consultation must be attributed to one person. Attribution cannot be divided between / among faculty.
- Personnel who work with faculty are not eligible for an independent allocation (please refer to Appendix for personnel classification).

• Junior faculty: 10 hours/grant for grant submission; maximum 30 hours lifetime allocation

- Junior faculty are defined according to the NIH designation of New or Early Stage Investigator (defined in Appendix).
- Junior faculty will need to identify a mentor at project initiation who will be responsible for charges beyond the free allocation.
- The investigator, working together with the research mentor(s), must submit a BRIEF (1 page) research roadmap that delineates the required statistical work; how it supports the grant application; and the grant submission timeline.
- The maximum lifetime allocation is 30 hours. However, at least the first 10 hours of any grant where the Biostatistics Core staff is included as a Collaborator/Co-investigator with % effort in the grant budget will not count towards the lifetime allocation. Time beyond 10 hours will need to be reviewed on a case-by-case basis
- o Personnel who work with junior faculty are not eligible for an independent allocation (please refer to Appendix for personnel classification).

- Any faculty member (defined in Appendix)
 - o 5 hours/grant, in preparation for grant submission; 20 hours maximum lifetime limit
 - 10 hours/grant <u>IF</u> Biostatistics Core staff is included as a Collaborator/Co-investigator with % effort in the grant budget. No lifetime limit.

*At this time, free hours are applicable only to two residents from UCSF East Bay Surgery Program, as designated by the Program Director/Division Chief.

Fee structure

Work that does not fit the criteria above will be billed either on an hourly basis (limited projects) based on actual hours worked or as % effort (extensive projects). The charge approach will be determined jointly by the Biostatistics Core Director and the principal investigator.

		Hourly rate
Core Director	Dr. Huang	\$175
Senior Biostatistician	Dr. Jin or Ms. Shui	\$100

Please note that any incidental cost incurred by the Biostatistics Core that are only attributable to your project, like the data storage cost or subscription to database/software, will be included in the project's cost estimates.

Percent effort over time is utilized for more involved projects with the following required minimum for at least one year.

- 5% effort for Dr. Huang, the DoS Core Director
- 10% effort for Dr. Jin or Amy Shui, DoS Core Senior Statistician

Appendix A: Definition of Terms

I. Definition of New Investigator and Early Stage Investigator (Junior Faculty)

A New Investigator is someone who has not yet competed successfully for a substantial, competing NIH research grant. For more information regarding the NI definition, please refer to the NIH policy: https://grants.nih.gov/policy/early-investigators/index.htm

An Early Stage Investigator is a new investigator who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet competed successfully for a substantial, competing NIH research grant. For more information regarding the ESI definition, please refer to the NIH policy: https://grants.nih.gov/policy/early-investigators/index.htm

II. Definition of Faculty

Faculty must hold a paid appointment of 50% of more in the Department of Surgery in the following series: Ladder Rank, In Residence, Clinical X, or Health Sciences. Please note that Clinical instructors (unless they are fellows; see below) and faculty in the Adjunct series are not eligible for an independent allocation.

Faculty and staff <u>not</u> eligible for independent allocation include clinical instructors (unless they are a clinical fellow in an ACGME or non-ACGME clinical fellowship; see below), specialists, researchers and postdoctoral scholar, students, volunteers, visiting scholars and any other without salary academic staff.

III. Definition of Residents

Residents refer to Department of Surgery ACGME¹ and NON-ACGME residents and fellows, including fellows with clinical instructor titles. Medical students do not get a separate allocation; their request will be counted towards their mentor's allocation.

¹ ACGME = Accreditation Council for Graduate Medical Education