	<b>SOP Number:</b> 1	<b>Approval Date:</b> 10/18/20
<b>Standard Operating Procedure Title:</b> Biostatistics Shared Resource Services and Fees	<b>Revision Date:</b> N/A	


**I. Purpose and Background:** The Chao Family Comprehensive Cancer Center has established the Biostatistics Shared Resource (BSR) to assist investigators associated with the Cancer Center to conduct and communicate research of the highest possible quality. The primary activities of the Biostatistics Shared Resource include: 1) statistical design for new studies; 2) statistical analysis of data and consultation; and 3) development of clinical research protocols. The BSR has been involved in data analyses in a wide variety of projects, including genetic epidemiology studies; cancer etiology research; clinical studies to evaluate biological markers, assessment of diagnostic methods and treatment modalities, cancer clinical trials, and in vitro studies. Priority is given to Cancer Center members and cancer-related studies. This document describes standard operating procedures for statistical consulting and for recharge policies. For information regarding administration of recharge fees, contact the CFCCC Finance Operations Manager.

- II. Acronyms:**
- a. **CFCCC:** Chao Family Comprehensive Cancer Center
  - b. **BSR:** Biostatistics Shared Resource
  - c. **PI:** Principal Investigator

- III. Applicable Regulations and Guidelines:**
- a. N/A

- IV. Staff Responsible:**
- a. BSR Director
  - b. BSR Manager
  - c. CFCCC Administration
  - d. CFCCC Finance Operations Manager

- V. Services:**
- a. **Grant preparation**  
A primary function of the BSR is to provide assistance to all funded Cancer Center members and their co-investigators with grant preparation for cancer-related studies. The effort for assistance with grant preparation for cancer-related studies will be free-of-charge to Cancer Center members and their co-investigators. This includes reviews for re-submission when addressing criticism of original submission. This effort is partially supported through the Cancer Center’s shared resource grant and provision of assistance will depend upon the current workload of the Resource as determined by the Director and faculty of the BSR. It is expected that submitted grant budgets should include the following for future statistical services: (1) percent effort for one or more named statisticians from the BSR, and (2) a budget allocation for statistical service to be paid on the basis of recharge. The BSR can provide assistance with budgeting for the appropriate form and level of statistical support. In order to maintain quality of collaboration, it is expected that the BSR biostatistician will be given adequate time to work on the submission prior to its due date and will be involved in all

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aspects of study development, including, but not limited to, study design, determining measures and outcomes, sample size calculations and data analysis. It is also expected that the BSR biostatistician will review the final grant application prior to submission to ensure consistency in the design, analysis and sample size consideration sections as well as ensuring that reasonable funds for statistical support are allocated in the event of funding.

**b. Data analysis and abstract, manuscript, and presentation preparation**

The BSR will assist Cancer Center members and their affiliates and non-Cancer Center members with data analyses and preparation of abstracts, manuscripts, and presentations. A recharge will be made for these services and standard hourly rates will apply. In the event that the work involves a funded award for which the biostatistician received a percent effort, these funds will replace the hourly recharge. The Cancer Center will pay for the 1st hour of service for all Members and their co-authors for any cancer-related activity. It is expected that the biostatistician performing the analysis will be a co-author on the publication to acknowledge the intellectual contribution to the work. Statistician co-authors will use their primary appointment affiliation on manuscripts and abstracts. Co-authorship is not considered as compensation. It is also expected that the biostatistician will be given adequate time to review any abstract or publication prior to submission and resubmission in order to ensure study and statistical integrity. The BSR can also assist non-Cancer Center members with data analyses and preparation of abstracts, manuscripts, and presentations regarding cancer related studies. The same policies as those for Members apply. Non-Cancer Center members will be encouraged to contact CFCCC Administration at [cfcccadmin@hs.uci.edu](mailto:cfcccadmin@hs.uci.edu) regarding application for Cancer Center membership. Regardless of membership, any publications resulting from assistance by the BSR should acknowledge that biostatistical collaboration was provided by the BSR. One example of an appropriate acknowledgment is: "Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number P30CA062203. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. Biostatistics collaboration was provided by the Biostatistics Shared Resource within the Chao Comprehensive Cancer Center at the University of California, Irvine."

**c. Non-Cancer Related Studies**

The BSR may assist with grant development, data analysis, and preparation of abstracts, papers, and presentations for non-cancer related studies. Provision of statistical help will depend upon the current workload of the Resource as determined by the Director and faculty of the BSR. A recharge will be made for statistical services. The potential of grant funding will not be considered as compensation. Grant budgets for non-cancer related studies should include the following for future statistical services (1) percent effort for one or more named statisticians from the BSR, and (2) a budget allocation for statistical service to be paid on the basis of recharge. Non-Cancer Center members will be advised to contact CFCCC Administration at [cfcccadmin@hs.uci.edu](mailto:cfcccadmin@hs.uci.edu) regarding application for Cancer Center membership. Regardless of membership any publications resulting from assistance by the BSR

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**VI. Consultation Rates**

The BSR assists with data analysis and abstract, manuscript, and presentation preparation. The Cancer Center will underwrite the 1st hour of service for all Members and their co-authors for any cancer related activity. Thereafter the following hourly rates will apply.

Type of Consultant	UCI Rate
Senior Consultant	\$80.00
Consultant	\$55.00
Junior Consultant	\$35.00

In the event that the work involves a funded award for which the biostatistician received a percent effort, these funds will replace the hourly recharge. Note that the effort for assistance with grant preparation for cancer-related studies is free-of-charge to all Cancer Center members and their co-investigators.

**VII. Procedures:**

- a. PI and/or one of the study team members will fill out the online statistical consultation request form (<https://www.cancer.uci.edu/biostatistics/consultation.asp>)
- b. BSR Manager will inform the biostatistician of the request and then set-up an initial meeting with the PI (via in-person or Zoom videoconference) to discuss the project. A series of meetings may be held after the initial meeting to ensure and maintain a strong collaboration.
- c. After the statistical request has been fulfilled and approved by the PI, BSR Manager will prepare the invoice, which includes the total billed amount and the daily activity log, and obtain approval from the biostatistician prior to sending to the PI.
- d. With the biostatistician’s approval, BSR Manager will forward the BSR invoice to the PI to request his or her approval and authorization of the invoice. If there is any questions or concern regarding the BSR invoice, the PI is welcomed to communicate with BSR Director or the biostatistician to discuss further.