

Working with **BERD**

The BERD core provides quality, accessible biostatistics service and guidance for every step of clinical studies, from conception to completion. We're excited to collaborate with you and would like to share some of our core's policies in order to make the process as efficient as possible for all involved.

1. Timeline

The timeline for completing our work is contingent on receiving the data from the investigator in a timely manner and appropriate format. Consulting with a biostatistician at the study design or data acquisition phase is highly recommended. We will try our best to accommodate any time constraints you may have, but **please understand that we are working on multiple projects with their own deadlines**. General guidelines for the time needed are as follows:

Nature of Work	Time Needed
Grant Preparation	At least 5 weeks before deadline
Data Acquisition	3 weeks
Statistical Analysis	2-6 weeks*
Writing Finalized Results	1-2 weeks
Manuscript Review (excludes re-analysis of data)	2 weeks
Responding to Reviewers	2 weeks
PhD Dissertations	At least 4 months before defense

*Depending on the complexity of the analysis. Data must be the clean and finalized version. Data dictionary should also be provided to the Biostatistician.

2. IRB/IACUC Approval

All ongoing projects must have the appropriate IRB/IACUC approval for human subjects or animal studies. We kindly ask for your IRB/IACUC number before beginning work, and you may be asked to add your biostatistician to the IRB study staff. Projects where data collection has not yet begun are excepted.

3. Data Cleaning

A clean data set is essential to ensure accurate data analysis and reliable conclusions. Time spent cleaning data detracts us from our main purpose of biostatistical analysis. Please review the attached **Data Cleaning Guide** to determine if your data are ready to share.

4. Confidentiality

All data submitted for analysis must be de-identified and safeguarded for the confidentiality of personal information. Data should not contain any personal identifiers such as name, MRN, or contact information.

Data are kept confidential per HIPAA guidelines on a password-protected secure server. Data and results are not shared with anyone outside the project except under explicit permission.

5. NIH Funding Acknowledgment

Biostatistical support through CTSI is subsidized by NIH and must be recognized as such.

Investigator Status	Citation
Not an SC CTSI Scholar (KL2, Other)	This work was supported by grants UL1TR001855 and UL1TR000130 from the National Center for Advancing Translational Science (NCATS) of the U.S. National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
NIH-Funded CTSI Clinical and Translational Scholars	This work was supported by grant KL2TR001854 from the National Center for Advancing Translational Science (NCATS) of the U.S. National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
Institutionally-Funded CTSI Clinical and Translational Scholars	This work was supported by grant UL1TR001855 from the National Center for Advancing Translational Science (NCATS) of the U.S. National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

6. Publication Expectations

Your biostatistician contributes significantly toward the successful publication of research. ICMJE publishes recommendations for authorship in the following summarized **Authorship Criteria**:

Contributing sections 1-4 below. Collaborators that help plan or conduct the study (1) should be given the opportunity for involvement in all other areas (2-4).

1	Planning <u>OR</u> conducting the study	Substantial contributions to the conception or design of the study; the acquisition, analysis , or interpretation of the study data.
2	Drafting the manuscript	Drafting the work or revising it critically for important intellectual content.
3	Finalizing the manuscript	Final approval of the version to be published.
4	Accountability	Agreement to be accountable for all aspects of the work. Helping ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

7. Recharge Policy

To support efficient and accurate data collection and analysis, and to help researchers avoid translational research pitfalls, SC CTSI provides a variety of free consultation services with the option to purchase additional services on a recharge basis. This includes all time related to the project including aspects such as formatting, e-mail correspondence, and manuscript review.

Free Services

Initial Consultation	up to 1 hour	The initial consultation for any research project based at USC, CHLA, and affiliated SC CTSI institutions is always free.
SC CTSI Pilot Funding Awardees	up to 2* hours	For any work related to the funded project.
Junior Investigators	up to 5* hours	As defined by NIH and/or in an Assistant Professor classification.
K Awardees	up to 15* hours	K awardees may receive up to 15 hours total free annually for their K-related project at USC, CHLA, and SC CTSI affiliated institutions.
T Scholars	up to 15* hours	T scholars may receive up to 15 hours total free annually for their T-related project at USC, CHLA, and SC CTSI affiliated institutions.
Extramural Grant Planning	up to 3* hours	For preparing grants for submission within 6 months, researchers may receive consultation on issues related to: <ul style="list-style-type: none"> • Study/experimental design, randomization schema • Power/sample size • Data cleaning and management • Statistical analysis plan • Analysis/interpretation of results • Data acquisition/sharing plan

PM516 Volunteers	up to 5* hours	Subject to availability, investigators wishing to present their research to PM516 may receive up to 5 free hours of service beyond time spent interacting with the class.
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*includes consultation

Recharge Rate (for hourly services)

To keep CTSI-BERD biostatistical consultation services available and affordable to the university, we are not able to perform any free work outside the above categories. Faculty may check with their department for any additional financial support/assistance that may be available.

Recharge Rate	\$125/hour	All consultation, analysis, or other work performed outside the above categories.
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Percent Effort (for longer-term projects)

A percent effort model is also available for projects that require longer-term assistance. The table below is the fee for hiring a staff-level biostatistician based on various percent efforts monthly and annually with a fringe rate of 33.5%. The rate includes supervision by a faculty-level biostatistician.

Effort	Monthly			Annual		
	Salary	Fringe	Total Fee	Salary	Fringe	Total Fee
20%	\$1,533	\$514	\$2,047	\$18,400	\$6,164	\$24,564
30%	\$2,300	\$771	\$3,071	\$27,600	\$9,246	\$36,846
40%	\$3,067	\$1,027	\$4,094	\$36,800	\$12,328	\$49,128
50%	\$3,833	\$1,284	\$5,118	\$46,000	\$15,410	\$61,410
60%	\$4,600	\$1,541	\$6,141	\$55,200	\$18,492	\$73,692
70%	\$5,367	\$1,798	\$7,165	\$64,400	\$21,574	\$85,974
80%	\$6,133	\$2,055	\$8,188	\$73,600	\$24,656	\$98,256
90%	\$6,900	\$2,312	\$9,212	\$82,800	\$27,738	\$110,538
100%	\$7,667	\$2,568	\$10,235	\$92,000	\$30,820	\$122,820

8. What Now?

We're excited to get started. After consulting with your biostatistician, you will receive an electronic **scope of work** via e-mail to sign. Once we have received this signed-off document we may officially begin working on your project.

Attachments

Data Cleaning Guide

Authorship Criteria

Scope of Work Help-Sheet