

Biostatistics and Data Management Core Rules of Engagement

We want to create lasting and fruitful scientific partnerships with the CHLA research community! Adhering to the following guidelines will help to ensure you get the most out of your experience with the Biostatistics and Data Management Core and improve the quality of your work.

1. Consult with statisticians very early in the study design phase of your project. Prior to your meeting:

- Fill out the **Biostatistics and Data Management Core Scope of Work** document
- Prepare details your study plan: what is the study design? how many groups? cross-sectional vs. longitudinal? primary outcome variable, secondary outcomes and confounders?
- Collect anything you have written so far, i.e., proposal, including objectives, research questions, hypotheses, data you plan to collect
- If you need power and sample size calculations:
 - What are the characteristics of your main study outcome variables (mean and SD for continuous variables, anticipated observed percents for categorical variables)?
 - This information can be estimated from any available pilot data on similar subjects, and/or published articles from similar studies.

Please bring these materials with you to your meeting. If you are unsure of any of the above, we can assist you in filling out the scope of work and developing a feasible study design.

For Fellows: Your mentor is REQUIRED to attend the initial consultation.

Here is an example of what our partnership might look like:

Initial consultation	Regular follow-up project meetings	Ad hoc discussions with the Core
Fill out a request form: sc-ctsi.org/bbr-consult	Regularly scheduled meeting over the course of the study to gauge progress, discuss changes, problems, timelines, and goals.	Between regular meetings, it's a good idea to consult with us on any questions or issues that arise.
Bring prepared materials to the first meeting (see above)		

2. Keep in mind the "time-to-completion" of projects and it is your responsibility to communicate what the deadlines are well in advance.

- Our ability to turn around your project in a timely manner depends our current workload, complexity of your required analysis and the quality of your data.
- In addition, your level of engagement with the Core will also be important driver of the timeline.
- For most projects, we require at least 6 weeks to complete analysis and produce a report, from the time we receive an **analysis-ready dataset**.

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- Assistance with statistical aspects of grant proposals requires additional time, up to 2 or 3 months, depending on complexity of the proposal and the level of our involvement.
- We always need to see the *entire* proposal.
- Since data preparation/data cleaning often comprises the majority of time spent on a project, we strongly recommend using a data management system such as REDCap for your data capture (http://sc-ctsi.org/index.php/resources/manage_your_data). It is also recommended that you review principles of constructing a research dataset (**see Database Requirements & Recommendations handout**).

3. Core Service Model and Charge Policy (see *Biostatistics and Data Management Core Service Model handout*)

- The Biostatistical Core is a charge-back service, with an initial free one-hour consultation.
- The Core also provides a set number of hours of free service determined by an individual investigator's needs and status.
- **The normal recharge rate is \$125/hour** after the initial consultation or use of free services
- Some money-saving things to consider:
 - Do your own data editing and cleaning – planning ahead will minimize
 - Avoid as much as possible, repeat analysis with new data, changes in endpoints, different groupings, etc. – planning ahead will minimize this as well!
 - Do your own tables and graphs

4. Services not provided by Biostatistics and Data Management Core include:

- Constructing databases and entering data
- 1-on-1 instruction on how to use statistical software
- Debugging statistical syntax written by others
- Lending statistical software to investigators
- Proofing analyses performed by others
- Justifying analytic methods to manuscript reviewers if we did not perform the analyses.

Please make sure to cite us for the help you received in all publications and presentations. For substantive scientific contribution to your work, we are expected to be included as co-authors in your work (**see Authorship Guidelines handout as a reference**). Please consult us prior to any citations/co-authorship.