

Biostatistical Consulting Service Operations

The Division of Biostatistics and Epidemiology in the Department of Health Evaluation Sciences has a Biostatistical Consulting Service to assist researchers with study design, analysis, statistical graphics, statistical reporting, and interpretation. We offer free experimental design assistance for grant proposals. In exchange for free assistance on grant proposals we require investigators to keep us apprised of the progress of proposals (submission dates, percent efforts of our personnel if any, priority score and percentile, funding date, and the start date). If you don't provide this information to us we will periodically contact the grant administrator you list on the request form.

For needs not directly related to grant proposals, we meet with researchers to understand the project and to be able to estimate the amount of statistician time that will be involved. Sometimes we can answer investigators' questions and solve their statistical problems during this initial meeting but more typically further work will be required. In those cases, we develop an initial budget after the meeting and present it to the researcher promptly. Typically we are unable to envision the scope of work for the project until work commences. It is very common for researchers to develop new ideas and new hypothesis and to refine measurements after initial data analyses. So our initial budget estimation will be sufficient to get the project started. We account accurately for all time spent on the project and will communicate to the researcher a better estimate of the required budget as the project unfolds. We will give an accounting of time spent on the project as frequently as desired by the researcher.

NOTE: Researchers can significantly lower the costs of a project by carefully checking the accuracy and subject inclusion criteria for their data before seeking biostatistical consulting services.

We bill at two hourly rates depending on the level of assistance needed. For internally funded UVa projects the rates are as follows: For work done by faculty the charge is \$104/hour, and for work done by M.S. level biostatisticians it is \$55/hour. For industry-sponsored projects the rates are \$300/hour for full professor level faculty, \$200/hour for other faculty, and \$100/hour for M.S. biostatisticians.

Our charge mechanism allows us to maintain a staff of highly qualified biostatisticians that can expand in direct proportion to the needs of the School of Medicine, especially to handle labor-intensive data analysis requests. The funding formula used by the Dean's office mandates that the only way we can maintain "open" percent efforts (FTE not allocated to specific grants) of M.S. biostatisticians is to charge for non-grant statistical consulting. Consulting charges take the place of clinical income for Division such as Biostatistics and Epidemiology. We encourage divisions to fund portions of statistical salaries on an ongoing basis so that we do not need to charge the division's faculty by the hour.

Authorship

A frequently asked question is whether biostatistical consultants should be co-authors on scientific papers. We (and Dean Carey) feel that decisions about authorship should be independent of consideration of funding sources. As recommended in published guidelines¹, "The basis of financial support should be the time/effort spent on a project and the basis for

¹ Parker RA, Berman NG: Criteria for authorship for statisticians in medical papers. *Statistics in Medicine* 17: 2289-2299 (1998).

authorship should be whether the statistician has made a scientific contribution to the project.” Examples of scientific contributions are the following.

1. The statistician has to develop new statistical methods to meet the project's needs, or she/he has to combine existing techniques in a novel way.
2. The statistician has a major role in designing the study.
3. The statistician writes part of the manuscript other than a standard paragraph or two describing which statistical methods were used.
4. The statistician is asked to critique an initial draft and the statistician spends a considerable amount of time suggesting alternative wording and presentation of results.
5. The statistician provides data analysis along with interpretation of results.

By JAMA's criteria for authorship for statistical experts involved in the analysis and interpretation of data used in a manuscript; a statistician is a co-author if (1) he/she took part in the drafting of the manuscript or (2) he/she was involved in a critical revision of the manuscript for important intellectual content.

It is our policy that acknowledgment of the contribution of the staff or faculty of the Division of Biostatistics and Epidemiology may not appear in a paper without that person's written approval.

Above all, it is important for the medical researcher and biostatistician(s) assigned to the project to agree on criteria for authorship early in their collaboration.

Manuscript Preparation

Whether or not the statistician is an author, it is important to allow sufficient time for the statistician to check statistical results and descriptions of statistical methods that appear in a manuscript. We frequently find inconsistencies between analyses we perform and basic descriptive statistics computed by the investigator. For example, the primary statistical comparison may emphasize differences in medians while the investigator quotes mean values elsewhere in the manuscript. When different analyses are carried out by different personnel, it is beneficial for the investigator and statistician to map out the entire analysis together in advance.