The Statistical Consulting Center POLICIES AND PROCEDURES

SERVICES

The Statistical Consulting Center (hereafter StCC) provides statistical and data management services in support of research. The services that the StCC provides can be broadly classified into three groups:

- *Quick Help* Quick help consists of brief assistance that can be provided in a short (less than one hour) meeting, such as guidance in using a software package, selecting an appropriate statistical methodology, interpreting results, etc. Those in need of quick help are encouraged to attend the Consulting Clinic, which convenes weekly at StCC offices.
- Consultation Extended client-consultant relationship, typically in which the consultant produces results for the client and the relationship terminates when the work is completed. The tasks typically involved in a consultation are listed below in the CHARGES & FEES section.
- *Collaboration* Long-term client-consultant relationship such as participation in funded research as in a grant. Collaboration is also fee-for-service, and can be billed at an hourly rate or as a percentage of a consultant's salary, subject to the availability of StCC consultants.

The activities involved in a consultation or collaboration include, but are not necessarily limited to,

- client-consultant meetings,
- study design, including power and sample size calculation, writing statistical analysis plans, etc.,
- data management, including the design of data collection and storage instruments, data cleaning and integrity verification, and data manipulation prior to statistical analysis,
- statistical data analysis such as estimation, hypothesis testing, modeling, plot generation, etc., and
- technical writing including grant and protocol writing, creation of consulting reports, and manuscript writing and editing.

The StCC does *not* provide tutoring services for students. StCC services are available to students needing statistical assistance for research projects. However, the StCC will not provide assistance to students whose projects are statistical in nature, i.e. when the purpose of the project/research is for the student to learn some aspect of statistics or statistical data analysis. Such judgments will be made by StCC consultants in concert with the director of the StCC.

$CHARGES \ {\mathcal C}FEES$

The hourly fees for StCC services vary according to the credentials of the consultant and whether or not the client affiliated with the University of Louisville. The fees are provided in the table below.

Consultant Level	UofL Client	Non-UofL Client
Graduate Student	\$40/hour	Negotiated
Master's	70/hour	Negotiated
Ph.D.	120/hour	Negotiated

For billing purposes, the level of the consultant is determined by the difficulty of the request *and* the availability of StCC consultants. In particular, StCC clients will not be able to "select" the level of the consultant for their requests.

Any time spent on activities related to fulfilling a client request, and in particular, those activities listed above in the *SERVICES* section is billed. The first hour of any consultation or collaboration is always free, as is any help provided during the walk-in Consulting Clinic. If a StCC consultant is preparing a grant protocol for submission to a funding agency, and a portion of the consultant's salary is to be covered by the grant, then the consultant may provide the "up front" services – study design, sample size calculation, analysis section writing – for free. This is completely at the discretion of the consultant.

Upon completion of a consultation in which billable time was logged, the StCC consultant will provide the client with an invoice for services provided. The invoice will contain the time billed for the work, the hourly rate for service, the total charge, and instructions for payment.

GRANT WORK

Preparatory work for submissions for funded research, such as in a grant, is provided for free to investigators *ONLY* when StCC consultants are to serve as named personnel in the grant for a percentage of the consultant's salary. StCC consultants work in collaboration with investigators to determine a suitable percent effort for each grant. For grants in which research infrastructure funds (RIF) are available, the percentage RIF allocated to an StCC consultant should be equivalent to the percentage effort for the StCC consultant listed on the grant application. Alternative arrangements for RIF must be approved by either the Director of the StCC or the Chair of the Department of Bioinformatics and Biostatistics.

PUBLICATION

The publication, in a poster, journal manuscript, or other official document, of any information that involves work conducted by an StCC consultant invokes the question of whether the consultant should be granted co-authorship. The StCC expects that all clients will abide by the guide-lines established by the University of Louisville ("Ethical Conduct and Reporting of Research") and by the International Committee of Medical Journal Editors (http://www.icmje.org/).

The ICMJE stipulates that each of the following three conditions be satisfied for authorship:

- 1. (a) substantial contributions to conception or design, or
 - (b) acquistion of data, or
 - (c) analysis and interpretation of the data
- 2. (a) drafting the article, **or**
 - (b) revising it critically for important intellectual detail, or
- 3. final approval of the version to be published.

If any StCC consultant provides services that meet each of the above 3 criteria, than said consultant should be granted co-authorship of the manuscript, poster, etc. In particular, whether or not the StCC consultant was paid should *not* be considered when evaluating co-authorship. Only the above criteria need to be met.

Should a client proceed with any publication containing results produced by a StCC consultant, the consultant assumes no responsibility for the publication, nor the results contained therein. Many journals require that "Any part of an article essential to its main conclusions must be the responsibility of one author ..." (Academic Medicine Complete 2006 Instructions for Authors, http://www.academicmedicine.org/). If the statistician is not listed as co-author of the publication, then one or more of the authors would assume responsibility of the statistical analysis. This would relieve the StCC consultant of any obligation to the client with respect to the publication and the results therein, including such items as responding to reviewer comments during the revision process

DATA USE

In keeping with the StCC's mission to provide statistical instruction, consultants may request that the client(s) make the data available to the StCC for use after completion of the research. This decision is entirely the client's. The StCC will take all precautions with such data with regard to protection of human subjects and personal information in accordance with HIPAA guidelines, and will suitably acknowledge the clients for permitting use of the data.

LIABILITY LIMITATIONS

A StCC consultant may be requested to perform services that are different from those that the consultant would recommend, such as in a request for a specific type of statistical analysis. In such cases, the consultant will endeavor to satisfy the needs of the clients(s) but will not endorse the methodology employed, as it was not recommended by the StCC consultant.

It is contingent upon the client to appropriately use the results of any statistical analysis conducted by a StCC consultant. This includes the use of any said results in presentations, posters, manuscripts, etc. Specifically, the client is responsible for preserving the actual results and the interpretation of the results provided by the StCC consultant. If any presentation of results is done without the assistance of the StCC consultant, the StCC offers no endorsement of said presentation.

In situations where consultants of the StCC submit sections of grant applications or research protocols, the client(s) are responsible for preserving the text submitted by the consultant. Changes to the text submitted by the consultant should only be made by or in collaboration with said consultant. Adjustments made without the knowledge or consent of the consultant, particularly those that change the nature of the service to be provided by the StCC, nullify the agreement between the client(s) and the StCC, and relieve the StCC of any obligation to the client. In such cases in which the client-consultant agreement is terminated, the client(s) will be responsible for compensating the StCC for the time already committed to the research.

TERMINATION OF SERVICE

The client reserves the right to terminate service at any time in the course of the research. The client will have access to the results of any services provided by consultants of the StCC, but

will be responsible for providing compensation for the time committed by the consultant. The StCC reserves the right to terminate service in any situation in which a consultant perceives that he/she can be of no further benefit to the research project.

ETHICAL ISSUES

Consultants of the StCC are also bound by the ethical principles of statistical research, specifically the "Ethical Guidelines for Statistical Practice" established by the American Statistical Association, the ethical codes of the University of Louisville, and the rules established by the Human Resources Department of the University of Louisville. Consultants are obligated to report any malfeasance against these principles to the appropriate persons. Particularly, the StCC will vigorously pursue those who accidentally or intentionally misrepresent the results of services performed by consultants of the StCC, pursuant to "Procedures for Handling Allegations of Unethical Conduct and Reporting of Research" of the University of Louisville.

Drafted and approved by the StCC, 4 December 2003

Approved by the Department of Biostatistics and Bioinformatics, 5 December 2003 Approved by the School of Public Health/Information Sciences, 10 December 2003 Amended, 23 February 2018