

Guidelines for Including Biostatistical Support in Tisch Cancer Institute (TCI) Conducted Research Projects

This document describes guidelines for incorporating adequate biostatistical support at PhD and MS levels on research grant and contract proposals.

Identified biostatistician(s) should be involved early on in the grant/contract submission process, and should be included in both the science and budgetary decisions about the statistical FTE, and related other expenses. Statistical expertise requires constant updating in intellectual and computing capacities. The benefits from cutting edge statistical and methodological expertise are shared and borne across all TCI projects. A portion of the statistician's time may be spent on development of methods that are related to (though not essential for) a project.

The following guidelines are **intended as a starting point for budget discussions with investigators**. They include recommendations for four collaboration levels: extensive, regular, limited and extremely limited, and three types of expenses: PhD co- investigator/biostatistician, MS biostatistician (senior ones could be co- investigator too) and other expenses (travel, special software, database purchase).

Level 1: Extensive: 20% or more of a PhD biostatistician and 40% of a MS statistician

High involvement in the development and implementation of the research project, which may take many forms, including:

- a. Development of and/or use and interpretation of new statistical methods
- b. Development and implementation of complex study designs
- c. Analysis and coordination of multi-center projects
- d. Active participation in publications, with opportunity for first authored papers
- e. Project-related travel and external presentations.

Level 2: Regular: 20% of a PhD biostatistician and 20% of a MS statistician

- a. Active participation in publications, with opportunity for first authored papers
- b. Involvement in study design, implementation and data collection
- c. Routine study design and analysis, e.g., analyses carried out using standard statistical software

Level 3: Limited: 10% of a PhD biostatistician and 10% of a MS statistician

This percentage is realistic in some cases, but is too low if the statistical analysis is at all complicated. Meeting attendance may be infrequent and restricted to discussion of statistical issues.

- a. Involvement through consultation with the PI about choice of statistical methods and advising of the analytic staff, limited statistical analysis.
- b. Co-author on papers, but not enough involvement or time to write a first- authored paper.

Level 4: Extremely Limited: Chargeback System

If the PI has some funds and their need is at the ‘extremely limited’ level, they can budget for statistical consultation at a rate of \$125 per hour for a minimum of 6 hours. A pool of MS level statisticians with oversight from a senior MS statistician will provide this service. A standard letter stating this commitment will be available from the core administrator.

Biostatistician FTE is tied to the level of involvement on the research.

Level of Involvement	Type of Expense		
	PhD Co-Investigator/ Biostatistician	MS Biostatistician	Other Expenses; rates are given
Extensive	More than 20%	40%	Travel Rate: \$1500
Regular	20%	20%	Software needed specifically for a project should be budgeted.
Limited	10%	10%	
Extremely Limited*	PhD Supervision Only	Chargeback System with support from a pool of MS statisticians; \$125 per hour with minimum of 6 hours	

* Standard Letter of Support stating the planned number of hours can be obtained from the TCI Biostatistics Core Administrator, Ms. Denise Williams (Denise.williams1@mountsinai.org)

Multiyear Planning and Changes: These guideline percentages are intended to be constant over the lifetime of the grant. For multi-year projects, it might be reasonable to support statisticians at a lower FTE during data collection periods, after design issues have been settled and before analysis has begun. A minimum of 5% of biostatistician time should be budgeted in every year of a multiple year grant to assure continuity. Any changes in percent support made during proposal writing or after research has been funded should be made jointly between the PI and co-investigators/statisticians.

Procedures for Including Biostatistical Support and Ensuring Fruitful Collaboration in Research Projects TCI Conducted under TCI Umbrella

The need to provide appropriate levels of support is driven by the dual responsibilities of PhD biostatisticians in a multi-disciplinary research enterprise. One is to support the research of other investigators at the Institute. The other is to stay connected to statistical research through their own work and be current with emerging statistical methods and techniques. The latter is essential for funding and growth of the Institute. In addition, statistician- investigators need first-authored and co-authored papers for career growth.

The process for working with a biostatistician is similar to the process involved when working with any scientific staff. Basic steps are outlined below.

1. Get the biostatistician involved early. Begin looking for a biostatistician to collaborate with shortly after deciding to submit a grant. You can find a biostatistician one of two ways:

- a. Request for collaborating biostatisticians using the TCI Link:
<https://erap.mssm.edu/Public/CancerRequestForServices.aspx>
- b. Directly contact the biostatistician collaborator you have developed as a long-term contract

TCI biostatisticians strive to meet the statistical needs of the Institute. However, it is possible that on occasion there will not be sufficient staff to meet these needs. It is possible that on some occasions, the biostatistician you work with to write the grant would later be replaced in order to more equally distribute the workload of the TCI. Any change would be accomplished with mutual consent of the PI and the collaborating biostatistician.

2. Plan an initial meeting. The following items should be discussed at this meeting, or at least very early on in the grant planning process.

- a. Discuss the overall study design and hypotheses, and begin discussion about the scope of statistical work. The scope of planned work determines both appropriate FTE levels and the amount of work required to write the statistical sections of the grant. Institute guidelines regarding biostatistician FTE on grants identify 4 general levels of involvement:
 - 1) “extensive” - complicated analyses that may require development of new statistical methods;
 - 2) “regular” - straightforward analyses;
 - 3) “limited” - primarily consultation with project team; and
 - 4) “extremely limited” - primarily used with a chargeback system
- b. Decide on the biostatistician’s specific responsibilities and other expectations.
The level of detail provided by a statistician can vary widely across projects and investigators. For example, responsibilities can include carrying out sample size and power calculations, writing the analysis and sample size sections, and contributing to multiple sections of the grant. During project development the biostatistician should be included in meetings as appropriate and be made aware of developments as the project unfolds. Expectations for biostatistician involvement during the implementation of the project (meeting attendance, contributions to papers and presentations) should be made explicit.

Discuss the need for 2nd Statistician requirements. Many tasks such as data management and documentation, simple analysis and preparation of data for presentations can be effectively performed by junior staff including research specialists and graduate assistants under the supervision of a senior biostatistician. Utilizing junior staff to perform routine work reduces the burden on senior staff and can have positive budgetary consequences. There could also be need for two senior statisticians with one of them in a consulting role for a very special method.

c. Discuss the budget, including

- 1) Planned biostatistician FTE level based on the expected scope of work
- 2) Use of trained research specialists and assistants as appropriate
- 3) Equipment and software needs
- 4) Travel

d. Discuss timelines and determine information that is needed to carry out task such as sample size calculations.

3. Continue communication throughout the grant writing process and during all phases of the research. Discuss revision of planned tasks and assess progress. Once the grant is submitted, provide a final version of the proposal and of relevant budget items (FTE levels, travel, software, and database) to the biostatistician. Once the project has begun the biostatistician should be informed of any changes that affect the study design, sample selection, data collection, etc. The methods for informing the biostatistician will differ depending on the level of involvement. If biostatistician involvement is extensive, regular meetings will convey the necessary information. If engagement is limited, active information sharing by the PI or designated staff is required.

Principal investigator's responsibilities

In addition to determining a grant's primary aims and writing the bulk of the grant, the PI is responsible for communicating with the biostatistician by:

- a. Providing drafts of the grant as it evolves, even if the biostatistician is not writing specific sections
- b. Providing information required for sample size and power calculations in a timely manner.
- c. Communicating relevant budget plans, and changes to these plans. Planned FTE levels should be communicated at least one month before the grant is submitted. Any changes to planned travel money, software, or equipment budgets also need to be discussed with the biostatistician before the grant is submitted, even if these are last minute changes.

Statistician's responsibilities

- a. Statistician needs to convey what they need to be able to compute the sample size calculation and the statistical analysis plan in writing to the PI.
- b. Statistician needs to provide detailed budget justification and provide list of deliverables with timeline. Any materials needed to provide the deliverables need to be clearly written.
- c. Statistician needs to supervise writing of a clear data management plan and ensure that resources are dedicated to this task to be able to produce the above said deliverables.