Division of Biostatistics and Bioinformatics
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Policies and Guidelines for Including
Biostatistics and Bioinformatics Support on Grants
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This document lays out policies and guidelines for inclusion of Biostatistics and Bioinformatics personnel in grant applications. The guidelines lay out common scenarios and are meant to serve as a starting point for discussion for planning and budgeting purposes. In all cases, discussion with faculty early in the grant preparation process is necessary to ensure that the appropriate level of support is provided. Work on proposal preparation is provided free of charge through institutional support provided that Biostatistics or Bioinformatics personnel are included in the proposal budget. If Biostatistics or Bioinformatics personnel are not included in the proposal budget, time spent on proposal development will be billed at the current hourly rate.

Mechanisms for including Biostatistics and Bioinformatics Personnel in Project Budgets

PhD faculty effort
Biostatistics and Bioinformatics faculty should be included as named co-investigators (typically as key personnel) on collaborative applications. While effort may vary from year to year, an average of 10% effort (1.2 calendar months per year) over the project period is suggested as a guideline for most clinical projects and more complex basic science projects (see effort allocation guidelines below). **Faculty may not be included on budgets for less than 5% effort without the approval of the Director of the Division of Biostatistics and Bioinformatics.**

For projects with limited statistical needs and budgets (e.g., R03 applications), provision for support of faculty time on a fee for service basis may be made through the Biostatistics/Bioinformatics Service Center (see below). In these cases, the division will provide a letter of support, but no biosketch will be provided.

Biostatistics/Bioinformatics Service Center
The Biostatistics/Bioinformatics Service Center (BSC) mainly provides master's-level data analysis support to Jefferson researchers. Personnel in the BSC provide assistance with data management, statistical programming, and preparation of reports and manuscripts. BSC statistical staff have experience developing REDCap and Access databases and using SAS, R,

Stata, and other statistical packages. Bioinformatics staff have experience developing genomic/transcriptomic/proteomic data analysis pipelines and methods utilizing R, Python, C++, Message Passing Interface in C, and other programming languages and Bash scripts. The Bioinformatics group analyzes these large-scale multi-omics data using the existing high-performing cluster computer.

For most projects, BSC support should be coupled with PhD faculty effort. BSC support should be included as a non-salary line item for statistical support or Biostatistics Services. BSC personnel are not named, but support is included as a percentage of charge per FTE. The current annual charge is $131,400 per FTE.

Division faculty also provide some support to the BSC. For small projects, a non-salary line item for Biostatistics and/or Bioinformatics Services may be included as a number of hours times the current hourly rate. Inclusion of support for faculty time using this mechanism requires the approval of the faculty member and the Director of the Division of Biostatistics and Bioinformatics. In this scenario, a Biostatistics and Bioinformatics Service Request Form will be asked to be completed followed by an invoice upon completion of the service.

An Inter-departmental Transfer (IDT) will be processed by the Financial Analyst in the Division of Biostatistics and Bioinformatics transferring a fee-for-service charged to a grant or departmental account into the Biostatistics/Bioinformatics Service Center.

Effort Allocation Guidelines
These guidelines provide suggested levels of support for projects of varying complexity and need of statistical expertise.

Large or complex projects (e.g. multi-site clinical trials, cores for program projects or SPORES): Total biostatistics annual effort 50–100+% per year, such as 20% or more of Faculty time plus 30–100% BSC staff FTE:
High level of involvement in the development and implementation of the research project and communication of study results, including:
- Development and/or implementation of complex study designs.
- Assembly of datasets from large, complex or poorly documented sources (e.g. administrative or survey databases).
- Development and/or implementation of interim data analyses during data collection phase of prospective studies.
- Coordination of analyses for multi-site projects.
- Development of and/or use and interpretation of novel or complex statistical or Bioinformatics methods.
- Developing algorithms to identify units of analysis and define analysis variables
- Developing new systems biology approaches, deep learning, or machine learning-based methods for analyzing or integrating large-scale high-throughput data
- Processing, analyzing, and integrating large-scale omics data (e.g., single-cell RNA-seq, spatial transcriptome, exome-seq, etc)

- Active participation in publications, with opportunity for first authored papers.

Regular Projects (e.g., R01 involving clinical data, basic science project with complex analysis): Total biostatistics/bioinformatics annual effort 20–50%, such as 10–15% Faculty time plus 10–35% BSC staff FTE. This effort profile is suitable for straightforward projects with uncomplicated analyses and includes:
- Collaboration and involvement of biostatisticians through all phases of the study, including regular meeting attendance.
- Involvement of biostatisticians/bioinformaticians in routine study design, implementation, and data collection.
- Well-documented primary datasets provided for statistical/bioinformatics analysis.
- Analyses carried out using standard procedures available in statistical software packages.
- Analyses carried out using Bioinformatics methods available in public repositories.
- Active participation of biostatisticians/bioinformaticians in publications, with opportunity for first authored papers.

Simple Projects: Total effort 5–20% per year, such as 5-10% Faculty time plus 5-10% BSC staff FTE.
This effort profile is suitable for simple projects requiring minimal PhD faculty collaboration and straightforward analyses performed by the BSC (for about one manuscript per year).

- Ongoing occasional consultations with PI about study issues, such as choice of bioinformatics/statistical methods to use. Support at the lower end of the range (i.e., 5%) is typically too low for a faculty-level biostatistician or bioinformatician to carry out analyses.
- This level of effort commitment and support for the faculty member is generally not compatible with smooth workflows and readily available consultation support, unless adequate BSC support is included on the project as well.

Limited Scope projects: Total effort <5% per year

On rare occasions, a limited amount of funding may be justified, for example, for assistance with small-scale Phase I trials, straightforward animal studies, or simple cell-based experiments. In these cases, some analysis will be needed, but the scope is limited. Such small projects may budget for faculty services through the Biostatistics/Bioinformatics Service Center using the hourly rate in place of effort (see funding mechanisms above).

Other Budgetary Considerations

Faculty effort is assessed a surcharge called the Biostatistics/Bioinformatics Fee (BF). The BF funds the computing and other operational (non-personnel) expenses incurred by the Division of Biostatistics in direct support of the proposed research project. The BF provides for support

of computer hardware and specialized software, including SAS, Stata, StatXact, Mplus, East, MatLab, SUDAAN, and NONMEM, as well as access to statistical journals. The BF does not include any indirect cost expenses (such as administrative support, phone, or rent), and none of the resources provided by the BF are included in indirect costs recovered by the Division of Biostatistics and Bioinformatics. The cost rate is computed and reviewed annually. The current BF is $11,000 per FTE.

A monthly IDT will be processed by the Division of Biostatistics and Bioinformatics Financial Analyst transferring the Biostatistics/Bioinformatics Fees from a grant account into the Biostatistics/Bioinformatics Service Center.