

## University of California Davis School of Medicine Guidelines for Estimating Biostatistician Effort and Resources on Grants

### Rationale and Context

Successful investigators recognize the benefits of including biostatisticians as collaborators on their research projects. Biostatisticians play a crucial role in research by ensuring the study objectives are clearly defined and testable, the study's design is powerfully and cost-efficiently aligned with the study objectives, the data necessary to meet the objectives are collected and well documented, and appropriate statistical analyses are conducted and accurately reported. These conditions are vital for successful and reproducible research. Biostatisticians have expertise in translating scientific hypotheses into actionable analyses. They also function as intellectual brokers who are exposed to and contribute innovative methods from a wide range of disciplines. Hence, biostatisticians are positioned well to make original and substantial contributions to a proposal's scientific aims and methods, both by identifying and correcting weaknesses and by spotting opportunities to apply and develop promising innovations from other fields. Early statistical collaboration thus leads to much better chances for a research proposal to be funded and for that research to lead to sustained and significant impacts.

This document provides guidance on determining the percentage of effort and the appropriate level of funding to allocate for biostatisticians on research projects. It aims to ensure that these critical team members are adequately supported, reflecting their pivotal role in the design, analysis, and interpretation of research data. This guidance is based on the collective experience of faculty and staff biostatisticians in the UC Davis Department of Public Health Sciences Division of Biostatistics and from peers from other Universities and research organizations nationwide.

Investigators are encouraged to consult with a biostatistician **at least 8 weeks before the grant proposal due date** for effective input into the proposal and to ensure that the budget is appropriate for the scope of work. We strongly recommend that biostatisticians be actively involved throughout the grant proposal development process, including participation in the specification of research objectives and approach, proposal writing, and budgetary decisions for biostatistician and programmer effort commitments, computer and software purchases, professional development activities, and scientific travel. Further, including a senior biostatistician as key personnel can strengthen the grant proposal and is strongly recommended.

### Effort Allocation Guidelines

In general, funding for a biostatistician should not fall below 10% effort at any time on a single project. Although there occasionally are valid reasons for a lower level of effort, **intervals with funded effort falling below 10% require prior approval by the department chair**. Funding should be matched to the size, scope, and complexity of the study design and data analysis. Key determinants include the number of study objectives and planned manuscripts, the number of primary and derived study variables that will be collected and analyzed, the quality and completeness of the data to be provided for analysis, and the complexity of the programming necessary to assemble the analytic data and implement descriptive and inferential statistical methods. For multi-year projects, effort commitments may vary throughout the study timeline, according to the needs in various phases, including randomization schemes for sampling and

experimental assignment (early), the development of data collection standards, the development and implementation of data and safety monitoring plans (during the middle phases of prospective studies), and the implementation of statistical analyses and communication of study results (later).

These guidelines assume that the number of days available for work in a year from a full-time UC Davis employee is approximately 200, after accounting for 14 University holidays, 12 days of sick leave, between 27 and 39 days of vacation leave (<https://hr.ucdavis.edu/employees/leave-time-off/holiday-accrual>), and 80 hours of professional development (<https://hr.ucdavis.edu/departments/learning/release-time>).

**A. Large or Complex Projects.** Total biostatistics annual effort 50–100+% per year, such as 20% of a PhD biostatistician plus 30–100% of an MS biostatistician. This category includes most NIH program project and center grants (and equivalent from other institutions), research groups with multiple R01s, and R01s over 500k, such as large cohort studies or clinical trials. These projects require a high and sustained level of biostatistician involvement in the development and implementation of the research project, collection and analysis of data, and dissemination of results. Specific activities conducted by statisticians may include:

- **Collaboration:** Actively participating in study phases, including regular meeting attendance.
- **Study Design and Analysis Planning:** Developing and implementing possibly complex study designs and preparing statistical analysis plans for all projects and aims.
- **Data Standards and Management:** Developing data collection standards, consulting on data collection forms, and performing minor data cleaning and validation. Data management, including assembling, reviewing, cleaning, validating, and documenting datasets from various sources, may require additional effort.
- **Data Safety Monitoring:** Designing data monitoring plans that are statistically sound and align with study objectives, setting interim analysis guidelines, developing data verification and validation methods, preparing reports for Data Safety Monitoring Board reviews, and advising on ethical considerations.
- **Algorithm Development:** Developing and validating algorithms for “unit of observation” identification and consolidation and for creating summary measures at specific analysis levels.
- **Statistical Analysis and Methods Development:** Researching and applying appropriate statistical methods for interim and final data analyses, possibly including novel method development and writing custom code for complex analyses.
- **Multi-site Coordination:** Coordinating statistical analyses for multi-site projects.
- **Reproducible Research:** Ensuring reproducibility through well-documented and maintained code and data files.
- **Reporting and Dissemination:** Summarizing and interpreting results, preparing internal reports, and collaborating on publications, potentially leading to first-authored papers.

**B. Regular Projects.** Total biostatistics annual effort 30–65% per year, such as 10–15% of a PhD biostatistician plus 20–50% of an MS biostatistician. This category commonly includes NIH R01 grants and equivalent from other institutions. For R01 renewals, larger amounts of biostatistics effort may be needed, as the accumulated data from the project can be used for more analyses.

This effort profile suits well-designed, straightforward projects with uncomplicated analyses using standard statistical methods. Well-documented primary data sets are assumed to be provided for statistical analyses such that minimal effort, if any, is needed on behalf of the biostatistician to clean and organize the data in preparation for statistical analyses. Biostatistician activities may include:

- **Collaboration:** Actively participating in study phases, including regular meeting attendance.
- **Study Design and Analysis Planning:** Developing and implementing possibly complex study designs and preparing statistical analysis plans for all projects and aims.
- **Data Standards and Management:** Developing data collection standards, consulting on data collection forms, and performing minor data cleaning and validation. Data management, including assembling, reviewing, cleaning, validating, and documenting datasets from various sources, may require additional effort.
- **Statistical Analysis:** Conducting statistical analyses using standard procedures available in statistical software packages.
- **Reproducible Research:** Ensuring reproducibility through well-documented and maintained code and data files.
- **Reporting and Dissemination:** Summarizing and interpreting results, preparing internal reports, and collaborating on publications.

**C. Simple Projects.** Total biostatistics effort 20–35% per year, such as 5-10% of a PhD biostatistician plus 10-25% of an MS biostatistician. This category includes most smaller scope NIH grants, such as R21s or R34s and equivalent from other institutions. This effort profile is suitable for simple projects requiring minimal PhD biostatistician collaboration and straightforward statistical analyses performed by an MS-level biostatistician, resulting in about one manuscript per year. Clean, well-organized primary data sets are assumed to be available, requiring minimal effort for data review and cleaning by the statistician. Specific activities conducted by statisticians for simple projects may include:

- **Consultation:** Meeting occasionally with PI to consult about study issues such as study design, data analysis and interpretation, or reporting.
- **Statistical Analysis:** Conducting focused statistical analyses on cleaned and well-documented data using standard procedures available in statistical software packages.
- **Reproducible Research:** Ensuring reproducibility through well-documented and maintained code.
- **Reporting and Dissemination:** Summarizing and interpreting results, preparing internal reports, and collaborating on publications.

This level of effort, commitment, and support for the PhD biostatistician is generally not compatible with smooth workflows and readily available consultation support unless an *experienced and capable* MS biostatistician is adequately supported on the project as well.

**D. Consultant Only Projects.** Total biostatistics effort 5% per year. This level of funding only supports limited meeting attendance and targeted consultation on study design, data analysis and interpretation, or reporting. This effort is not sufficient for the biostatistician to conduct analyses, but they may consult with a data analyst supported by the investigator's project.

**E. Hourly Rate Projects.** Occasionally, a limited amount of biostatistician funding may be justified, for example, for assistance planning very small-scale Phase I trials, modest proof-of-concept animal studies, or very small, focused studies where only simple statistical analysis will be needed (e.g., two-sample  $t$ -test, but not regression modeling). Very small projects with limited scope may budget for biostatistics services using the approved biostatistics recharge rate in place of personnel effort. These unique situations need to be discussed with the project biostatistician to determine the appropriate effort level and/or use of the recharge rate. Hourly rate projects for hire can generally only be conducted by staff statisticians, not faculty.

For these projects, it is assumed that a very clean, well-organized, and well-documented data set will be available for analysis, so the biostatistician will not need to do any data cleaning.

Information on how to format and prepare data for analysis is available at <https://health.ucdavis.edu/ctsc/area/biostatistics/other-resources>. Specific activities conducted by statisticians on an hourly rate project are limited to:

- **Consultation:** Meeting a couple of times with PI to consult about study issues such as study design, analytic methods, or analysis results.
- **Statistical Analysis:** Conducting a focused statistical analysis on cleaned and well-documented data to answer a pre-defined question using standard procedures available in statistical software packages.
- **Reproducible Research:** Ensuring reproducibility through well-documented and maintained code.
- **Reporting and Dissemination:** Summarizing and interpreting results and collaborating on publications.

**F. K Awards and Other Training Grants.** Having a faculty biostatistician mentor on K awards and other training grant mechanisms is often needed for the success of the award. These mechanisms generally do not support funded effort for biostatistician faculty. In this case, the PI should discuss the proposal with the division chief. Effort may be suitably budgeted for a staff biostatistician to conduct the programming and analytic work needed for the project that is not part of the mentoring plan.

### **G. Other Budgetary Considerations**

- Generally, biostatisticians help develop proposals without compensation, including such aspects as conducting power and sample size calculations and writing statistical analysis sections, because it is assumed that the major biostatistical effort on the project will be via allocated funded effort post-award.
- Any changes to the budget in sponsored effort commitment made during proposal writing or after research has been funded must be made jointly between the PI and biostatisticians with adequate lead time. It is expected that the PI will not remove/reduce the biostatistics effort for a biostatistician who helped develop the proposal after the grant is funded. All such changes should obtain prior approval. If funding for biostatistician efforts is reduced due to budget cuts, then the scope of work of the biostatistician must also be reduced, which requires consultation between the PI and the biostatistician. Reducing sample sizes does not reduce the amount of work to do the analysis! (In most cases, this would increase the work needed). If reductions to effort must be made, it is critical that the PI provide sufficient lead time (at least 1 month) so that the planned effort can be reoriented to alternative projects.

- There may be a modest level of funding from biostatistics cores, including the CTSC and the Cancer Center Biostatistics Shared Resource, to support unfunded statistical efforts. These resources should not be used for a funded project. Through the Biostatistics Cores, up to 10 hours of statistical support per unique project is available for projects without external funding, after which compensation via an FTE arrangement or hourly recharge rate is necessary. At best, 10 hours is only sufficient for a statistician to generate summary statistics and conduct one or two simple inferential analyses for one or two outcomes and predictors of interest. Provision of a data set that is clean, documented, and formatted in a manner that is ready for analysis is mandatory (see, e.g., <https://health.ucdavis.edu/ctsc/area/biostatistics/other-resources>). Regular, large, or complex projects cannot be supported without extramural or departmental funding for the statistical effort.
- Additional resources are always appreciated and sometimes required, such as specialized software, publication costs, or professional development activities potentially including attendance at and travel to scientific meetings to learn a new analytic method needed to meet the project aims or to support continuing professional education for a statistician supported primarily by research grants and contracts. Please discuss this in advance during the budget development phase.

**H. Authorship Considerations:** Authorship, according to ICMJE guidelines (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>), should be based on contributions and not on financial issues. In particular, a biostatistician who both (i) contributed substantially either to study design or to data analysis and interpretation and (ii) drafted or revised the manuscript should generally be presumed to be a co-author and should be asked to give final approval to the version of the article to be published.