

Design and Analysis Support Standard Operating Procedure
ESFCOM Office of Research

The Elson S. Floyd College of Medicine Office of Research (ESFCOM-OOR) provides a variety of design and analysis (D&A) services supporting both foundational and applied research. Biostatisticians, bioinformaticists, economists, psychometricians, data analysts, and other methodologists should be consulted early in a research project. Early involvement in your research projects is critical because if data are not collected in pre-specified ways amenable to current analytic methods, there may be limited ability to address research questions. The ESFCOM-OOR can assist you in study design and development of budgets for biostatistical support.

Notably, if an ESFCOM-OOR methodologist is intended to be part of a grant submission per Table 1, that person is expected to be fully engaged in the proposal development process, including power calculations and designing, drafting, and finalizing the statistical analysis plan. Such involvement is critical to the grant development process.

The below guidelines are intended as a starting point for budget discussions between investigators and ESFCOM-OOR personnel.

Hourly Invoicing

If you contact ESFCOM-OOR after data has already been collected, or a project is about to start, but the research team needs brief consultation, you may simply purchase the time of an ESFCOM-OOR methodologist. In most instances, an ESFCOM-OOR methodologist will meet the investigator for 1 hour to scope the project and provide brief consultation at no-charge. In some instances, this interaction may be all that is needed for the investigative team. However, if follow-up hourly work is necessary to procure a dataset, perform analyses, provide additional consultation or other activity that requires additional time, the investigative team will be charged an hourly rate of \$95/hour. ESFCOM-OR will provide a preliminary estimate for the necessary work upon an initial consultation and scoping of the project.

Tier Level	Hourly Rate
Conventional Analytics/Master Level	\$99.00
Conventional Analytics/PhD Level	\$149.00
Advanced Analytics/PhD Level	\$199.00

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Grant FTE Buyout

Table 1. Research Activities of Personnel by Level of Engagement

Research Activities	Extensive	Regular	Limited	Extremely Limited
Effort of Personnel	25%	20%	10%	5%
Summary of Activities	Extensive involvement in the development and implementation of the research project including the development and/or use of complex study designs, advanced statistical methods and the coordination of multi-center projects.	Serving as a consultant in the development and implementation of the research project classified as routine study design and analysis. Services typically include consulting on study design, implementation and data collection.	Involvement through consultation with the investigator about the choice of statistical methods and advising of the programmer/analyst with limited statistical analysis.	Consult with the investigator about choice of statistical methods to use and no further services related to analysis.
Participation in Team Meetings	Regular Attendee.	Frequent Attendee.	Infrequent Attendee.	Does Not Attend.
Personnel Involvement in Publications	Active participation in publications, with opportunity for first authored manuscripts.	Active participation in publications, with opportunity for co-authored manuscripts.	Supporting participation in publications, with opportunity for co-authored manuscripts.	Does not participate in publication development.
Personnel and Conference Presentations	Budget for project related travel.	No budget for project related travel.	No budget for project related travel.	No budget for project related travel.

Additional considerations

1. Changes in level of support made during proposal writing or after research has been funded should be made jointly between the PI and ESFCOM-OOR personnel, with involvement of relevant ESFCOM-OR leadership early on and certainly before a final decision is made with regard to how much to budget.
2. The proportions of effort are intended to be constant over the lifetime of a grant. For multi-year projects, it may be reasonable to support methodologist(s) at a lower amount during data collection periods, after design issues have been settled and before analysis has begun.

Authorship on papers

1. Authorship on papers should be discussed as early as possible. Usually a methodologist working 10% or more on a project will have contributed enough to your research project to serve as co-

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author on project manuscripts. Authorship is also merited for a supervising methodologist(s) who guides the analyses carried out by more junior researchers/methodologists.

2. A methodologist working 20% or more on a project should have the opportunity to write one methodological manuscript and/or first-author a substantive project related manuscript.

Other Budget Items: Travel, Computing, Training

1. The need for computers and software should be discussed with ESFCOM-OOR personnel. Methodologists generally need faster computers with more storage capacity than other investigators. Specialized software may be also required for some projects.
2. Project-based travel funding should allow for one to two meetings per year per FTE. For example, a 25% grant should budget for attendance at one meeting every other year. Funding at lower FTE's can partially support meeting attendance by paying for either airfare or hotel and registration. Attendance at meetings necessitate at least one presentation of project-specific results.
3. In some cases, workshops (often offered in conjunction with scientific meetings) may be needed to gain methodological tools needed to carry out required analyses.